Regence

Medical Policy Manual Surgery, Policy No. 232

Vertebral Body Tethering and Stapling

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Vertebral body stapling and vertebral body tethering, both fusionless surgical procedures, have been evaluated to determine whether the procedures could be used as alternatives to traditional orthotic bracing.

MEDICAL POLICY CRITERIA

Vertebral body stapling and vertebral body tethering for the treatment of scoliosis are considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

SCOLIOSIS

Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis is the most common form of idiopathic scoliosis, defined by the U.S. Preventive Services Task Force as “a lateral curvature of the spine with onset at ≥10 years of age, no underlying etiology, and risk for progression during puberty.”[1] Progression of the curvature during periods of rapid growth can result in deformity, accompanied by cardiopulmonary complications. Diagnosis is made clinically and radiographically. The curve is measured by the Cobb angle, which is the angle formed between intersecting lines drawn perpendicular to the top of the vertebrae of the curve and the bottom vertebrae of the curve. Patients with adolescent idiopathic scoliosis are also assessed for skeletal maturity, using the Risser sign, which describes the level of ossification of the iliac apophysis.

The Risser sign measures remaining spinal growth by progressive anterolateral to posteromedial ossification. Risser sign ranges from 0 (no ossification) to 5 (full bony fusion of the apophysis). Immature patients will have 0% to 25% ossification (Risser grade 0 or 1), while 100% ossification (Risser grade 5) indicates maturity with no spinal growth remaining. Children may progress from a Risser grade 1 to grade 5 over a brief (eg, 2-year), period.

Males and females are equally affected by scoliosis, but curve progression is up to 10 times more common in females than males.[2] Patients who are overweight or obese have a greater risk of presenting with larger Cobb angles and more advanced skeletal maturity, possibly due to delayed detection.[3] A retrospective review of 341 patients with adolescent idiopathic scoliosis who underwent surgery at a single tertiary pediatric hospital between 2013 and 2018 found that the major curve magnitude at presentation was significantly higher in patients with public compared to private insurance (50.0° versus 45.1°; p=.0040 and in Black compared to White patients (51.8° versus 47.0°; p=.042). Additionally, the odds of having an initial major curve magnitude <40° within the range of nonoperative treatment were 67% lower among Black patients with public insurance compared to Black patients with private insurance (odds ratio [OR], 0.33; 95% CI, 0.13 to 0.83; p=.019).[4]

Treatment

Treatment of scoliosis currently depends on 3 factors: the cause of the condition (idiopathic, congenital, secondary), the severity of the condition (degrees of the curve), and the growth of the patient remaining at the time of presentation. Children who have vertebral curves measuring between 25° and 40° with at least 2 years of growth remaining are considered to be at high risk of curve progression. Genetic markers to evaluate the risk of progression are also being evaluated. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more.

Bracing

Bracing is used to reduce the need for spinal fusion by slowing or preventing further progression of the curve during rapid growth. Commonly used brace designs include the Milwaukee, Wilmington, Boston, Charleston, and Providence orthoses. The longest clinical experience is with the Milwaukee cervical-thoracic-lumbar-sacral orthosis. Thoracic-lumbar-sacral orthoses, such as the Wilmington and Boston braces, are intended to improve tolerability and compliance for extended (>18-hour) wear and are composed of lighter weight plastics with a low profile (underarm) design. The design of the nighttime Charleston and Providence braces is based on the theory that increased corrective forces will reduce the needed wear time (ie, daytime), thereby lessening social anxiety and improving compliance.

The smart brace consists of a standard rigid brace with a microcomputer system, a force transducer, and an air-bladder control system to control the interface pressure. Braces that are more flexible than thoracic-lumbar-sacral orthoses or nighttime braces, such as the SpineCor® Scoliosis System, are also being evaluated. The SpineCor is composed of a thermoplastic pelvic base with stabilizing and corrective bands across the upper body.

