

Vertebral Body Stapling

A Fusionless Treatment Option for a Growing Child With Moderate Idiopathic Scoliosis

Randal R. Betz, MD,* Ashish Ranade, MD,* Amer F. Samdani, MD,* Ross Chafetz, DPT,*
Linda P. D'Andrea, MD,† John P. Gaughan, PhD,‡ Jahangir Asghar, MD,*
Harsh Grewal, MD,* and Mary Jane Mulcahey, PhD*

Study Design. Retrospective review.

Objective. To report the results of vertebral body stapling (VBS) with minimum 2-year follow-up in patients with idiopathic scoliosis.

Summary of Background Data. While bracing for idiopathic scoliosis is moderately successful, its efficacy has been called into question, and it carries associated psychosocial ramifications. VBS has been shown to be a safe, feasible alternative to bracing for idiopathic scoliosis.

Methods. We retrospectively reviewed 28 of 29 patients (96%) with idiopathic scoliosis treated with VBS followed for a minimum of 2 years. Inclusion criteria: Risser sign of 0 or 1 and coronal curve measuring between 20° and 45°.

Results. There were 26 thoracic and 15 lumbar curves. Average follow-up was 3.2 years. The procedure was considered a success if curves corrected to within 10° of preoperative measurement or decreased >10°. Thoracic curves measuring <35° had a success rate of 77.7%. Curves which reached ≤20° on first erect radiograph had a success rate of 85.7%. Flexible curves >50% correction on bend film had a success rate of 71.4%. Of the 26 curves, 4 (15%) showed correction >10°. Kyphosis improved in 7 patients with preoperative hypokyphosis (<10° of kyphosis T5–T12). Of the patients, 83.5% had remaining normal thoracic kyphosis of 10° to 40°. Lumbar curves demonstrated a success rate of 86.7%. Four of the 15 lumbar curves (27%) showed correction >10°. Major complications include rupture of an unrecognized congenital diaphragmatic hernia and curve overcorrection in 1 patient. Two minor complications included superior mesenteric artery syndrome and atelectasis due to a mucous plug. There were no instances of staple dislodgement or neurovascular injury.

Conclusion. Analysis of patients with idiopathic scoliosis (IS) with high-risk progression treated with vertebral

body stapling (VBS) and minimum 2-year follow-up shows a success rate of 87% in all lumbar curves and in 79% of thoracic curves <35°. Thoracic curves >35° were not successful and require alternative treatments.

Key words: vertebral body stapling, fusionless, bracing, idiopathic scoliosis. **Spine 2010;35:169–176**

Current treatment for moderate scoliosis (20° to 45°) involves nonsurgical methods including observation and bracing, which are aimed at stopping the curve progression. Meta-analysis by Rowe et al has shown bracing for 23 hours per day to be effective.¹ Danielsson *et al* studied the rate of scoliosis surgery and progression of curves at a mean follow-up of 16 years.² In their series, no patient treated with bracing required surgery, compared to 10% of patients in the observation group. Despite these reports, many do not believe in the efficacy of brace treatment. Dolan and Weinstein conducted a systematic review of clinical studies and compared surgical rates after observation and bracing for adolescent idiopathic scoliosis.³ In this article, the pooled surgical rate was 23% after bracing and 22% after observation. Based on these findings, the authors found no evidence to recommend bracing over observation.

There are other problems associated with bracing. Although compliance issues are seen in both boys and girls, bracing is especially challenging in boys.^{4,5} Poor compliance has been associated with poor results.^{6–8} Bracing can also have a negative effect on self-image.⁹

Stapling across physes of the long bones has been accepted for many years as a predictable method of treating limb malalignment in young children.^{10,11} Animal studies using a rat tail model confirm the ability to modulate vertebral growth plates with skeletal fixation devices.¹² In 1951, Nachlas and Borden performed vertebral interbody stapling across the physal endplates and discs in a dog scoliosis model.¹³ Correction was seen in many dogs, and in some the curve progression was arrested. Some staples failed because they spanned 2 interspaces instead of just one.

Results for humans with congenital scoliosis were presented as early as 1954,¹⁴ but the results were disappointing. Correction of the scoliosis was limited because the children had little growth remaining and the curves were severe, with considerable rotational de-

From the *Shriners Hospitals for Children, Philadelphia, PA; †Brandywine Institute of Orthopaedics, Pottstown, PA; and ‡Temple University School of Medicine, Philadelphia, PA.

Acknowledgment date: October 29, 2008. Revision date: July 15, 2009. Acceptance date: October 15, 2009.

The device(s)/drug(s) that is/are the subject of this manuscript is/are exempt from FDA or corresponding national regulations because of retrospective IRB study of 510K approved device used off label for scoliosis.

No funds were received in support of this work. One or more of the author(s) has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript: e.g., honoraria, gifts, consultancies, royalties, stocks, stock options, decision making position.

This study was approved by the Institutional Review Board of Temple University as a retrospective review.

Address correspondence and reprints requests to Randal Betz, MD, Shriners Hospital, 3551 North Broad Street, Philadelphia, PA 19140; E-mail: rbetz@shrinenet.org

formity. Some staples broke or became loose, possibly because of motion through the intervertebral discs.

