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An Innovative Technique of Vertebral Body Stapling for the Treatment of Patients With Adolescent Idiopathic Scoliosis: A Feasibility, Safety, and Utility Study

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Study Design. Retrospective review.

Objectives. To report the feasibility, safety, and utility of vertebral body stapling without fusion as an alternative treatment for adolescent idiopathic scoliosis.

Summary of Background Data. The success rate of brace treatment of adolescent idiopathic scoliosis ranges from 50% to 82%. However, poor self-image and brace compliance are issues for the patient. An alternative method of treatment such as a motion-preserving vertebral body stapling to provide curve stability would be desirable.

Methods. We retrospectively reviewed 21 patients (27 curves) with adolescent idiopathic scoliosis treated with vertebral body stapling. Patients were immature as defined by Risser sign ≤2.

Results. The concept of vertebral body stapling of the convex side of a patient with adolescent idiopathic scoliosis is feasible. The procedure was safe, with no major complications and three minor complications. One patient had an intraoperative segmental vein bleed resulting in an increased estimated blood loss of 1500 cc as compared to the average estimated blood loss of 247 cc for all patients. One patient had a chylothorax and one pancreatitis. No patient has had a staple dislodge or move during the follow-up period (mean 11 months, range 3–36 months), and no adverse effects specifically from the staples have been identified. Utility (defined as curve stability) was evaluated in 10 patients with stapling with greater than 1-year follow-up (mean 22.6 months) and preoperative curve <50°. Progression of ≥6° or beyond 50° was considered a failure of treatment. Of these 10 patients, 6 (60%) remained stable or improved and 4 (40%) progressed. One of 10 (10%) in the stapling group had progressed beyond 50° and went on to fusion. Six patients required stapling of a second curve, three as part of the primary surgery, and three as a second stage, because a second untreated curve progressed. The results need to be considered with caution, as the follow-up is still short.

Conclusions. The data demonstrate that vertebral body stapling for the treatment of scoliosis in the adolescent was feasible and safe in this group of 21 patients. In the short-term, stapling appears to have utility in stabilizing curves of progressive adolescent idiopathic scoliosis. [Key words: vertebral body, stapling, fusionless, bracing, adolescent idiopathic scoliosis] **Spine 2003;28:S255–S265**

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Adolescent idiopathic scoliosis (AIS) is diagnosed between 10 and 18 years of age.[1–3] The natural history of curve progression in AIS is dependent on the patient's skeletal maturity, the curve pattern, and the curve severity.[2] Patients with significant growth potential and large curves at presentation are more likely to progress without treatment 74% of the time.[1,3,4] Those with curves between 50° and 75° at maturity, particularly thoracic curves, will progress an average of 29.4° in adulthood, and prevention of curve progression beyond 50° therefore would be most prudent.[5] The standard of care currently for immature patients with AIS curves measuring 20° to 40° is a cervicothoracolumbosacral orthosis (CTLSO) or a thoracolumbosacral orthosis (TLSO). These braces are used to control progression of curves measuring 20° to 40° but 18% to 50% of these curves will progress in spite of bracing.[1–4,6–9]

Convex apical vertebral body/hemiepiphyseal stapling theoretically affords immediate and possible reversible cessation of growth of the anterior vertebral physes.[10,11] Stapling across physes of the long bones has long been accepted as a predictable method of treating limb malalignment in young children.[12,13] In 1949, Blount and Clarke were the first to report lower extremity angular correction with hemiepiphyseal stapling.[13] Animal studies using a rat tail model confirm the ability to modulate vertebral growth plates with skeletal fixation devices.[14,15] Nachlas and Borden[16] performed vertebral interbody stapling across the physeal end plates and discs in a dog scoliosis model. Many dogs exhibited some correction, and some animals exhibited arrest of their curve progression. Some staples failed because they spanned three vertebrae. Results for human patients with congenital scoliosis were presented as early as 1954,[17] but the results were disappointing. The scoliosis correction was limited because the children had little remaining growth and the curves were severe, with considerable rotational deformity. Some staples broke or became loose, possibly because of motion through the intervertebral discs.

In 1997, James Ogilvie (personal communication) began performing scoliosis stapling *via* thoracoscopic assistance on six patients—three with infantile scoliosis, two with juvenile scoliosis, and one with myelodysplasia. Before surgery, their curves had progressed despite bracing for the previous 12 months. At the 2-year follow-up, 4 of the 6 curves stabilized following stapling. In two patients, the staples partially dislodged, and additional surgery was needed to replace the staple.