Surgery

Fusionless surgical procedures, such as vertebral body stapling and vertebral body tethering, are being evaluated as alternatives to bracing. Both procedures use orthopedic devices off-label. The goal of these procedures is to reduce the rate of spine growth unilaterally, thus allowing the other side of the spine to “catch up.” The mechanism of action is believed to be down-regulation of the growth plate on the convex (outer) side by compression and stimulation of growth on the endplate of the concave side by distraction. In the current stapling procedure, nickel-titanium alloy staples with shape memory are applied to the convex side of the curve. The shape memory allows the prongs to be straight when cooled and clamp down into the bone when the staple returns to body temperature. Anterolateral tethering uses polyethylene ligaments that are attached to the convex side of the vertebral bodies by pedicle screws or staples. The ligament can be tightened to provide greater tension than the staple. The optimum degree of tension is not known. The polyethylene ligaments are more flexible than staples and are predicted to allow more spinal mobility. The goal of a fusionless growth modulating procedure is to reduce the curve and prevent progression, maintain spine mobility following correction, and provide an effective treatment option for patients who are noncompliant or who have a large curve but substantial growth is remaining. Observational data suggest that overweight patients may be at higher risk for scoliosis progression after surgery.[5]

Regulatory Status

Staples, using a shape memory nickel-titanium alloy, have been cleared for marketing by the FDA through the 510(k) process for various bone fixation indications. For example, nitinol staples (Sofamor Danek) are indicated for fixation with spinal systems. Other memory shape staples cleared for marketing by the FDA through the 510(k) process for bone fixation include the OSStaple™ (BioMedical Enterprises) and the reVERTO™ Dynamic Compression Device. FDA product code: JDR. Vertebral body stapling in scoliosis is considered off-label use.

A vertebral body tethering device (The Tether™; Zimmer Biomet Spine) received an FDA Humanitarian Device Exemption (HDE) (H190005, product code QHP) in June 2019. The FDA HDE states that this device is indicated for "skeletally immature patients that require surgical treatment to obtain and maintain correction of progressive idiopathic scoliosis, with a major Cobb angle of 30 to 65 degrees whose osseous structure is dimensionally adequate to accommodate screw fixation, as determined by radiographic imaging. Patients should have failed bracing and/or be intolerant to brace wear."

EVIDENCE SUMMARY

VERTEBRAL BODY STAPLING

Review of Evidence

Nonrandomized Comparative Study

In a multicenter study, Cuddihy (2015) reported on a matched comparison of VBS and bracing for immature patients with moderate (25° to 44°) idiopathic scoliosis.[6] Forty-two consecutive patients in the VBS group (57 curves) met inclusion criteria, and 52 patients in the bracing group (66 curves) were matched by initial Cobb angle, age at the start of treatment, follow-up of at least 2 years, and sex. The average curve size was 31°, and the average follow-up was 40.8 months in the VBS group and 105 months in the bracing group (maturity). For smaller thoracic curves (25° to34°), there was a nonstatistically significant trend for stapling to be more effective (progression <10°, 81%) compared with bracing (61%; p=.16). For larger thoracic curves (>35°), VBS did not halt curve progression, with a success rate of 18% compared with 50% for bracing. For lumbar curves (25° to 34°), results were comparable for VBS and bracing. There were insufficient numbers of patients with lumbar curves of 35° or greater to compare results.

Observational Studies

Several case series and one case-control study evaluating VBS are described below and in Tables 1 and 2.

Cuddihy (2015) compared VBS to bracing in a matched cohort of skeletally immature patients with moderate idiopathic scoliosis.[6] A total of 52 patients (66 curves) were matched according to age at the start of treatment (10.6 years vs. 11.1 years, respectively) and gender. In smaller thoracic curves (25° to 34°) there was a nonsignificant trend toward better results with VBS versus bracing. For those with thoracic curves ≥35°, VBS was not found to be effective, and for lumbar curves 25° to 35°, results appear to be similar for both VBS and bracing.