To address the issue of staple stability, Medtronic Sofamor Danek (Memphis, TN) has designed staples using Nitinol, a shape memory alloy, which have 510(k) approval from the FDA specifically for fixation in the anterior spine or for fixation of hand and foot osteotomies. These staples are unique in that the prongs are straight when cooled but clamp down into the bone in a “C” shape when the staple returns to body temperature, thus providing secure fixation. This Nitinol staple has been tested in a goat scoliosis model by Braun *et al* and has been shown to be safe and have utility for arresting iatrogenic curves of $<70^\circ$ in the goat.¹⁵

The feasibility, safety, and utility of vertebral body stapling for treatment of adolescent idiopathic scoliosis have been reported previously.^{16,17} The purpose of this article is to describe the 2-year follow-up of patients having had the VBS procedure for treatment of idiopathic scoliosis.

Materials and Methods

After obtaining IRB approval, we retrospectively reviewed our database of 93 patients and identified 29 who met our inclusion criteria of: (1) idiopathic scoliosis; (2) coronal curve magnitude of 20° to 45° ; (3) proportional staples only (staple design was changed in 2002 to shorten the tines according to the disc height. Each staple had the correct proportional tine length as opposed to an earlier generation with one tine length for all staples, which prevented the tines from being close to the growth plate in the smaller staples); (4) Risser 0 or 1; and (5) minimum 2-year follow-up.

Of 29 patients, 28 (96%) were specifically reviewed for this article, with 1 patient lost to follow-up after 1 year.

Data collection included patient's age at the time of index procedure, gender, surgery date, and complications, if any. Measurements were made on preoperative; first erect, 1 year, 2 year, and most recent follow-up radiographs. At each visit, standing posteroanterior and lateral radiographs were obtained, and preoperative supine bending films were obtained before surgery. On the posteroanterior views, the following measurements were obtained: (1) Cobb angle for the largest curve; (2) Risser grade; and (3) status of triradiate cartilage (open *vs.* closed). On the lateral view, the following measurements were obtained: (1) thoracic kyphosis measured as an angle between the superior endplate of T5 and the inferior endplate of T12; and (2) lumbar lordosis measured as an angle between the superior endplate of L1 and the superior endplate of S1. In addition, all radiographs were examined for signs of loosening, breakage, and staple dislodgment.

For this review, thoracic and lumbar curves were separately analyzed, because thoracic and lumbar curves respond differently to bracing. There were not enough curves to subanalyze the data by curve pattern (thoracic *vs.* thoracolumbar/lumbar *vs.* double major).

“Improvement” was defined as improvement in the preoperative Cobb angle of $>10^\circ$, measured on the final follow-up radiograph. “No change” was defined as a $+10^\circ$ to -10° change in the preoperative Cobb angle (both values inclusive)

(Figures 1A–D). Progression was defined as worsening of the curve greater than 10° . Because the goal in this series was to see if stapling could be used as an alternative to bracing, “success” was defined as either improvement or no change on the final follow-up Cobb angle. No change is the hope of a patient and parents undergoing brace treatment, and any correction for a patient having stapling would be a bonus. Ten degrees was chosen so as to be clearly outside the range of possible error in measurement due to films being obtained at different locations. In addition, based on a previous study comparing various types of braces,¹⁸ 10° was chosen to represent a large and clinically significant change in curve size. Statistical analysis was performed using the Statistical Analysis Systems software package version 9.1 (SAS Institute, Cary, NC). Regression analysis was done to evaluate multiple variables. A *P* value of 0.05 or less was considered statistically significant.

Surgical Technique

While under general anesthesia, the patient is positioned in the lateral decubitus position with the convex side of the curve facing up. An axillary roll is used underneath the concave side. All vertebral bodies in the Cobb angle of the curve are included. Single-lung ventilation and carbon dioxide (CO₂) insufflation are used for better visualization of the anatomy. At this point, vertebral bodies are identified using biplanar fluoroscopy. The thoracoscope is placed through the anterior portal. Intercostal portals for staple insertion are placed close to the posterior axillary line.

After incision, nasal speculum dilators are used to enlarge the portals. Under fluoroscopic control, a trial is used at every level to gauge the size. Optimal placement requires the tines of the staple to be close to the vertebral endplate. In the sagittal profile, the staple is placed anterior to the rib head. In patients with hypokyphosis, more anterior position is desired. In the lumbar spine, the staple is placed in the posterior half of the vertebral body. The tines of the trial are used to make pilot holes. The trial device can be used to push on the apex of the curve, thus helping the correction. Care is taken to protect the segmental vessels. After the holes are made, a staple of appropriate size (range, 5–12 mm wide in a 4-pronged design) is selected and its tines straightened using a distracter. Staples are placed in ice. Then the trial is removed and the staple is quickly inserted using a specially-made insertion device. Tines of the staple are matched with the pilot holes. Optimal position of the staple is reconfirmed fluoroscopically, and the staple is impacted in the vertebral body. After removal of the inserter, if the staple is not flush with the disc, an impactor is used to further drive the staple into the vertebral body.

In the lumbar spine, we use the direct lateral approach with a minimal open incision. Staples are placed at 3 to 4 levels. During the approach, the psoas is either retracted posteriorly or carefully separated longitudinally directly over the posterior half of the disc under neuromonitoring control.

At the end of the procedure, position of the staples is reconfirmed using fluoroscopy. A chest tube drain coming out through the anterior portal is used. After surgery, the patient is transferred to the pediatric intensive care unit for an overnight stay.