The concept of stapling the anterior vertebral spinal growth plates for growth modulation and curve stabilization seems sound, but the staples designed for the long bones are prone to dislodge in the spine because they were not designed for movement which occurs in the spine. To address this concern, Medtronic Sofamor Danek (Memphis, TN) has designed a specific spine staple called the Nitinol (Nickel Titanium Naval Ordnance Laboratory) Staple, which has 510 K approval from the Food and Drug Administration (FDA) specifically for use as an anterior spinal staple. The uniqueness of this staple is that it is made out of a shape memory alloy in which the prongs are straight when cooled but clamp down in a "C" shape in the bone for secure fixation when the staple returns to body temperature.

Nitinol is a biocompatible shape memory metal alloy of 50% nickel and 50% titanium. It is currently best known for its use in cardiovascular stents.[18–21] The temperature at which the staples will undergo the shape transformation can be controlled by the manufacturing process.[22] Injury to surrounding tissues through the transformation temperature has not been seen in animal[22] or human experience with cervical spine fusions.[23–25]

Nitinol has a very low corrosion rate and has been used in orthodontic appliances.[22] Implant studies in animals have shown minimal elevations of nickel in the tissues in contact with the metal; the levels of titanium are comparable to the lowest levels found in tissues of titanium hip prostheses,[22,26–30] and titanium is considered a biologically safe implant material.[31,32] No method of sterilization used in operating rooms has been shown to have any effect on the metal's properties.[22]

Although sensitivity to nickel occurs in a very low percentage of the population, it is not anticipated to occur through use of this Nitinol staple. The crystal structure in Nitinol is different than the small amount of nickel crystal structure in stainless steel such that the nickel does not leach out in Nitinol compounds as it can on occasion with stainless steel.

The newly developed Nitinol staple has been tested in a goat model by Braun *et al*[33–35] and was shown to be safe and have utility for arresting the iatrogenic curves of less than 70° in the goat.

The goal of this current study was to determine the feasibility, safety, and utility of vertebral body stapling without fusion as a treatment to stabilize the curves in patients with AIS. For the purpose of this study, "feasibility" was defined as successful placement of staples at every planned level; "safety" was defined by the number of perioperative complications (within 3 months); and "utility" refers to the ability to which staples produce or achieve curve stability, with "curve stability" defined as the curve showing less than 6° of progression and the prevention of curve progression past 50°, the generally accepted tidemark for surgery.[5]

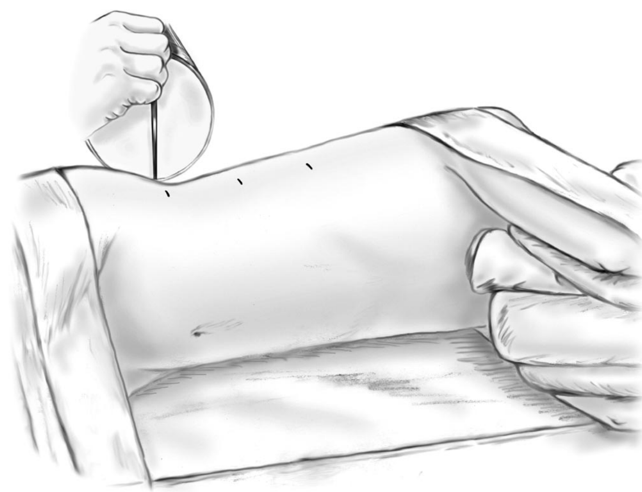

Figure 1. The patient is placed in a lateral decubitus position. Using fluoroscopic imaging, the levels of the spine to be stapled (in the coronal plane) can be confirmed. Markings show the portals, through which 2–3 discs per portal can be stapled.

Materials and Methods

This was a retrospective review of patients who had undergone vertebral stapling for treatment of AIS either as an alternative to bracing as primary treatment or if the patient desired to change their treatment from a brace to stapling. Inclusion criteria for this review: onset after age 9 years and skeletally immature, with Risser sign ≤2. Exclusion criteria: >40° kyphosis, a medical contraindication to general anesthesia, reduced pulmonary function that would contraindicate anterior spine surgery, or sensitivity to nickel.

Twenty-one consecutive patients met the inclusion criteria and have had vertebral body stapling of 27 curves. The preoperative curves ranged from 18° to 52°. The average age at surgery was 12.0 years (range 10–14 years). This group of 21 patients was analyzed for feasibility and safety. Ten patients with ≥1 year follow-up and preoperative curves <50° will be analyzed for utility of the procedure.