Murray (2020) described VBS in 7 patients with a mean age of 9.3 years (range, 7.8 to11.1 years) and an average preoperative Cobb angle of 30° (standard deviation [SD], 6°); the mean follow-up was 83 months (range, 72 to 95 months).[7] At the first postoperative visit and most recent follow-up visit, the average Cobb angle was 20° (SD, 7°) and 37° (SD, 22°), respectively. One patient showed improvement of greater than 10° from preoperative to final postoperative Cobb angle, 4 patients showed no change in their curve, and 2 showed progression of their curves by greater than 10° compared with preoperative imaging.

Bumpass (2015) described VBS in 31 consecutive patients with a mean age of 10.5 years (range, 7.0 to 14.6 years) and scoliotic curves of 25° to 40°.[8] Not all patients could (or would) wear a brace. At a mean follow-up to maturity of 48 months (range, 25 to 79 months), curves less than 35° had a control rate (<10° progression) of 75% while curves with a Cobb angle of at least 35° had a control rate of 22% (p=.01). The overall control rate was 61%, with 11 (31%) patients requiring subsequent fusion and 2 (6%) overcorrections.

Theologis (2013) described VBS in 12 children younger than 10 years old (range, 6.3 to 9.7 years) who were considered extremely likely to require fusion (ie, curves of 30° to 39° in a young child).[9] At an average 3.4-year follow-up (range, 2.2 to 5.4 years), curves had decreased by a mean of 10° (range, -3° to 20°). All curves in this high-risk population were successfully treated, with either no change (within 10°) or improvement in the curve (>10°).

Laituri (2012) retrospectively reviewed 7 children ages 8 to 11 years old who had undergone VBS and had at least 2 years of follow-up.[10] All children either had curve progression, despite bracing, or were unable to wear a brace. Before stapling, the mean angle was 34.1°. The mean percentage correction was 36% (range, 16.2% to 56%). None of the children had curve progression or required postoperative bracing or spinal fusion.

O’Leary (2011) reported that VBS in young children with large Cobb angles was ineffective.[11] Patients with adolescent idiopathic scoliosis were not included in this report. Diagnoses included myelodysplasia, congenital scoliosis, juvenile and infantile idiopathic scoliosis, Marfan syndrome, paralytic scoliosis, and neuromuscular scoliosis. At an average 22-month follow-up, curves averaged 69°, and 8 of 11 patients had undergone or were scheduled to undergo further spinal surgery for curve progression. It is unknown whether the young age at surgery, the severe preoperative curve, or the nature of underlying scoliosis contributed to the high failure rate.

Betz (2010) reported on 29 patients with juvenile or adolescent idiopathic scoliosis (from a database of 93 patients) who met the study inclusion criteria.[12] Selected were patients with idiopathic scoliosis, a coronal curve magnitude of 20° to 45°, Risser grade 0 or 1, and staples with tines proportional to staple size (beginning in 2002). The average age at the time of stapling was 9.4 years (range, 4 to 13 years), with an average follow-up of 3.2 years (range, 2 to 5.3 years). For thoracic curves greater than 35° at baseline, 75% progressed to greater than 50° (the threshold for recommending spinal fusion). For thoracic curves less than 35° at baseline, 6% of patients progressed to greater than 50° (the threshold for surgery).

Table 1. Summary of Key Observational Study Characteristics for Vertebral Body Stapling

Study	Country	Study Design	N[a]	Participants			Minimum FU, y
				Mean Age, y	***Curve***	***Risser Grade***	
Murray (2020)[7]	U.S.	Case series	7	9.3	27.3° to 37.9°	NR	6
Cuddihy (2015)[6]	U.S.	Case control	123	11	25° to 44°	0	2
Bumpass (2015)[8]	U.S.	Case series	33	11	25° to 40°	0	2
Theologis (2013)[9]	U.S.	Case series	12	8	30° to 39°	NR	2
Laituri (2012)[10]	U.S.	Case series	7	9	25° to 41°	NR	2
O'Leary (2011)[11]	U.S.	Case series	11	7	68° to 105°	0	1
Betz (2010)[12]	U.S.	Case series	29	9	20° to 45°	0	2

FU: follow-up; NR: not reported; U.S.: United States

[a] Number of patients in all studies, except for Bumpass et al (2015) and Cuddihy et al (2015), where N is the number of curves.