Postoperative Care

In these patients, the chest tube was usually removed on the first postoperative day. All patients received opioid analgesia

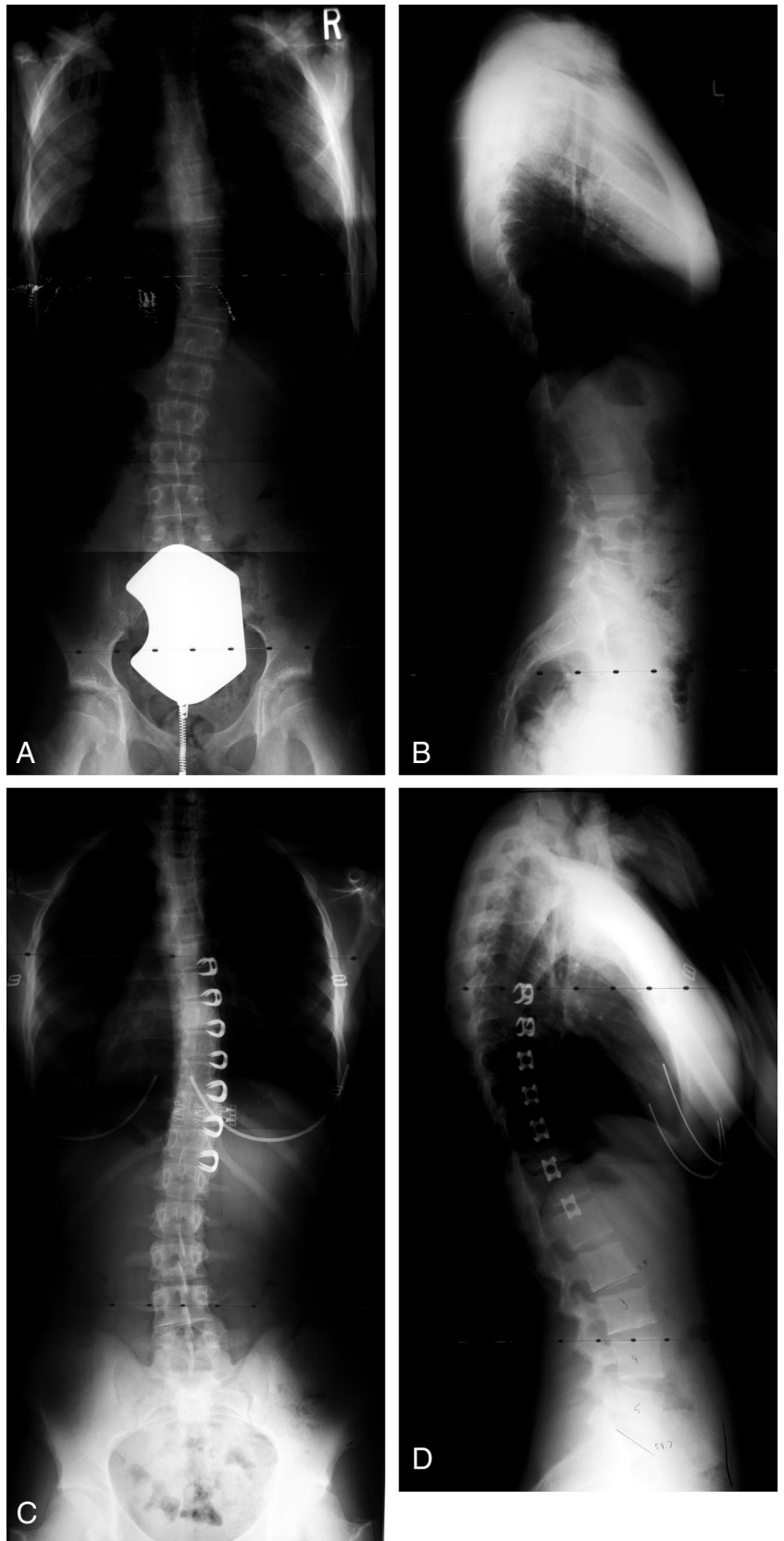


Figure 1. **A–D**, PA (**A**) and lateral (**B**) erect radiographs of a 12-year-old girl demonstrate a 31° right thoracic curve and 15° thoracic kyphosis. The patient underwent a thoracoscopic VBS from T5–T12. Her first erect radiographs demonstrate curve correction to 19°. (**C**, **D**) Latest follow-up shown here at 4.1 years postop demonstrates maintenance of curve correction at 22° and a thoracic kyphosis of 28°.

combined with Ketorolac for pain relief. Initially, a noncorrecting soft corset brace was prescribed for lumbar curves for 4 weeks to help with stabilization of the staples by decreasing the patients' motion. No restrictions of activity were placed on the

patients after 6 weeks. Dressings were removed before discharge and a standing radiograph obtained. Activities as tolerated were permitted after 4 weeks, and patients were observed radiographically every 3 months.

Table 1. Results for Thoracic Curves

	Improved	No Change	Progression	Progression $\geq 50^\circ$	<i>P</i>
Preoperative curve $< 35^\circ$	3 (16.7%)	11 (61.1%)	4 (22.2%)	1 (5.6%)	0.0029*
Preoperative curve $\geq 35^\circ$	1 (12.5%)	1 (12.5%)	6 (75%)	6 (75%)	

**P* value: Fisher exact test comparing preop $< 35^\circ$ versus $\geq 35^\circ$.

■ Results

Of the 29 original patients, 28 (96%) were available for follow-up. One patient was lost to follow-up after 1 year. At 1 year, this patient's curve was stable (preop 30° and current 20°). There were 4 boys and 24 girls. The mean preoperative thoracic and lumbar curves measured 31° and 30° , respectively. Average follow-up was 3.2 years (range, 2–5.3 years). Diagnosis was juvenile idiopathic scoliosis (JIS) (age at diagnosis < 10 years) in 12 patients (42.9%) and adolescent idiopathic scoliosis (age ≥ 10 years at diagnosis) in the remaining 16. There were 41 curves in 28 patients (JIS 18 [43.9%]; adolescent idiopathic scoliosis, 23 [56%]). The average age at the time of the index procedure was 9.4 years (range, 4 to 13 years). Average blood loss for the procedure was 212 mL.