Surgical Technique for Stapling. General anesthesia is utilized. The patient is positioned in the lateral decubitus position with the convex side of the scoliosis in the up position. Visualization with fluoroscopic imaging is confirmed (Figures 1 and 2). The table is not flexed. All the vertebrae in the measured Cobb curve are stapled. For thoracic curves, a thoracoscopic-assisted approach is preferable. A double lumen endotracheal tube is inserted so that the convex lung can be collapsed. The first portal is made in the fifth to seventh intercostal interspaces along the anterolateral chest line for the visualization with the scope. Additional portals are made in the posterior axillary line

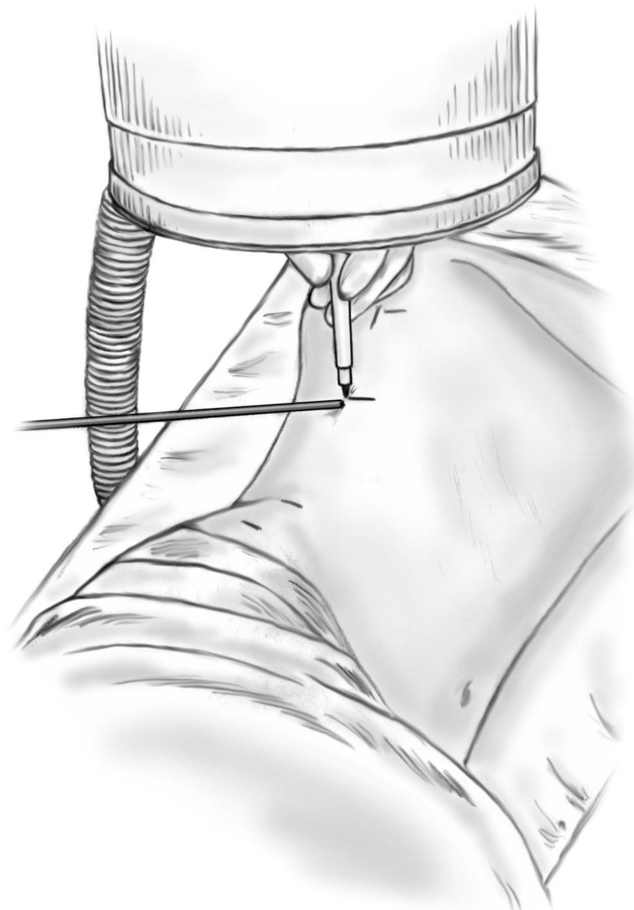

Figure 2. A lateral image of the patient can be utilized to again confirm the levels of the vertebral stapling and also to center the portals over the midportion of the vertebral bodies.

for insertion of the staples (Figure 3). As an alternative to posterolateral portals, two mini (<5 cm) thoracotomy incisions may be used (for example, one centered at T4–T5 and the other at T9–T10). Fluoroscopic image is used to confirm the levels to be stapled. A trial inserter is used to obtain the dimension of the staple (4 to 14 mm) and to create pilot holes (Figure 4). The staple, which has been cooled over a basin of ice, is placed over the pilot holes (Figure 5). Once inserted and position is confirmed by radiograph, final seating is done (Figure 6). Ideally, two single staples or a double staple are placed laterally, spanning each disc space of the measured Cobb curve (Figure 7). In most cases, the parietal pleura is not excised, and the segmental vessels are preserved. On occasion, it is necessary to make a small incision parallel to the segmental vessels to allow slight movement of the vessel away from the staple prong. If there is significant hypokyphosis (kyphosis <10°) of the apex of the thoracic spine, the staples are placed more anteriorly to the midbody of the vertebra, or a third staple is used and placed along the anterolateral aspect of the vertebral body (Figure 8). Final confirmatory fluoroscopic images are taken. If a staple is not in the desired position, it can be pulled out with a moderate pull using a clamp. A chest tube is placed to prevent a pneumothorax and for drainage of any effusions. Lumbar vertebrae were approached with a mini-open retroperitoneal approach. Staples that crossed the thoracolumbar junction required partial reflection of the diaphragm anteriorly off the spine.

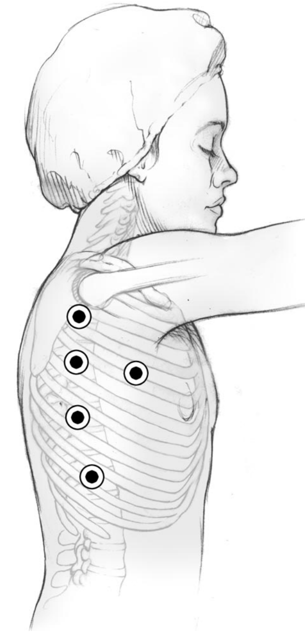

Figure 3. Generally, 3 to 4 portals in the posterolateral line are utilized with the thoracoscope being inserted in the anterior axillary line at the apex of the curve.