Table 2. Summary of Key Observational Study Outcomes for Vertebral Body Stapling

Study	Tx	Change In Curve				
		>10° Progressed	***Stable***	***>10° Improved***		
Murray (2020)[7]	VBS	2	4			
		>10° Progressed	***Stable/Improved***	***p***	**Progressed ≥50°**	**Subsequent Fusion**
Cuddihy (2015)[6]	VBS	Thoracic curves 25° to 34°: (19) Thoracic curves 35° to 44°: (82) Lumbar curves 25° to 34°: (20) Lumbar curves 35° to 44°: (40)	Thoracic curves 25° to 34°: (81) Thoracic curves 35° to 44°: (18) Lumbar curves 25° to 34°: (80) Lumbar curves 35° to 44°: (60)	>.05 for all comparisons of VBS vs. brace	NR	NR
	Brace	Thoracic curves 25° to 34°: (39) Thoracic curves 35° to 44°: (50) Lumbar curves 25° to 34°: (19) Lumbar curves 35° to 44°: (100)	Thoracic curves 25° to 34°: (61) Thoracic curves 35° to 44°: (50) Lumbar curves 25° to 34°: (81) Lumbar curves 35° to 44°: (0)			
		>10° Progressed	**Stable**	**>10° Corrected**		

Study	Tx	Change In Curve				
Bumpass (2015)[8]	VBS	13 (39)	14 (42)	6 (18)	9 (27)	11 (31)
Theologis (2013)[9]	VBS	0 (0)	5 (42)	7 (58)	0 (0)	0 (0)
Laituri (2012)[10]	VBS	0 (0)	2 (29)	5 (71)	0 (0)	0 (0)
O'Leary (2011)[11]	VBS	3 (27)	6 (55)	2 (18)	0 (0)	8 (73)
		Baseline Curve	**>10° Progressed**	**Stable/Improved**		
Betz (2010)[12]	VBS	<35° ≥35°	4 (22) 6 (75)	14 (78) 2 (25)	1 (6) 6 (75)	NR NR

Values are n (%) unless otherwise indicated.
NR: not reported; Tx: treatment; VBS: vertebral body stapling.

Section Summary: Vertebral Body Stapling

Evidence on the use of VBS for patients with idiopathic scoliosis consists of a nonrandomized comparative study, a case-control study, and several small case series. Results from the nonrandomized comparative study and case-control study have indicated that VBS might slow curve progression in children with thoracic curves less than 35° and is at least as effective as bracing, but VBS appears to be less effective than bracing in patients with Cobb angles of 35° or more. Results from these studies are considered preliminary because few patients have been followed to skeletal maturity. Studies from other centers are consistent with results from those of the inventor of the procedure. Complications can include broken staples, staple dislodgement, curve overcorrection, congenital diaphragmatic hernia rupture, contralateral pleural effusion, pneumothoraces, and superior mesenteric artery syndrome. Investigators have commented that their approach is almost always to recommend bracing first and offer stapling only if the child or adolescent has difficulty wearing the brace. Notably, for patients with thoracic curves of 35° or greater, Cuddihy (2015) now perform vertebral body tethering (see next section) instead of VBS.

VERTEBRAL BODY TETHERING

Review of Evidence

Systematic Reviews

Mariscal (2023) published a meta-analysis of 12 studies on the efficacy and safety of anterior vertebral body tethering (AVBT) in adolescent idiopathic scoliosis[13]. Significant corrections of the main thoracic, proximal thoracic, and thoracolumbar/lumbar curves were seen at 1-2 years post procedure, but no significant corrections were seen in the sagittal plane. Follow-up time was 24-60 months. The most common complications were overcorrection (8%) and tether breakage (5.9%) The reoperation rate was 10%. The studies included case series and cohort studies with no control groups, and there were no clinical trials. The authors note that while AVBT corrects curve deformities in the coronal plane, full assessment of AVBT is not possible with the available evidence.