In 13 patients, the thoracic curve only was stapled, and 13 patients had both thoracic and lumbar curves stapled. The lumbar curve only was stapled in 2 patients.

Thoracic Curves

A total of 26 thoracic curves were divided into 2 groups, those measuring $< 35^\circ$ and those measuring $\geq 35^\circ$. This criterion was used based on a previous study.¹⁹ Of the 18 curves $< 35^\circ$, improvement was seen in 3 (16.7%), no change in 11 (61.1%), and progression in 4 (22.2%), for a success rate (improvement or no change) of 77.7%. In this group, only 1 curve (5.5%) progressed past 50° . Of the 8 thoracic curves $\geq 35^\circ$, improvement was seen in 1 (12.5%), no change in 1 (12.5%), and progression in 6 (75%), for a success rate of only 25%. In this group, the 6 of 8 curves (75%) that progressed went past 50° . The results were statistically significant ($P = 0.029$) between preoperative curves $< 35^\circ$ and those $\geq 35^\circ$ (Table 1). In the group of 12 JIS curves (patients aged between 4 and 10 years), the success rate was 75%, with progression noted in 25%.

Curve Flexibility. Curves bending more than 50% of preoperative measurement correction had a success rate of 71.4% in comparison to 25% success in the curves with less than 50% flexibility. Curves which reached 20° on first erect radiograph had a success rate of 85.7%. Curves which remained $\geq 20^\circ$ on first erect radiograph were less successful (success rate of 52.6%, $P = 0.095$) (Table 2). In this group of 26 thoracic curves, 7 curves (27%) progressed $\geq 50^\circ$ (patients 5, 7, 11, 14, 15, 23, 24), with 6 of the 7 having preoperative curves $> 35^\circ$.

Table 2. Effect of First Erect Radiograph on Results of Thoracic Curves

First Erect Radiograph	Success	Failure	<i>P</i>	Progression $\geq 50^\circ$
$< 20^\circ$	6 (85.7%)	1 (14.3%)	0.095	1 (14.3%)
$\geq 20^\circ$	10 (52.6%)	9 (47.4%)		

Sagittal Profile. Thoracic kyphosis improved in 7 patients with hypokyphosis ($< 10^\circ$ of kyphosis T5–T12) (patients 13, 15, 21, 24, 26, 27, 28) (Figures 1A–D). At the most recent follow-up, thoracic kyphosis in 83% of patients remained in the 10° to 40° range. Results are summarized in Table 3.

Curves With Improvement. There were 4 thoracic curves that improved $> 10^\circ$ (patients 10, 12, 22, 27). Their characteristics are outlined in Table 4.

Lumbar Curves

Fifteen lumbar curves were analyzed. All were within 20° to 45° before surgery. Of the 15 curves, 3 (20%) improved, 10 (66.6%) showed no change, and 2 (13.3%) progressed, for an overall success rate of 86.7%. In this group, only 1 patient with a 40° preoperative curve (patient 12) progressed to 50° . In the lumbar group, we evaluated the 7 patients with JIS separately. The success rate in these patients was 100%.

Curve Flexibility. Curve flexibility does not seem to have any effect on results in the lumbar group. Cobb angle on first erect radiograph does not seem to have any effect on the final outcome. Curves that measured $< 20^\circ$ on first erect radiograph had a success rate of 88.9%, and curves $\geq 20^\circ$ had a success rate of 83.3%.

Sagittal Profile. In the lumbar curves, lumbar lordosis averaged 53.8° before surgery and 49° at latest follow-up. Five patients had $> 10^\circ$ loss of lumbar lordosis (patients 6, 12, 17, 20, 21); however, in all those, lumbar lordosis at latest follow-up remained within the normal range of 40° to 60° .

Curves With Improvement. There were 4 lumbar curves (patients 1, 4, 8, 22) that showed improvement (Table 4).

Both Curves. Of the 13 patients with both curves stapled, 61% were considered a success, but the numbers are too small to know if double curves behaved worse than single curves (there were only 2 patients with primary lumbar curves).

Complications

Complications were divided into 3 categories: major (resulting in permanent sequelae or necessitating a second

Table 3. Changes in the Sagittal Profile Following Vertebral Body Stapling

Thoracic Kyphosis	$< 10^\circ$	10– 40°	$> 40^\circ$
Preop (no. patients)	7 (26.9%)	19 (73%)	0
Recent (no. patients)	3 (12.5%)	20 (83.3%)	1 (4.2%)

Table 4. Curves With Improvement in the Curve Magnitude

Patient Number	Curve	Age at Surgery	Recent Age (yrs)	Preop Curve	First Erect	Recent	Improvement	Follow-up (Yrs)	% Improvement
1	L	12	17.3	25	11	14	11	5.3	44%
4	L	6	10.8	25	12	-25	50	4.8	200%
8	L	7	11.1	32	13	15	17	4.1	53.1%
10	T	12	16.1	29	19	17	12	4.1	41.4%
12	T	13	16.7	33	21	21	12	3.7	36.4%
22*	T	5	7.6	44	34	22	22	2.6	50%
22	L	5	7.6	41	18	18	23	2.6	56.1%
27	T	7	9	30	30	16	14	2.0	46.7%

