
Subject:	Vertebral Body Stapling for the Treatment of Scoliosis in Children and Adolescents	Publish Date:	02/27/2019
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Description/Scope

This document addresses vertebral body stapling as a surgical treatment of scoliosis.

Vertebral body stapling has been proposed as an alternative to bracing in the treatment of scoliosis in children and adolescents. The staples are surgically inserted into the vertebrae of the individual and designed to prevent further curvature of the spine.

Position Statement

Investigational and Not Medically Necessary:

Vertebral body stapling as a treatment of scoliosis in children and adolescents is considered **investigational and not medically necessary**.

Rationale

Betz and colleagues (2003) reported the results of a study carried out at the Shriners Hospital (Philadelphia) to determine the efficacy of vertebral body stapling in 21 individuals (27 curves) with adolescent idiopathic scoliosis. No major, but three instances of minor complications were noted. One individual experienced an intraoperative segmental vein bleed which resulted in an estimated blood loss of 1500 cc as compared to the average estimated blood loss of 247 cc for all participants. One subject developed a chylothorax and another developed pancreatitis. None of the individuals experienced staple dislodgement or movement during the follow-up period (mean 11 months, range 3-36 months), and no adverse effects specifically related to the staples were identified. Utility (defined as curve stability) was evaluated in 10 individuals with stapling with greater than 1 year follow-up (mean 22.6 months) and preoperative curve less than 50 degrees. Treatment failure was considered progression of greater than or equal to 6 degrees or beyond 50 degrees. Of these 10 individuals, 4 (40%) progressed and 6 (60%) remained stable or improved. One of 10 (10%) in the stapling group had progressed beyond 50 degrees and underwent spinal fusion. Six of the subjects required stapling of a second curve, 3 as part of the primary surgery, and 3 as a second stage because a second untreated curvature progressed. The authors concluded that vertebral body stapling for the treatment of scoliosis in adolescents was feasible and safe in this group of 21 subjects. However, the results need to be considered with caution, inasmuch as the follow-up period was short and there was no comparison of this technique with conventional treatment, such as bracing.

In 2005, Betz and colleagues carried forward their clinical series and presented the retrospective findings of 39 consecutive individuals (52 curves) who received vertebral body stapling as treatment for idiopathic scoliosis or scoliosis associated with other conditions, such as Marfan syndrome or skeletal dysplasia (syndromic scoliosis). Complications were reported in 6 cases. A 4-year-old with infantile idiopathic scoliosis developed a rupture of a pre-existing undiagnosed diaphragmatic hernia which required emergency repair. One participant experienced a

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puncture in a segmental spinal vein secondary to a staple prong and required both transfusion and conversion to an open procedure to control blood loss. One subject developed chylothorax as a result of a staple puncture of the thoracic duct at T12. This individual was treated with a chest tube and total parenteral nutrition. Another participant experienced mild pancreatitis. Clinically significant atelectasis was experienced by 2 individuals and 2 other participants required prolonged chest tube drainage (greater than 4 days). In 31 subjects who were followed for an average of 12 months, there were no reports of staple dislodgement or migration. However, there was one report of staple fracture. Five participants (15%) progressed during follow-up and required spinal fusion.

In another study, Betz and colleagues (2010) reported the findings of vertebral body stapling in 28 individuals with idiopathic scoliosis for a minimum follow-up period of at least 2 years. The authors reported a success rate (curves corrected to within 10 degrees of preoperative measurement or decreased > 10 degrees) in 87% of all of the lumbar curves and 77% in thoracic curves measuring less than 35 degrees. In the cases of thoracic curves which measured greater than 35 degrees, vertebral body stapling was not considered successful and required alternative treatments. In the conclusions section of the article, the authors acknowledged the limitations of the study and cautioned the reader that the "results should be considered preliminary as follow-up to skeletal maturity will be needed before definitive results can be described."

Laituri and colleagues (2013) reported the results of a retrospective study on children who underwent thoracoscopic vertebral body stapling for juvenile scoliosis from January 2007 to December 2010. Only individuals with a follow-up of at least 2 years were included in this study group. Data considered were demographics, indications for vertebral body stapling, degree of curvature, treatment, complications, and follow-up. Cobb angle was used to measure the initial degree of curvature on a standing posterior-anterior spine X-Ray. During the study period, 11 individuals underwent thoracoscopic vertebral body stapling for juvenile idiopathic scoliosis using single lung ventilation in a lateral position. The study group consisted of 7 subjects between the ages of 8-11 years with at least a 2-year follow-up. Indications for stapling in these 7 participants were progression of scoliosis (n=3), noncompliance with brace (n=3), and double curve with progression (n=1). The mean preoperative Cobb angle was $34.1 \pm 5^\circ$ (range, 25-41°), and the mean immediate postoperative Cobb angle measurement was $23 \pm 5^\circ$ (range, 16-30°). The staples encompassed a mean number of 6.4 vertebral bodies. The mean duration of chest drainage was 2.7 days, the mean length of hospitalization was 3.9 days and the mean operative time was 156.2 ± 39.5 minutes. The authors indicated there were no intraoperative complications or mortality. During the postoperative period, 1 individual developed a pleural effusion on the contralateral side that required drainage. These 7 participants were followed for a mean of 34 months (range, 29-44 months). The mean Cobb angle at last follow-up was 24.7° (range, 15-38°). At the time of last follow-up, none of the participants required postoperative bracing or spinal fusion. The authors concluded that thoracoscopic vertebral body stapling is a safe and effective method for treating progressive scoliosis in young children.

