

Insertion of Spinal Stabilization Device, Vertebral Body Tether

ICD-10-PCS Coordination & Maintenance
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Disclosures

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- Faculty member (Zimmer Biomet The Tether™ medical education training)
- Sponsorship of two investigator-initiated studies provided by Zimmer Biomet (both anterior vertebral body tethering related)

Idiopathic Scoliosis

What is scoliosis?

- Scoliosis is a sideways curvature of the spine
- Most common form is idiopathic
- In some cases, the curve may worsen over time

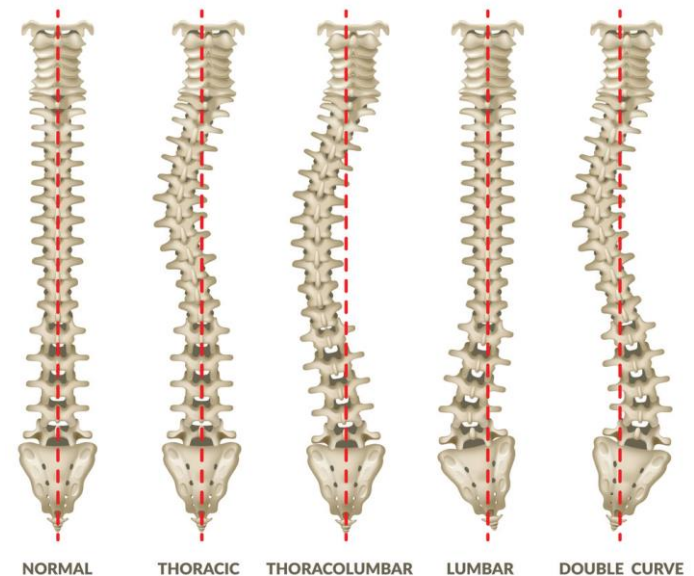
Symptoms

- Visible unevenness
- Increasing or daily pain
- Reduced lung function is possible

Treatments

- Physical therapy
- Bracing
- Surgical fusion

TYPES OF SCOLIOSIS OF SPINE



Demographics

- Juvenile or adolescent thoracic/lumbar idiopathic scoliosis (M41.114 - .116; M41.124 - .126)
 - 8,117 inpatient discharges in 2018 (Principal Dx)*
 - 97.1% were operative; 4.0 days ALOS
 - Females accounted for 77.3% of discharges
- Anterior vertebral body tethering is not indicated for all types of scoliosis cases
 - Idiopathic scoliosis in young individuals -- juvenile or adolescent idiopathic scoliosis
 - Skeletally immature
 - Average age at time of surgery in IDE study = 12.4 (10.1 - 15.0)
 - Cobb angle of 30 – 65 degrees
 - Excludes patients with severe spinal deformity

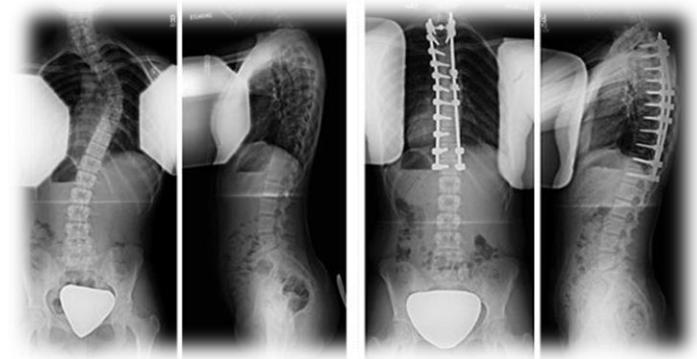
The Tether™: Vertebral Body Tethering System

- Rather than stiff metal rods, The Tether uses a strong, flexible cord to pull on the outside of a scoliosis curve to straighten out the spine.
- The system permanently straightens the spine using the patient's own growth process ("growth modulation").
- The spine is still able to bend and flex, rather than being fixed in place by metal rods and spinal fusion.

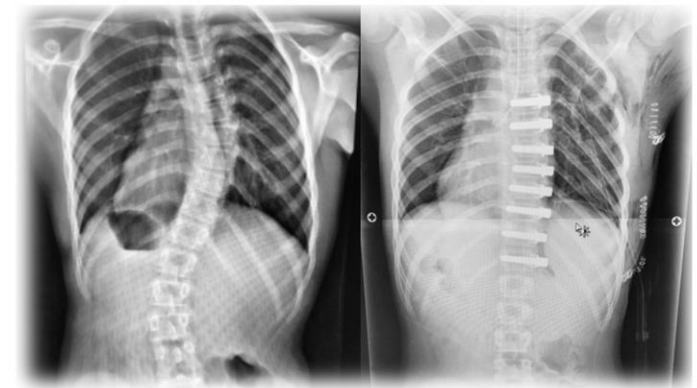
Indication (HDE Approval 08/16/2019)

Humanitarian Device. Authorized by Federal law for use in the treatment of 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. The effectiveness of this device for this use has not been demonstrated.