Postoperative Protocol. After surgery, patients wore a custom noncorrecting TLSO full-time for 4 to 12 weeks to allow the staples to stabilize. After brace removal, there were no restrictions of activity. Patients were seen after surgery at 1 and 2 months for wound checks and then every 6 months thereafter. Standing posteroanterior and lateral radiographs from the cervicothoracic junction to the sacrum were obtained at each 6-month visit.

Data Analysis. Feasibility is defined as the ability to place staples at every level of the measured Cobb curve. Safety was analyzed as the number of perioperative complications (within

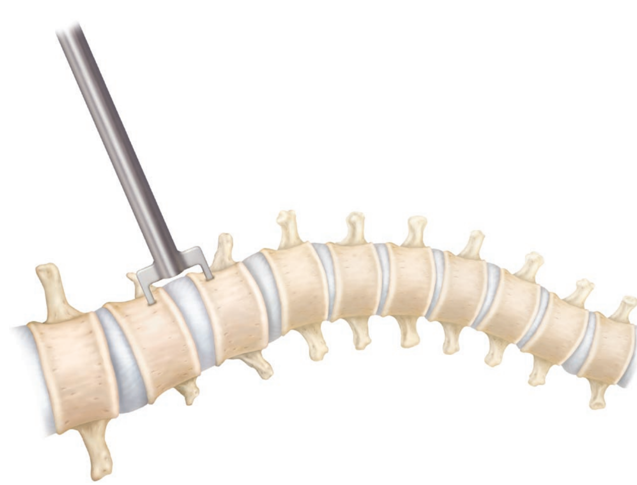

Figure 4. The trial inserter is passed through one of the posterolateral portals and can be centered over the intervening disc space for measurement. The surgeon needs to get the prongs as close to the endplate as possible. Once the position is confirmed through an anteroposterior image, starting holes are then placed. Generally, the posterior holes are inserted first, just anterior to the rib heads.

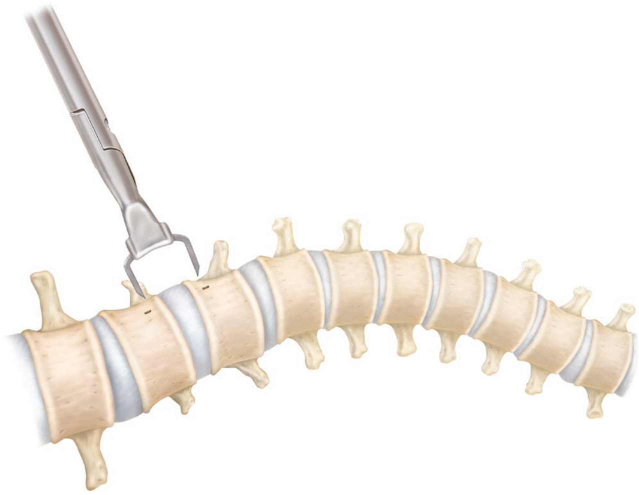

Figure 5. The staple then is inserted into the pilot holes. The position is confirmed with fluoroscopic image. The pilot holes for a second 2 prong staple to be placed posterior to the first staple can be seen.

3 months) in this consecutive series of all 21 patients with AIS who underwent the stapling procedure. The perioperative complications are reported as major, minor, or insignificant as defined by Weis *et al*[36]: major complications were those that caused permanent sequelae, necessitated a second major operation, or required a prolonged hospital stay (≥3 weeks). Minor complications were those that necessitated a minor operation, caused significant temporary hardship, caused persistent minor problems, or prolonged the hospital stay (<3 weeks). Insignificant complications are not reported.

For utility results on curve stability, 11 patients who had >1 year follow-up and preoperative curves <50° were analyzed. The stapling group consisted potentially of 12 patients with ≥1 year follow-up; however, one patient was lost to follow-up after 3 months and one had a curve of 50°, leaving a group of 10 patients with which to analyze utility. Curve stability is defined as the Cobb angle showing less than 6° of increase from the preoperative measurement.[7] Utility is also reported as prevention of the curve progression to 50° or better, as this is the tidemark most surgeons use for surgery because of the risk for curve progression after maturity.[5]

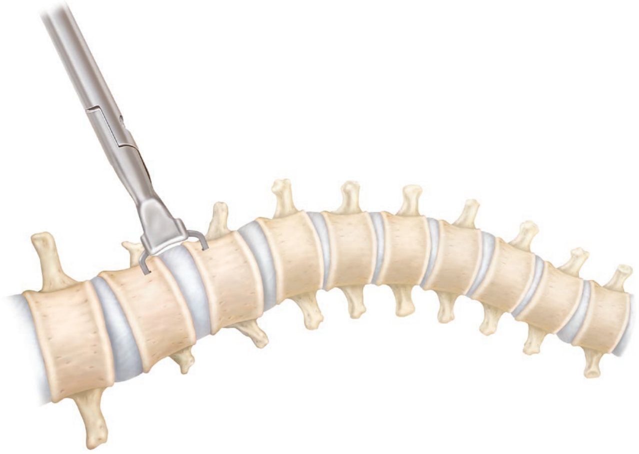

Figure 6. Once the staple is impacted in position and the position checked by radiograph, it is seated with an impactor, taking care not to impact too firmly, breaking bone trabeculae and causing additional bleeding.