*Patient 22 had both curves stapled and thus is listed twice.

major operation), minor (resulting in a prolonged hospital stay, necessitating a minor operation, and/or resulting in a significant temporary hardship or persistent minor problem), and insignificant (anything less than minor).²⁰ In this series of patients, there were 2 major complications. One patient developed rupture of a congenital diaphragmatic hernia in the postoperative period. Although it was probably unrelated to the surgery itself, it was still considered a complication, as it is possible that the diaphragm was weakened with placement of staples at T11 and T12. In one patient, overcorrection occurred and required staple removal for reversal of the curve to 35° the other way (Figure 2A–C) (see Discussion for more details). There was 2 minor complications: supe-

rior mesenteric artery syndrome (treated with nonoperative measures) and a mucous plug leading to atelectasis requiring bronchoscopy. Finally, 3 broken staples were noticed (insignificant complication) (Figure 3A–B). None of the broken staples necessitated removal, nor did any staples in this series become dislodged (Table 5).

■ Discussion

Results of this study show that some patients with scoliosis and growth remaining and high-risk idiopathic curves can be treated successfully with vertebral body stapling. Best results were seen in all lumbar curves and thoracic curves <35° and in those whose first erect radiograph measured <20°.

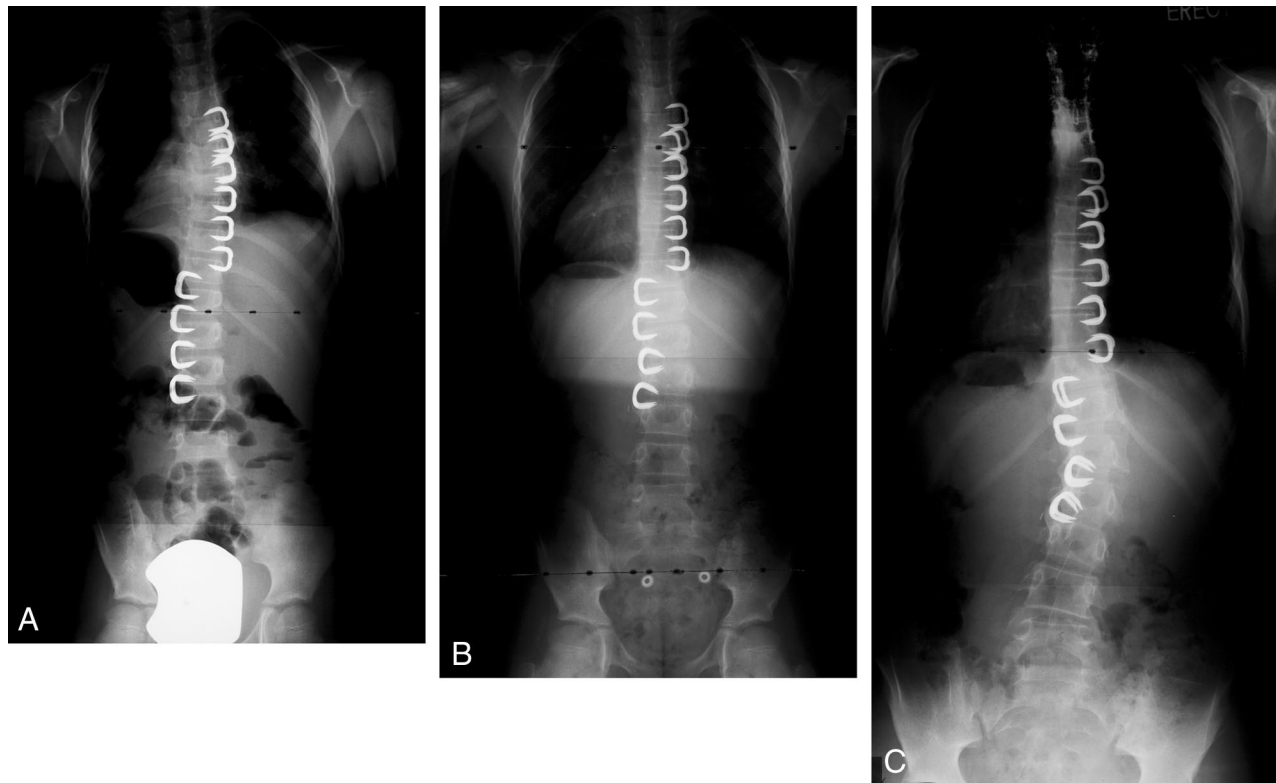


Figure 2. **A**, This is a 6-year-old female with a 21° thoracic curve and a 25° lumbar curve. She underwent thoracoscopic vertebral body stapling from T5–T11 on the right side and, on the left, had vertebral body stapling through a mini-open incision from T11 to L3. **B**, The PA radiograph at 2 years postop shows maintenance of the curve correction in the thoracic spine and the beginnings of overcorrection in the lumbar spine, specifically seen between the L1 and L2 vertebrae. **C**, PA radiographs from 4 years postsurgery show overcorrection of the lumbar spine and beginnings of overcorrection in the thoracic spine. The lumbar staples were then removed, but there turned out to be spontaneous fusion between L1 and L2 causing permanent reverse deformity of the lumbar curve.