Zhu (2022) published a systematic review and meta-analysis of 26 studies representing 1045 subjects (mean age range, 11.1 to 14.9 years) treated with vertebral body tethering (VBT) for scoliosis, finding that the Cobb angle of the major curve was significantly corrected from 40.0° to 59.0° at baseline to 15.9° to 38.0° immediately post-surgery and 10° to 38° at final follow-up.[14] The overall clinical success rate was 73.02% (95% CI, 68.31% to 78.05%). The pooled overall unplanned reoperation rate after VBT was 8.66% (95% CI, 5.53% to 13.31%; 23 studies). The top 3 reinterventions were conversion to posterior spinal fusion (3.51%; 95% CI, 2.45% to 5.01%), tether removal (2.3%; 95% CI, 1.47% to 3.58%), and tether replacement (1.09%; 95% CI, 0.57% to 2.08%). The overall complication incidence rate was 36.8% (95% CI, 23.9% to 49.7%; 24 studies). Most common complications included curve progression with tether breakage (16.79%; 95% CI, 7.43% to 26.15%), pulmonary complications (6%; 95% CI, 4.66% to 7.68%), and overcorrections (4.55%; 95% CI, 3.4% to 6.06%). A subgroup analysis of patients with more than 36 months follow-up time indicated that these patients had increased clinical success (73.88% vs. 65.93%), unplanned reoperation (15.8% vs. 4.55%), and complication rates (52.17% vs. 23.79%) compared to those with less than 36 months follow-up, respectively. Thus, based on the increased reoperation and complication rates observed with longer follow-up, the authors concluded that further improvements to the implant and refinement of patient selection criteria are warranted and should be assessed in the

context of high-quality randomized controlled trials. Study demographics and outcomes based on race, ethnicity, and sex were not reported, potentially limiting the generalizability of these findings.

Observational Studies

As noted in the Regulatory section above, in June 2019, the U.S. Food and Drug Administration (FDA) granted a Humanitarian Device Exemption to a new vertebral body tethering device called The Tether (Zimmer Biomet Spine, HDE #H190005, product code QHP). Available evidence for The Tether includes only one small retrospective cohort study of 57 pediatric patients that is yet unpublished and is only summarized in the FDA's Humanitarian Device Exemption Summary of Safety and Probable Benefit report.[15] In this study, pediatric patients who failed brace treatment (e.g., greater than 5° of progression and/or intolerance to brace wear) received vertebral body tethering with Dynesys vertebral body screws, which are similar to those of the marketed version of The Tether , but that have a slightly higher screw profile. Study participants were 86.4% female, with a mean age of 12.4 years. At baseline, mean Cobb angles were 30° to 44° in 75.4% of participants and 45° to 65° in 24.6% of participants. After 2 years, among the 44 subjects with 24-month data (out of the original 57), 43 met the probable benefit success criteria of achievement of a Cobb angle of 40°or less. Overall, the mean Cobb angles improved from 40.4° to 14.3° (+65%). Although assessment of quality of life at the last follow-up visits were described as "positive" based on the Pediatric Quality of Life Inventory, the clinical importance of this data is unclear as no baseline assessments were completed for comparison. A total of 8 participants had serious adverse events (14%), including overcorrection of the instrumented curve (8.8%), definite cord break (1.8%), development of a new curve (1.8%), and spondylolisthesis (1.8%). Other common adverse events were back pain (24.6%), overcorrection of the instrumented curve (21.1%), nausea/vomiting (21.1%), and extremity pain (21.1%). A total of 8 patients (6%) required surgical revision due to adverse events.

As noted in a 2015 review article, other devices used for vertebral body tethering are under development, and the optimum tension for vertebral body tethering is currently unknown.[16]

Other studies not included in the Zhu (2022) systematic review[14] are discussed below.