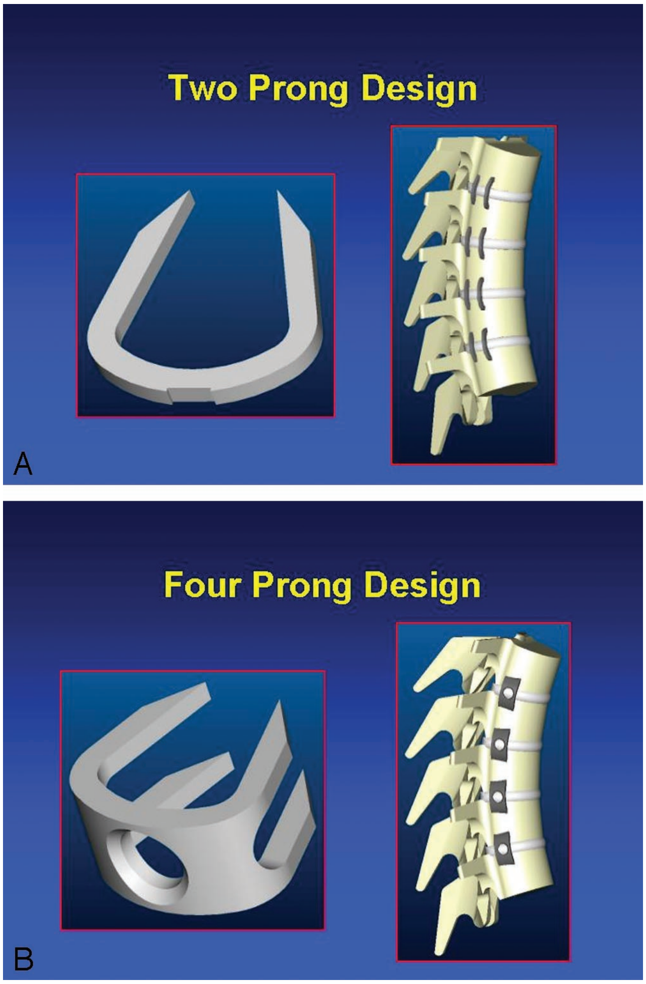

Figure 7. **A**, Generally, two staples are utilized at each vertebral segment. This can be in the form of two single staples, which allow the flexibility of adding a third anterior staple if desirable. **B**, However, to facilitate time, a double staple is commonly used.

Results

Feasibility

Feasibility was demonstrated for each patient in that surgery was successful for placement of staples at every

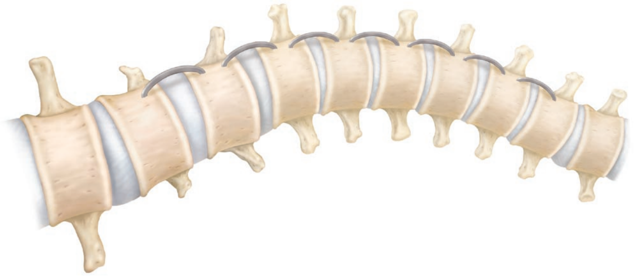

Figure 8. After checking final images, if a staple is not in a desirable position, then one can use a specially designed grasper to remove the staple. This takes a firm pull to remove the staple, but it can be done. Bone wax can then be applied to the staple holes, and the staple can be repositioned.