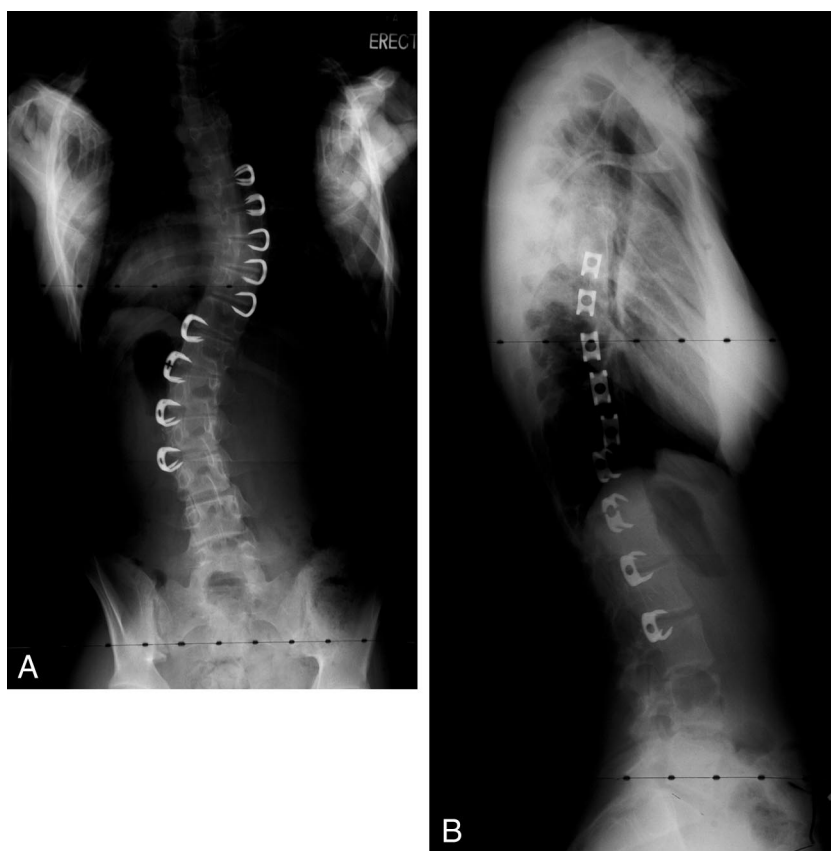


Figure 3. **A, B**, A 13-year-old female presents with a double curve (thoracic curve: 30°, lumbar curve: 28°). She underwent vertebral body stapling with essentially no correction, with the thoracic curve measuring 31° and the lumbar curve 27° at her first postoperative erect radiograph. On her 18-month follow-up AP and lateral radiograph, it was noted that she had a broken staple at the T12–L1 disc space. The staple did not dislodge. Her thoracic curve progressed to 40° and lumbar curve to 35°; however, it was felt that the staple did not lead to the progression of the curve, due to the fact that there was minimal to no displacement of the broken staple.

Treatment options such as bracing are associated with compliance and self image issues. The efficacy of brace treatment has been questioned in many studies.^{3,21} Currently, there are no alternatives to bracing other than observation. Vertebral body stapling offers just such an alternative; its early results are encouraging when compared to those of bracing and observation.

Dolan and Weinstein systematically reviewed the published clinical studies to estimate the prevalence of surgery after observation and brace treatment in patients with adolescent idiopathic scoliosis.³ They compared 139 patients in 3 studies treated with observation only to 1814 patients in 15 studies treated with a brace. In this review, the surgical rate in the observation studies was 22% (range, 13 to 38%) and the rate after bracing was 23% (range, 1 to 43%). In the same review, the surgical rate after bracing for curves <30° at the beginning of treatment was 5%, and 34% in curves >30°. The rate was 12% and 14.5%, respectively, for curves <30° and >30° in the observation group. Risk factors such as Ris-

ser 0 or 1 at presentation with a thoracic curve of >30° is associated with a risk for surgery of >30%. In a study by Noonan *et al*, 102 patients were studied following the use of Milwaukee brace.²¹ The average preoperative curve was 34°. In Noonan's series, 33% of patients had a curve progression >10°. In our series of VBS, 22% of patients progressed >10°. Our results seem comparable such that stapling might be used as an alternative to bracing. A study by Katz *et al* has examined the natural history and effectiveness of brace treatment for curves ranging between 36° and 45°. In this study, 83% of patients treated with the Charleston brace had a curve progression of >5°, compared with 43% in the Boston brace group. In this study by Katz, there seemed to be a significant division of results above or below 35°; therefore, 35° was chosen as the variable for curve severity subanalysis in our study of thoracic curves treated with VBS.

Although the idea of vertebral body stapling has been studied in the past, few studies describe the clinical results.^{14,16,17} Smith *et al* have reported its use in congenital scoliosis.¹⁴ Large curve magnitude and presence of rotation were associated with poor results. Betz *et al* have demonstrated feasibility, safety, and utility of the Nitinol staples in adolescent idiopathic scoliosis.¹⁷ In another study, Betz *et al* have reported results in 39 patients, in whom 87% of curves demonstrated coronal stability at a minimum 1-year follow-up.¹⁶ There are several animal studies using the prin-

Table 5. Complications Associated With Vertebral Body Stapling Procedure

Type of Complication	
Major	1 overcorrection 1 congenital diaphragmatic hernia rupture
Minor	1 superior mesenteric artery syndrome 1 mucus plug
Insignificant	3 broken staples

ciple of stapling for scoliosis correction.^{15,22,23} In a bovine study evaluating biomechanics of the shape memory alloy staple, Puttlitz *et al* have shown that the staples were able to achieve reduction in axial rotation and lateral bending motion.²⁴ Motion in the adjacent segment was preserved. Wall *et al* have applied the principle of spinal hemiepiphysiodesis, using an endoscopic approach in a porcine model.²³ Results show that the curve progression can be halted and possible correction can be achieved.