Samdani (2014, 2015) published 2 retrospective reviews on the off-label use of the Dynesys system for anterior vertebral body tethering for idiopathic scoliosis.[17, 18] They reported pursuing vertebral body tethering at their children’s hospital due to lack of success with VBS for thoracic curves greater than 35°. At the time of these reports, 32 patients had a minimum of 1-year follow-up,[18] and 11 consecutive patients had a 2-year follow-up.[17] The mean age at surgery was 12 years, and all patients were skeletally immature. Three patients also had VBS for their lumbar curves. For the 11 patients with 2-year follow-up, on average, 7.8 levels (range, 7 to 9 levels) were tethered. Thoracic Cobb angle averaged 44.3° preoperatively, was corrected to 20.3° after surgery, and improved to 13.5° at 2 years. The lumbar curve improved from 25.1° preoperatively to 7.2° at 2 years. Two patients required that tension be reduced after 2 years due to overcorrection.

Pehlivanoglu (2021) conducted a prospective cohort study of 13 skeletally immature patients (mean age, 11.8 years) who underwent vertebral body tethering with the Dynesys system for adolescent idiopathic scoliosis with double curves.[19] At baseline, the mean thoracic/thoracolumbar and lumbar curve magnitudes were 48.2° and 45.3°, respectively. An average of 11.8 levels of tethering were undertaken. Postoperatively, mean

thoracic/thoracolumbar curve magnitudes were 14.3° to 17.3°. At the last follow-up (mean, 36.4 months), the mean thoracic/thoracolumbar curve magnitudes were 8.2° to 9.7°. No major complications were reported.

Meyers (2022) performed a retrospective review of adolescent scoliosis patients (N=49; 74% female) treated with VBT via the Dynesys system after reaching peak height velocity (Risser stage 3-5).[20] Mean patient age was 15 ±- 1.9 years with mean follow-up duration 32.5 ± 9.1 months. In patients with thoracic major curvatures (n=24), the Cobb angle improved from 51.1 ± 6.9° to 27.2 ± 8.1° (47.7% correction; p<.01). In those with thoracolumbar major curves, curvature improved from 37.2 ± 10.7° to 18.8 ± 9.4° (49.5% correction; p<.01). Improvements in major curve inclinometer measurements and SRS-22 domains improved significantly (p≤.05), except for the SRS-22 activity domain. Overall, 37/49 (76%) of patients were deemed clinically successful with residual major curves ≤30°. At final follow-up, 2 major complications were reported. At 3.1 years after VBT, 1 patient required posterior fusion of the thoracic curve due to curve progression and revision of the thoracolumbar tether due to tether breakage. A second patient developed late onset superior mesenteric artery syndrome (SMAS) 1 year postoperatively which required Ladd's derotation surgery. Overall, 20 (41%) patients experienced tether breakage. However, only 4 of 19 (21%) patients with broken tethers failed to meet criteria for clinical success which was comparable to the 7 of 29 (24%) patients with intact tethers. Thus, treatment success in subjects with limited remaining skeletal growth was feasible. While treatment success was not impacted by age or Risser stage, patients with treatment failures reported slightly larger major Cobb angles at baseline.

Section Summary: Vertebral Body Tethering

There is limited published evidence on vertebral body tethering. The Tether is the only vertebral body tethering device that the FDA has approved for marketing based on a June 2019 Humanitarian Device Exemption. Available evidence for The Tether is limited to a small, single-center, uncontrolled, unpublished retrospective cohort study of 57 pediatric patients. Although reported Cobb angle corrections are promising, serious adverse events occurred, data are lacking on other important health outcomes, and there are important study design limitations, including lack of a control group. Additional early reports of a correction in Cobb angle from published reports on the Dynesys system are also promising, but little is known about longer-term outcomes with this procedure. A meta-analysis of vertebral body tethering studies with more than 36 months follow-up reported a 74% clinical success rate, a 52% complication rate, and a 16% unplanned reoperation rate. Most commonly reported complications were tether breakages, pulmonary complications, and overcorrections. Larger, controlled studies are needed to verify these preliminary findings.