FUSION – Pre/Post






THE TETHER – Pre/Post



The Tether Procedure

The Tether is made up of three different parts that are used together.

IMPLANT	IMAGE	PURPOSE
Anchors		Circular implants placed against vertebrae to provide additional support for the bone screw.
Vertebral Body Assembly		<p>The bone screws are placed into the vertebra to capture the cord and allow the surgeon to pull each individual vertebra.</p> <p>The set screw (shown assembled into the top of the screw) captures the cord within the U-shaped head of the bone screw to maintain tension along the cord. Maintaining this tension is important for maintaining the surgeon's correction of the scoliotic curve.</p>
Cord		<p>After all of the screws are inserted, a cord is placed into the U-shaped head on the top of the screws.</p> <p>There are three different types of "zones" for the cord. A functional zone that is eventually implanted, two work zones to help pull the cord, and two introduction zones to help thread the cord through the U-shaped screw heads.</p>



The Tether Procedure

- Patient placed in the lateral decubitis position
- Access: thoracotomy or VATS; lumbar spine may be performed through an open approach
- Single-lung ventilation may be required



3-4 incisions are made into intercostal spaces. Thoracoscopic ports are inserted.



The Tether Procedure



An anchor and bone screw is inserted into each desired vertebrae. The cord is seated in the U-shaped head of each bone screw.



Counter-tensioners are used to reduce the deformity. The cord is tightened between each screw ("tensioning") and set screws are used to secure the cord in place.

The Tether Procedure



Pre-Op



First Erect (Post-Op)



12-Months Post-Op

Example of an anterior vertebral body tethering (AVBT) procedure to correct a scoliotic curve. The three radiographs show the pre-operative curve as well as how the curve obtains correction from the initial tensioning (first erect) and growth modulation (12-months post-op)

IDE Study Design

IDE G150001 Background

- IDE Study Approved in 2015; enrollment began in 2016
- Study Design
 - Single-site, consecutive, observational study with retrospective enrollment/prospective follow-up
 - N=56
- Study Objectives
 - Evaluate safety & effectiveness of VBT in Lenke 1a,b; Sanders ≤ 5 or Risser ≤ 3
 - Capture retrospective demographic, operative, and early follow-up data from patients implanted with VBT devices, and follow prospectively through skeletal maturity/18 yrs age.
 - The primary endpoint is the proportion of subjects with $\leq 40^\circ$ thoracic Cobb angle at 2 years follow-up; success is defined as $\geq 85\%$ of subjects within the defined range.
- Long term data on 56 subjects expected to be completed in 2023

IDE Study: Results to Date

- IDE G150001 Status – Enrollment complete (57 subjects; 1 not eligible)
 - Average age at time of surgery in IDE study = 12.4 (10.1 - 15.0)
 - 48 females, 8 males
 - 30+ subjects are at skeletal maturity; Sanders = 8
 - Average number of vertebral bodies tethered = 7-8
- Results:
 - Primary endpoint met (Cobb Angle $\leq 40^\circ$ @ 24 months post-op & last visit)
 - Cobb angle of curve reduced by $> 50\%$ (from 40.4° to 17.6°)

Cohort	N	Success % (n/N)		Last visit Cobb Angle (n, %)
		Visit at 24 months	Last visit ≥ 24 months	
All subjects	56	97.7% (43/44)	92.8% (52/56)	$< 30^\circ$ (43, 76.7%) $< 35^\circ$ (48, 85.7%) $< 40^\circ$ (52, 92.8%)
Pre-Op Cobb $< 45^\circ$	43	97.3% (36/37)	90.6% (39/43)	$< 30^\circ$ (35, 81.4%) $< 35^\circ$ (38, 88.3%) $< 40^\circ$ (39, 90.6%)
Pre-Op Cobb $\geq 45^\circ$	13	100% (7/7)	100% (13/13)	$< 30^\circ$ (8, 61.5%) $< 35^\circ$ (10, 76.9%) $< 40^\circ$ (13, 100%)

IDE Study: Results to Date (*cont.*)

Results (*continued*)

- Rib hump prominence reduced from average of 13.6° to 8.7°
- Patients rated quality of life (QoL) as 90.8% of maximum
- Patients rated physical function as 92.0% of maximum

Complications

- Most common complications (back pain, overcorrection of curve, nausea/vomiting, pain in arms/legs, need for additional surgery, and temporary numbness along the side of the chest or hip)
- 9 significant adverse events (SAEs) reported in 8 subjects (14.0%)
 - Overcorrection of curve requiring resurgery (e.g., loosening or cutting the cord) accounted for 6 of the 9
 - One surgery required because of cord breakage
 - One patient developed curve in another area of their spine
 - One developed spondylolisthesis unrelated to the tethering procedure



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