Use of a shape memory alloy staple offers many advantages. The fixation is more secure than that of the conventional staple. This is reflected in the 0% dislodgment rate in the current study. Preservation of motion is another advantage. Use of staples does not preclude future surgery; if the curve progresses $>50^\circ$ and fusion becomes necessary, the procedure can be performed and the desired correction achieved.

In this study, thoracic and lumbar curves were separately analyzed, because each respond differently to bracing. There were not enough curves to subanalyze the data by curve pattern (thoracic *vs.* thoracolumbar/lumbar *vs.* double major).

Complications were divided into 3 categories: Major, minor, and insignificant.²⁰ In this group of patients, 3 broken staples were noticed, none of which necessitated removal, and none of the staples dislodged. Subsequent to this study, with placement of over 1400 staples, the authors have seen 2 cases where the staple has moved (not dislodged). A major complication consisting of overcorrection was noticed in 1 patient. A 6-year-old girl underwent VBS for a double curve (thoracic 21° , lumbar 25°). Her thoracic curve remained stable and the lumbar curve corrected. At 29-month follow-up, it was noticed that her lumbar curve was bending in the opposite direction by 12° . She was followed closely with serial radiographs. At 4-year follow-up, her lumbar curve measured -33° . Following discussion with the family, the decision was made to remove the staples from the bottom 3 levels. Following the removal, some improvement was seen, and her lumbar curve measured -25° . At her most recent visit, her thoracic curve measured -12° . We continue to monitor both curves closely. Based on this experience, if a patient overcorrects 10° or more, we will remove the staples. Also, we recommend waiting until the patient is at least 8 years old or the curve has reached 30° if they are younger than 8 years old. However, we do not have enough data to give specific recommendations.

Limitations of this study include its retrospective nature and lack of a control group. This study is not an IDE study, and use of staples in this application is off label, which precludes the collection of prospective data. Hence, certain parameters are lacking, such as scoliometer reading depicting angle of trunk rotation, patient outcome questionnaires, *etc.*, and also data points in some of the parameters. In the current study,

patients have yet to reach skeletal maturity. In the interim, we continue to follow them closely. Ideally, the senior author would have liked to study bracing and observation along with VBS and did apply for grant monies. However, a level I or level II study would have been extremely costly and thus was not funded. This left us with the ability to conduct only a level III study of a select cohort to help advance the knowledge of fusionless treatment of early scoliosis.

This study did reveal important information that has led to a change in using VBS as a treatment option for idiopathic scoliosis. For stiff thoracic curves $>35^\circ$, a fusionless option would be to use staples along with some kind of posterior growing system. We are currently using a rib to spine single rod hybrid construct across the concavity. We also understand the importance of maximizing correction on the OR table in that our best results were seen when the first erect radiograph showed the curve reduced below 20° . We now use intraoperative techniques to maximize correction of each curve segment before stapling each disc space. Because of the trend we have seen in obtaining correction, we now offer patients with significant growth remaining (Sanders digital score <5) VBS as a corrective option and not just a way to hold the curve. In addition, if on first erect film the curve does not measure $<20^\circ$, the patient should consider wearing a nighttime corrective brace until the curve does measure $<20^\circ$. These strategies have just recently been adopted by the authors of this article based on this review, and it will take several years until the results of these strategies are available.

For future study, genetic testing (when available) may also help with patient selection in further refining the subset of patients who will definitely progress and with curves refractory to bracing.^{25,26} In addition, use of additional skeletal maturity points such as the digital scoring system of Sanders *et al*²⁷ and elbow scoring as reported by Dimeglio *et al*²⁸ to better determine patients who are Risser 0 will lead to further refinement in indications. Because of the retrospective nature of this series, these additional data are not available.

Based on this review, the senior author currently uses the following indications for recommending stapling to patients: (1) age <13 years in girls and <15 years in boys; (2) Risser 0 or 1 with 1 year of growth remaining by wrist radiograph; (3) thoracic and lumbar coronal curve $<45^\circ$ with minimal rotation and flexible to $<20^\circ$; and (4) sagittal thoracic curve $<40^\circ$. If the thoracic curve measures 35° to 45° and does not bend below 20° , then consideration is given to adding a posterior rib to spine hybrid construct at the same time (doing the posterior first). Also, if the curve on first erect film does not measure $<20^\circ$, the patient should wear a corrective nighttime brace until the curve measures $<20^\circ$.

■ Conclusion

In conclusion, vertebral body stapling may be an option for the treatment of idiopathic scoliosis with high-risk of

progression due to growth remaining. These results should be considered preliminary, as follow-up to skeletal maturity will be needed before definitive results can be described.

■ Key Points

- While bracing for idiopathic scoliosis is moderately successful, its efficacy has been called into question, and it carries associated psychosocial ramifications.
- We retrospectively reviewed 28 of 29 patients (96%) with idiopathic scoliosis treated with VBS followed for a minimum of 2 years. Inclusion criteria: Risser sign of 0 or 1 and coronal curve measuring between 20° and 45°.
- Analysis of patients with idiopathic scoliosis with high-risk progression treated with vertebral body stapling and a minimum 2-year follow-up shows a success rate of 87% in all lumbar curves and in 79% of thoracic curves <35°.