PRACTICE GUIDELINE SUMMARY

SOCIETY ON SCOLIOSIS ORTHOPAEDIC AND REHABILITATION TREATMENT

The guidelines from the Society on Scoliosis Orthopaedic and Rehabilitation Treatment (2016) included recommendations on the following conservative treatments for idiopathic scoliosis[21]: assessment, bracing, physiotherapy, physiotherapeutic scoliosis-specific exercises and other conservative treatments for idiopathic scoliosis, exercises, special inpatient rehabilitation, and bracing (nighttime rigid bracing, soft bracing, part-time rigid bracing, full-time bracing). The guidelines did not address vertebral body stapling or vertebral body tethering.

SCOLIOSIS RESEARCH SOCIETY

The Scoliosis Research Society has indicated that the treatment of adolescent idiopathic scoliosis falls into 3 main categories (observation, bracing, surgery) and is based on the risk of curve progression.[22] Vertebral body stapling and tethering are not addressed by the Society.

AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

Information updated on the American Academy of Orthopaedic Surgeons' OrthoInfo website indicates that the type of treatment required for idiopathic scoliosis in children and adolescents depends on the kind and degree of the curve, child's age, and the number of remaining growth years until the child reaches skeletal maturity.[2] Vertebral body tethering and VBS are not addressed.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

In 2022, the National Institute for Health and Care Excellence (NICE) published an interventional procedures guidance on vertebral body tethering for idiopathic scoliosis in children and young people.[23] Recommendations stated that "evidence on the safety of vertebral body tethering for idiopathic scoliosis in children and young people is limited but raises concerns of serious complications. Evidence on its efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research."

SUMMARY

There is not enough evidence to show that vertebral body tethering or stapling improves net health outcomes in patients with scoliosis. No clinical practice guidelines based on research recommend the use of vertebral body tethering or stapling for the treatment of scoliosis. Therefore, vertebral body tethering and/or stapling for the treatment of scoliosis is considered investigational.

REFERENCES

1. U.S. Preventive Services Task Force (USPSTF). Final Recommendation Statement: Adolescent Idiopathic Scoliosis: Screening. 2018. [cited 11/14/2023]. Available from: https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/adolescent-idiopathic-scoliosis-screening.
2. American Academy of Orthopaedic Surgeons (AAOS). Idiopathic Scoliosis in Children and Adolescents. April 2021. [cited 11/14/2023]. Available from: https://orthoinfo.aaos.org/en/diseases--conditions/idiopathic-scoliosis-in-children-and-adolescents.
3. A Margalit, G McKean, A Constantine, CB Thompson, RJ Lee, PD Sponseller. Body Mass Hides the Curve: Thoracic Scoliometer Readings Vary by Body Mass Index Value. *J Pediatr Orthop.* 2017;37(4):e255-e60. PMID: 27861214
4. MJ Heffernan, M Younis, B Song, et al. Disparities in Pediatric Scoliosis: The Impact of Race and Insurance Type on Access to Nonoperative Treatment for Adolescent Idiopathic Scoliosis. *J Pediatr Orthop.* 2022;42(8):427-31. PMID: 35856501
5. A Mishreky, S Parent, F Miyanji, et al. Body mass index affects outcomes after vertebral body tethering surgery. *Spine Deform.* 2022;10(3):563-71. PMID: 35013996