Table 1. Safety Data

Patient No.	DOB	DOS	Age at Surgery (yrs)	Follow-up (months)	Preop Curve	Levels	EBL	POD	CTD	Complications	Comments
1	9/27/1987	4/25/2000	12	36	38	T7–L2	1500	11	10	Segmental vein bleed, required transfusion prolonged chest tube drainage	
2	5/5/1987	8/29/2000	13	30	35	T6–T12	200	4	3	None	
3	9/25/1989	12/18/2000	11	24	36	T5–T11	500	12	3	None	Progressed to fusion
4	12/15/1987	1/2/2001	13	24	40	T8–L2	100	7	5	Prolonged chest tube drainage	
5	10/21/1986	3/6/2001	14	22	30	T6–T12	300	9	6	Prolonged chest tube drainage	
6	1/12/1987	4/23/2001	14	17	33	T6–L1	200	15	14	Prolonged chest tube drainage; chylothorax, TPN	
7	12/10/1990	5/14/2001	10	22	35	T6–T12	150	4	3	None	
		9/16/2002	11	6	37	T12–L4	50	3	3	None	2nd untreated curve stapled for progression
8	8/21/1988	6/25/2001	12	21	36	T10–L3	500	5	3	None	
9	9/25/1988	10/15/2001	13	15	28	T5–T12	150	5	4	None	
10	3/15/1990	11/26/2001	11	15	38	T5–T12	200	5	4	None	
		10/14/2002	12	6	45	T12–L4	150	4	2	None	2nd untreated curve stapled for progression
11	10/8/1991	12/17/2001	10	3	22	T9–L2	600	6	3	None	Lost to follow-up
12	3/12/1989	2/26/2002	12	12	50	T6–T11	100	6	4	None	Progressed to fusion
13	4/6/1992	4/15/2002	10	6	21	T6–T12	200	5	4	None	
14	8/23/1989	5/2/2002	12	6	51	T11–L4	150	6	4	None	
		12/2/2003	13	3	41	T5–T11	200	5	4	None	2nd untreated curve stapled for progression
15	3/24/1990	6/17/2002	12	6	24	T11–L3	75	7	3	None	
16	10/31/1988	8/5/2002	13	3	55	T11–L3	300	7	3	Pancreatitis/braced 10/02	
17	10/9/1988	8/12/2002	13	3	18	T5–T10	150	7	6	Prolonged chest tube drainage	
18	3/27/1990	11/12/2002	12	6	52	T6–T12	50	6	3	None	2nd curve stapled as part of index procedure
		11/12/2002	12	3	37	T12–L4	50	6	2	None	
19	7/31/1991	11/13/2002	11	3	39	T5–T12	200	7	2	None	2nd curve stapled as part of index procedure
		11/13/2002	11	3	28	T12–L4	200	7	0	None	
20	6/18/1990	12/17/2002	12	3	27	T7–T12	150	6	2	None	2nd curve stapled as part of index procedure
	1/0/1900	12/17/2002	12	3	39	T12–L4	150	6	0	None	
21	5/28/1990	12/18/2002	12	3	40	T6–L1	100	6	3	None	
		Average	11.9	11.1	36.1		247	6.6	3.8		
		SD	1.1	9.9	9.5		285	2.6	2.8		

DOB = date of birth; DOS = date of surgery; EBL = estimated blood loss; POD = postop days; CTD = chest tube drainage.

planned level. Two patients had only one staple placed instead of two at the upper thoracic level because of the small vertebral body size. No patient required conversion to open thoracotomy for placement of staples.

Safety

There were no major complications and 3 minor complications (14%) in the stapling group (Table 1). One patient (Case 1) had a segmental spinal vein that was punctured by a staple prong, requiring conversion of the thoracoscopic portal to a mini-incision and ligation of the vein. This resulted in a blood loss of 1500 cc, which is significantly more than the estimated blood loss (EBL) of the collective surgeries (average 247 cc ± 285 cc). A second patient developed a chylothorax from a staple prong puncture of the thoracic duct at T12 that was not noticed at surgery and was treated conservatively with chest tube and total parenteral nutrition. One patient developed pancreatitis. Two additional patients had pro-

Table 2. Stapling Patients With at Least 1 Year Follow-up and Preop Curves <50°

Patient No.	DOB	DOS	Age at Surgery (yrs)	Risser	Menses	Levels	Follow-up (mos)	Preop Curve (°)	Follow-up (°)	Change in Curve (°)
1	9/27/1987	4/25/2000	12	0	Male	T7–L2	36	38	22	−16
2	5/5/1987	8/29/2000	13	1	Yes	T6–T12	30	35	27	−8
3	9/25/1989	12/18/2000	11	0	No	T5–T11	24	36	55	19*
4	12/15/1987	1/2/2001	13	0	No	T8–L2	24	40	47	7
5	10/21/1986	3/6/2001	14	2	Yes	T6–T12	22	30	40	10
6	1/12/1987	4/23/2001	14	1	Yes	T6–L1	17	33	33	0
7	12/10/1990	5/14/2001	10	0	No	T6–T12	22	35	40	5
8	8/21/1988	6/25/2001	12	0	No	T10–L3	21	36	25	−11
9	9/25/1988	10/15/2001	13	1	No	T5–T12	15	28	38	10
10	3/15/1990	11/26/2001	11	0	No	T5–T12	15	38	42	4
						Average	22.6	34.9	36.9	2.0
						SD	6.6	3.7	10.3	10.8

* Went to fusion.
DOB = date of birth; DOS = date of surgery.

longed chest tube drainage beyond 4 days, which was considered an insignificant complication. A strict criteria of <100 cc per 24 hours for chest tube removal was enforced. The average hospital stay was 6.6 ± 2.6 days, and the average number of days with a chest tube was 3.8 ± 2.8 days.