References

1. Rowe DE, Bernstein SM, Riddick MF, et al. A meta-analysis of the efficacy of non-operative treatments for idiopathic scoliosis. *J Bone Joint Surg Am* 1997;79:664-74.
2. Danielsson AJ, Hasselius R, Ohlin A, et al. A prospective study of brace treatment versus observation alone in adolescent idiopathic scoliosis: a follow-up mean of 16 years after maturity. *Spine* 2007;32:2198-207.
3. Dolan LA, Weinstein SL. Surgical rates after observation and bracing for adolescent idiopathic scoliosis: an evidence-based review. *Spine* 2007;32: S91-100.
4. O'Neill PJ, Karol LA, Shindle MK, et al. Decreased orthotic effectiveness in overweight patients with adolescent idiopathic scoliosis. *J Bone Joint Surg Am* 2005;87:1069-74.
5. Karol LA. Effectiveness of bracing in male patients with idiopathic scoliosis. *Spine* 2001;26:2001-5.
6. Emans JB, Kaelin A, Bancel P, et al. The Boston bracing system for idiopathic scoliosis. Follow-up results in 295 patients. *Spine* 1986;11:792-801.
7. Rahman T, Bowen JR, Takemitsu M, et al. The association between brace compliance and outcome for patients with idiopathic scoliosis. *J Pediatr Orthop* 2005;24:420-2.
8. Wiley JW, Thomson JD, Mitchell TM, et al. Effectiveness of the Boston brace in treatment of large curves in adolescent idiopathic scoliosis. *Spine* 2000; 25:2326-32.
9. Clayton D, Luz-Alterman S, Cataletto MM, et al. Long-term psychological sequelae of surgically versus nonsurgically treated scoliosis. *Spine* 1987;12: 983-6.
10. Stevens PM, Maguire M, Dales MD, et al. Physical stapling for idiopathic genu valgum. *J Pediatr Orthop* 1999;19:645-9.
11. Zuege RC, Kempken TG, Blount WP. Epiphyseal stapling for angular deformity at the knee. *J Bone Joint Surg Am* 1979;61:320-9.
12. Mente PL, Aronson DD, Stokes IA, et al. Mechanical modulation of growth for the correction of vertebral wedge deformities. *J Orthop Res* 1999;17: 518-24.
13. Nachlas IW, Borden JN. The cure of experimental scoliosis by directed growth control. *J Bone Joint Surg Am* 1951;33:24-34.
14. Smith AD, Von Lackum WH, Wylie R. An operation for stapling vertebral bodies in congenital scoliosis. *J Bone Joint Surg Am* 1954;36:342-8.
15. Braun JT, Ogilvie JW, Akyuz E, et al. Fusionless scoliosis correction using a shape memory alloy staple in the anterior thoracic spine of the immature goat. *Spine* 2004;29:1980-9.
16. Betz RR, D'Andrea LP, Mulcahey MJ, et al. Vertebral body stapling procedure for the treatment of scoliosis in the growing child. *Clin Orthop Relat Res* 2005;55-60.
17. Betz RR, Kim J, D'Andrea LP, et al. An innovative technique of vertebral body stapling for the treatment of patients with adolescent idiopathic scoliosis: a feasibility, safety, and utility study. *Spine* 2003;28:S255-65.
18. Howard A, Wright JG, Hedden D. A comparative study of TLSO, Charleston, and Milwaukee braces for idiopathic scoliosis. *Spine* 1998;23:2404-11.
19. Katz DE, Richards BS, Browne RH, et al. A comparison between the Boston brace and the Charleston bending brace in adolescent idiopathic scoliosis. *Spine* 1997;22:1302-12.
20. Weis JC, Betz RR, Clements DH III, et al. Prevalence of perioperative complications after anterior spinal fusion for patients with idiopathic scoliosis. *J Spinal Disord* 1997;10:371-5.
21. Noonan KJ, Weinstein SL, Jacobson WC, et al. Use of the Milwaukee brace for progressive idiopathic scoliosis. *J Bone Joint Surg Am* 1996;78:557-67.
22. Braun JT, Hoffman M, Akyuz E, et al. Mechanical modulation of vertebral growth in the fusionless treatment of progressive scoliosis in an experimental model. *Spine* 2006;31:1314-20.
23. Wall EJ, Bylski-Austrow DI, Kolata RJ, et al. Endoscopic mechanical spinal hemiepiphysiodesis modifies spine growth. *Spine* 2005;30:1148-53.
24. Puttlitz CM, Masasru F, Barkley A, et al. A biomechanical assessment of thoracic spine stapling. *Spine* 2007;32:766-71.
25. Ward K, et al. Genetic profile predicts curve progression in adolescent idiopathic scoliosis. Scoliosis Research Society Annual Meeting, Salt Lake City, UT, September 10-13, 2008.
26. Ogilvie, et al. Predicting brace-resistant adolescent idiopathic scoliosis. Scoliosis Research Society Annual Meeting, Salt Lake City, UT, September 10-13, 2008.
27. Sanders JO, Browne RH, McConnell SJ, et al. Maturity assessment and curve progression in girls with idiopathic scoliosis. *J Bone Joint Surg Am* 2007;89: 64-73.
28. Dimeglio A, Charles YP, Daures JP, et al. Accuracy of the Sauvegrain method in determining skeletal age during puberty. *J Bone Joint Surg Am* 2005;87: 1689-96.