6. L Cuddihy, AJ Danielsson, PJ Cahill, et al. Vertebral Body Stapling versus Bracing for Patients with High-Risk Moderate Idiopathic Scoliosis. *Biomed Res Int.* 2015;2015:438452. PMID: 26618169
7. E Murray, R Tung, A Sherman, RM Schwend. Continued vertebral body growth in patients with juvenile idiopathic scoliosis following vertebral body stapling. *Spine Deform.* 2020;8(2):221-26. PMID: 32026438
8. DB Bumpass, SK Fuhrhop, M Schootman, JC Smith, SJ Luhmann. Vertebral Body Stapling for Moderate Juvenile and Early Adolescent Idiopathic Scoliosis: Cautions and Patient Selection Criteria. *Spine (Phila Pa 1976).* 2015;40(24):E1305-14. PMID: 26655807
9. AA Theologis, P Cahill, M Auriemma, R Betz, M Diab. Vertebral body stapling in children younger than 10 years with idiopathic scoliosis with curve magnitude of 30 degrees to 39 degrees. *Spine (Phila Pa 1976).* 2013;38(25):E1583-8. PMID: 23963018
10. CA Laituri, RM Schwend, GW Holcomb, 3rd. Thoracoscopic vertebral body stapling for treatment of scoliosis in young children. *J Laparoendosc Adv Surg Tech A.* 2012;22(8):830-3. PMID: 23039706
11. T O'Leary P, PF Sturm, KW Hammerberg, JP Lubicky, SM Mardjetko. Convex hemiepiphysiodesis: the limits of vertebral stapling. *Spine (Phila Pa 1976).* 2011;36(19):1579-83. PMID: 21681138
12. RR Betz, A Ranade, AF Samdani, et al. Vertebral body stapling: a fusionless treatment option for a growing child with moderate idiopathic scoliosis. *Spine (Phila Pa 1976).* 2010;35(2):169-76. PMID: 20081512
13. G Mariscal, J Morales, S Pérez, et al. Meta-analysis on the efficacy and safety of anterior vertebral body tethering in adolescent idiopathic scoliosis. *Eur Spine J.* 2023;32(1):140-48. PMID: 36443510
14. F Zhu, X Qiu, S Liu, K Man-Chee Cheung. Minimum 3-year experience with vertebral body tethering for treating scoliosis: A systematic review and single-arm meta-analysis. *J Orthop Surg (Hong Kong).* 2022;30(3):10225536221137753. PMID: 36420934
15. U.S. Food and Drug Administration (FDA). SUMMARY OF SAFETY AND PROBABLE BENEFIT (SSPB): The Tether Vertebral Body Tethering System. 2019. [cited 11/14/2023]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf19/H190005b.pdf.
16. A Courvoisier, A Eid, E Bourgeois, J Griffet. Growth tethering devices for idiopathic scoliosis. *Expert Rev Med Devices.* 2015;12(4):449-56. PMID: 26027921
17. AF Samdani, RJ Ames, JS Kimball, et al. Anterior vertebral body tethering for idiopathic scoliosis: two-year results. *Spine (Phila Pa 1976).* 2014;39(20):1688-93. PMID: 24921854
18. AF Samdani, RJ Ames, JS Kimball, et al. Anterior vertebral body tethering for immature adolescent idiopathic scoliosis: one-year results on the first 32 patients. *Eur Spine J.* 2015;24(7):1533-9. PMID: 25510515
19. T Pehlivanoglu, I Oltulu, Y Erdag, et al. Double-sided vertebral body tethering of double adolescent idiopathic scoliosis curves: radiographic outcomes of the first 13 patients with 2 years of follow-up. *Eur Spine J.* 2021;30(7):1896-904. PMID: 33611658
20. J Meyers, L Eaker, J Zhang, T di Pauli von Treuheim, B Lonner. Vertebral Body Tethering in 49 Adolescent Patients after Peak Height Velocity for the Treatment of Idiopathic Scoliosis: 2-5 Year Follow-Up. *J Clin Med.* 2022;11(11). PMID: 35683548
21. S Negrini, S Donzelli, AG Aulisa, et al. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. *Scoliosis Spinal Disord.* 2018;13:3. PMID: 29435499

22. Scoliosis Research Society (SRS). Adolescent Idiopathic Scoliosis. n.d. [cited 11/14/2023]. Available from: http://www.srs.org/professionals/online-education-and-resources/conditions-and-treatments/adolescent-idiopathic-scoliosis.
23. National Institute for Health and Care Excellence (NICE). Interventional procedures guidance: Vertebral body tethering for idiopathic scoliosis in children and young people [IPG728]. June 29, 2022. [cited 11/14/2023]. Available from: https://www.nice.org.uk/guidance/ipg728.

CODES

Codes	Number	Description
CPT	0656T	Vertebral body tethering, anterior; up to 7 vertebral segments
	0657T	Vertebral body tethering, anterior; 8 or more vertebral segments
	0790T	Revision (eg, augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed
	22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments
	22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments
	22838	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed
	22899	Unlisted procedure, spine
HCPCS	None	

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