Over follow-up averaging 11 months (range 3–36 months), there has been no evidence of staple dislodgement or migration in the entire group of 21 patients. Data on the 10 patients with follow-up > 1 year and preop curves <50° are reported in Table 2.

Utility

For the 10 patients evaluated for utility, the average preoperative curve measured 35 ± 3.7° (range 28°–40°) and average follow-up curve measured 37 ± 10.2° (range 22°–55°). With minimum 1-year follow-up, the change in the curves ranged from a decrease of 16° to an increase of 19°. The average curve progression was 2.2°. At most recent follow-up, 6 of the 10 patients had curves within 6° of their baseline preoperative curve measurement. Three of the 6 had significant improvement: Case 1, 16° (Figure 9); Case 2, 8°; and Case 8, 11°. Four of the 10 (40%) showed progression of 19°, 10°, 10°, and 7°, respectively. Using progression to beyond 50° is the tidemark most surgeons use for risk of significant progression after maturity. One of the 10 (10%) progressed beyond 50°; this patient (Case 4, 11-year-old female) underwent surgery for progression of her thoracic curve (Figure 10). The thoracic curve was stable for 1 year, but the untreated lumbar curve progressed. Finally, the thoracic curve progressed, which was felt to be in response to the severe increase in the unstapled, nonbraced lumbar curve.

One additional patient with >1 year follow-up (Case 12, 12-year-old female) was scheduled for stapling on presentation with a 40° curve. Her magnetic resonance imaging (MRI) was normal. Within 5 weeks, the preoperative radiograph showed the curve to be 50°. The family wanted to proceed with the stapling procedure. After initial improvement to 40°, the curve progressed to 55°, and a fusion was performed.

When evaluating the second (untreated) curve, 4 patients with >1 year follow-up had progression of their unstapled lumbar curve after the thoracic curve was stabilized with stapling. One patient (Case 4) went on to require a fusion because of this progression, and 3 patients underwent stapling of the second curve.

Vertebral body wedging changes in the apical vertebrae was assessed in the 10 patients having >1 year follow-up. It improved in 2 patients (Case 1 and Case 6) an average of 3° and was unchanged in the other 8 patients.

Discussion

This preliminary work demonstrates the feasibility, safety, and utility of vertebral body stapling without fusion as an alternative treatment to stabilize the curves in patients with AIS. Technically, it was feasible to place staples on all levels of the measured Cobb curve from T5 to L4, with the majority of levels having 2 or 3 staples. In 2 patients, T5 was too small for two staples. The smaller staples available at that time did not have different length tines, and the tines would have protruded anterolateral on the concave side. Now, the 4-mm and 6-mm staples have proportionally shorter tines.

The perioperative complications of 21 consecutive patients reported included 3 (14%) minor complications. The one case of pancreatitis was probably related to the postoperative narcotic effect on the common bile duct. This rate falls within the ranges reported in the literature for complications of similar surgery. The reported rate of major complications in the fusion treatment of thoracic AIS is 0.4% and minor complications 4.8%, with rates in both the anterior and posterior approaches.[37] Grossfeld *et al*[38] reviewed 599 anterior procedures in children (51 with idiopathic scoliosis) and reported a 7.5% incidence of major complications and 33% minor complications. In the Grossfeld *et al* article, the complication rate spe-