Theologis and colleagues (2013) evaluated 12 females older than 10 years of age with idiopathic thoracic or lumbar scoliosis of 30° to 39° who were treated with vertebral body stapling. The participants were followed for a minimum of 24 months. Outcome variables included curve progression and magnitude, surgical complications and a need for reoperation. The preoperative and postoperative curve magnitudes were compared. A total of 13 curves were treated with vertebral body stapling (lumbar: n=4, thoracic: n=9). The follow-up period ranged from 2.2-5.4 years and averaged 3.4 years. The average preoperative curve magnitude was 33.4° (range, 30-39°) compared to most recent curve magnitude measurement at follow-up of 23.0° (range, 10-34°). All curves, both thoracic and lumbar, were treated successfully. Postoperative curve magnitudes did not change significantly between the first erect radiographs and the most recent follow-up. Two of the study participants had pneumothorax, and 1

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participant had symptomatic pleural effusion. None of the study participants required definitive fusion for curve progression. The authors concluded that vertebral body stapling is an effective method to control curve progression in the high-risk group of children younger than 10 years with idiopathic scoliosis between 30° and 39° in whom bracing may be ineffective.

In 2018, Cahill and colleagues performed a retrospective review on 63 subjects between 7 to 15 years of age with idiopathic scoliosis. The aim of this study was to evaluate the change in Cobb angle measurements over time in subjects treated with vertebral body stapling. Outcomes were assessed by using three categories. Cahill (2018) stated:

“Improvement” was defined as a decrease in the preoperative Cobb angle of greater than 10°. “No change” was defined as a +10° to -10° change in the preoperative Cobb angle (both values inclusive). “Progression” was defined as an increase of the curve by greater than 10°. These assessments allowed for the classification of success versus failure, with “success” defined as either improvement or no change and “failure” defined as progression.

The authors reported that of the subjects who had vertebral body stapling of the lumbar curve, 82% were successful, and of the subjects who had vertebral body stapling of the thoracic curve, 74% were successful. Limitations to this study include retrospective design and small sample size.

In summary, at the time of this review, the clinical evidence on vertebral body stapling is not robust enough to make determinations regarding its safety and efficacy. There is still considerable risk of curve progression for these study participants and it may be premature to conclude that vertebral body stapling is an effective means of controlling curve progression in high-risk individuals who have not reached skeletal maturity. Study results once the individuals have reached skeletal maturity are warranted in order to determine the definitive benefit of vertebral body stapling in these individuals at high risk for continued curve progression.

Background/Overview

Vertebral body stapling is being investigated as an alternative to bracing or spinal fusion for the treatment of progressive idiopathic scoliosis in skeletally immature individuals. Because this procedure avoids fusion of the spine, it is proposed that this treatment will permit a gradual correction of the spinal curvature as the child grows while maintaining movement and flexibility and decreasing the risk for back pain in adulthood.

Historically, the use of staples for intervertebral procedures was problematic because the staples were not designed to withstand the movement of the spine. In light of this, the Nitinol (nickel-titanium alloy) staple is being investigated as a surgical device to treat scoliosis. At room temperature the staple is shaped like a clamp. However, when immersed in an ice bath, the staple can be straightened to allow spinal insertion. After the clamp is inserted into the spine with a thoracoscope under fluoroscopy, the body temperature warms the device causing it to deflect inward creating a “C” shaped configuration for secure fixation. There is no FDA market approval of the use of the Nitinol staple in the treatment of adolescent scoliosis.

Vertebral body stapling is being investigated as an alternative to bracing because it is believed to be more comfortable and less embarrassing than bracing for the child. When compared to spinal fusion, vertebral body stapling offers the advantage of allowing the individual to retain the flexibility of their spine. It is likely that this

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procedure could gain significant preference over conventional techniques if its long-term effectiveness and safety can be established. However, at the time of this review, there is insufficient clinical evidence demonstrating the safety and efficacy of this surgical procedure for the treatment of scoliosis.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

22899 Unlisted procedure, spine [when specified as vertebral body stapling]

ICD-10 Procedure

For the following codes, when specified as vertebral stapling:

- OPH404Z Insertion of internal fixation device into thoracic vertebra, open approach
- OPH434Z Insertion of internal fixation device into thoracic vertebra, percutaneous approach
- OPH444Z Insertion of internal fixation device into thoracic vertebra, percutaneous endoscopic approach
- OQH004Z Insertion of internal fixation device into lumbar vertebra, open approach
- OQH034Z Insertion of internal fixation device into lumbar vertebra, percutaneous approach
- OQH044Z Insertion of internal fixation device into lumbar vertebra, percutaneous endoscopic approach

ICD-10 Diagnosis

- M41.00-M41.9 Scoliosis
- Q67.5 Congenital deformity of spine (congenital scoliosis NOS)

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Peer Reviewed Publications:

1. Betz RR, D'Andrea LP, Mulcahey MJ, Chafetz RS. Vertebral body stapling procedure for the treatment of scoliosis in the growing child. Clin Orthop Relat Res. 2005; (434):55-60.
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3. Betz RR, Ranade A, Samdani AF, et al. Vertebral body stapling: a fusionless treatment option for a growing child with moderate idiopathic scoliosis. Spine (Phila Pa 1976). 2010; 35(2):169-176.
4. Cahill PJ, Auriemma M, Dakwar E, et al. Factors predictive of outcomes in vertebral body stapling for idiopathic scoliosis. Spine Deform. 2018; 6(1)28-37.

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5. Guille JT, D'Andrea LP, Betz RR. Fusionless treatment of scoliosis. *Orthop Clin North Am.* 2007; 38(4):541-545, vii.
6. Laituri CA, Schwend RM, Holcomb GW 3rd. Thoracoscopic vertebral body stapling for treatment of scoliosis in young children. *J Laparoendosc Adv Surg Tech A.* 2012; 22(8):830-833.
7. Theologis AA, Cahill P, Auriemma M, et al. Vertebral body stapling in children younger than 10 years with idiopathic scoliosis with curve magnitude of 30° to 39°. *Spine.* 2013; 38(25):E1583-E1588.
8. Torre-Healy A, Samdani AF. Newer technologies for the treatment of scoliosis in the growing spine. *Neurosurg Clin N Am.* 2007; 18(4):697-705.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Horizon Scanning Technology Prioritising Summary. Vertebral body stapling for idiopathic scoliosis. December 2005. Available at: [http://www.health.gov.au/internet/horizon/publishing.nsf/Content/BA087FAAAC9BA8ABCA2575AD0080F355/\\$File/vertebral.pdf](http://www.health.gov.au/internet/horizon/publishing.nsf/Content/BA087FAAAC9BA8ABCA2575AD0080F355/$File/vertebral.pdf). Accessed on February 20, 2019.
2. U.S. Food and Drug Administration (FDA) 510 (k) Premarket Notification Summary. OSStaple™ Staple System. No. K061385. Rockville, MD. FDA. May 30, 2007. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K061385.pdf. Accessed on December 21, 2018.

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CD Horizon® Spinal System
 Nitinol Staple
 OSStaple™

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	01/24/2019	Medical Policy & Technology Assessment Committee (MPTAC) review.
Reviewed	01/25/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale and References sections.
Reviewed	02/02/2017	MPTAC review. Updated the review date, References and History sections of the document.
Reviewed	02/04/2016	MPTAC review. Updated the review date, References and History sections of the document. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated the review date, Description/Scope, References and History sections of the document.
Reviewed	02/13/2014	MPTAC review. Updated the review date, Rationale, References and History sections of the document.
Reviewed	02/14/2013	MPTAC review. Updated the review date, References and History sections of the document.
Reviewed	02/16/2012	MPTAC review. Updated the review date, References and History sections of the document.

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Reviewed	02/17/2011	MPTAC review. Updated the review date, Rationale, References and History sections of the document.
Reviewed	02/25/2010	MPTAC review. Updated the review date, Description/Scope, Rationale, Background/Overview, References and History sections of the document.
Reviewed	02/26/2009	MPTAC review. Changed title to “Vertebral Body Stapling for the Treatment of Scoliosis in Children and Adolescents.” Revised Position Statement to indicate that vertebral body stapling is investigational and not medically necessary as a treatment of scoliosis in both children and adolescents. Updated review date, Rationale, Background/Overview, References and History sections of the document.
Reviewed	02/21/2008	MPTAC review. Updated review date, References and History sections of the document. The phrase “investigational/not medically necessary” was clarified to read “investigational and not medically necessary.” This change was approved at the November 29, 2007 MPTAC meeting.
New	03/08/2007	MPTAC review. Initial document development.

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