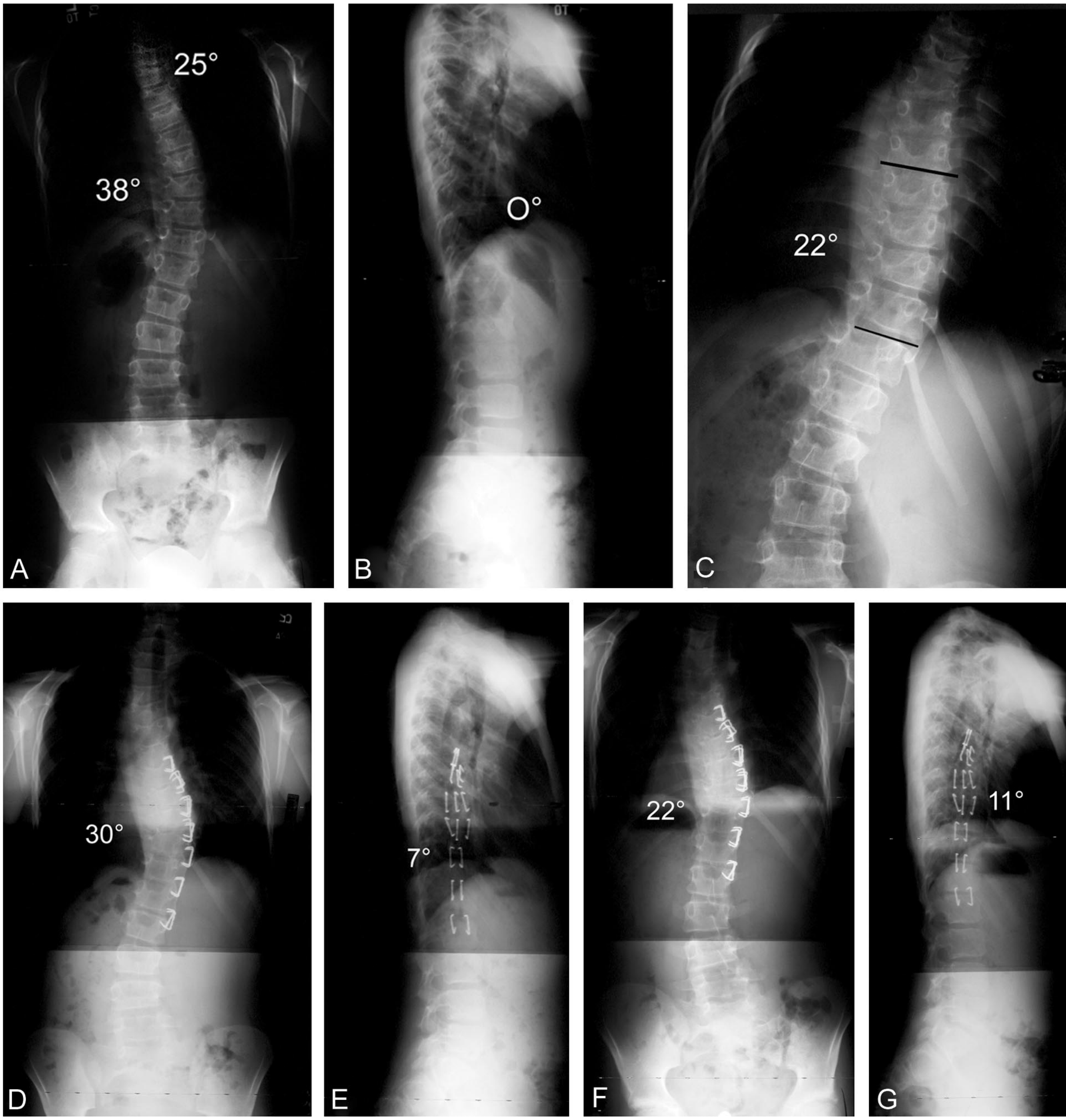

Figure 9. Case 1. **A**, Preoperative anteroposterior and (**B**) lateral in a 12-year-old male. He had been braced for adolescent idiopathic scoliosis for 2 years and had progressed from 25° to 38° and was considering a spinal fusion. He was Risser 0, with open triradiate cartilages. The lateral radiograph (B) shows 0° of thoracic kyphosis. The right supine bend (**C**) shows the curve to reduce to 22°. The patient underwent a vertebral body stapling from T7 to L2. The 1-year follow-up erect posteroanterior film (**D**) shows the thoracic scoliosis to be reduced to 30°. The lateral radiograph (**E**) shows the kyphosis to have increased to 7°. At 36-month follow-up, the patient's scoliosis reduced to 22° (**F**) and the thoracic kyphosis had increased to 11° (**G**). During the 36-month follow-up period, the patient grew 11 inches.

cific for the patients with idiopathic scoliosis was not specified, and the paper included both perioperative and long-term complications. In the Weis *et al*[36] series of patients less than 21 years old, there were no major complications, and 20% had a minor complication. This study did not subdivide the data by curve type. Lenke *et al*[39] described early postoperative complications occurring in 3 of 95 patients (3.16%) after posterior spinal fusion with Cotrel-Dubousset instrumentation. In the Lenke *et al* article, there was one case of pneumonia, one chylothorax, and one superior mesenteric artery syndrome.

It is encouraging to report that no patient has had staple dislodgement or migration during the follow-up period. No patients have reported adverse effects (such as restricted motion or pain) from the stapling procedure. However, this was not studied prospectively.

The early vertebral body stapling results of this cohort of curve stability are better than the predicted natural history of progression for these patients (60% stable,

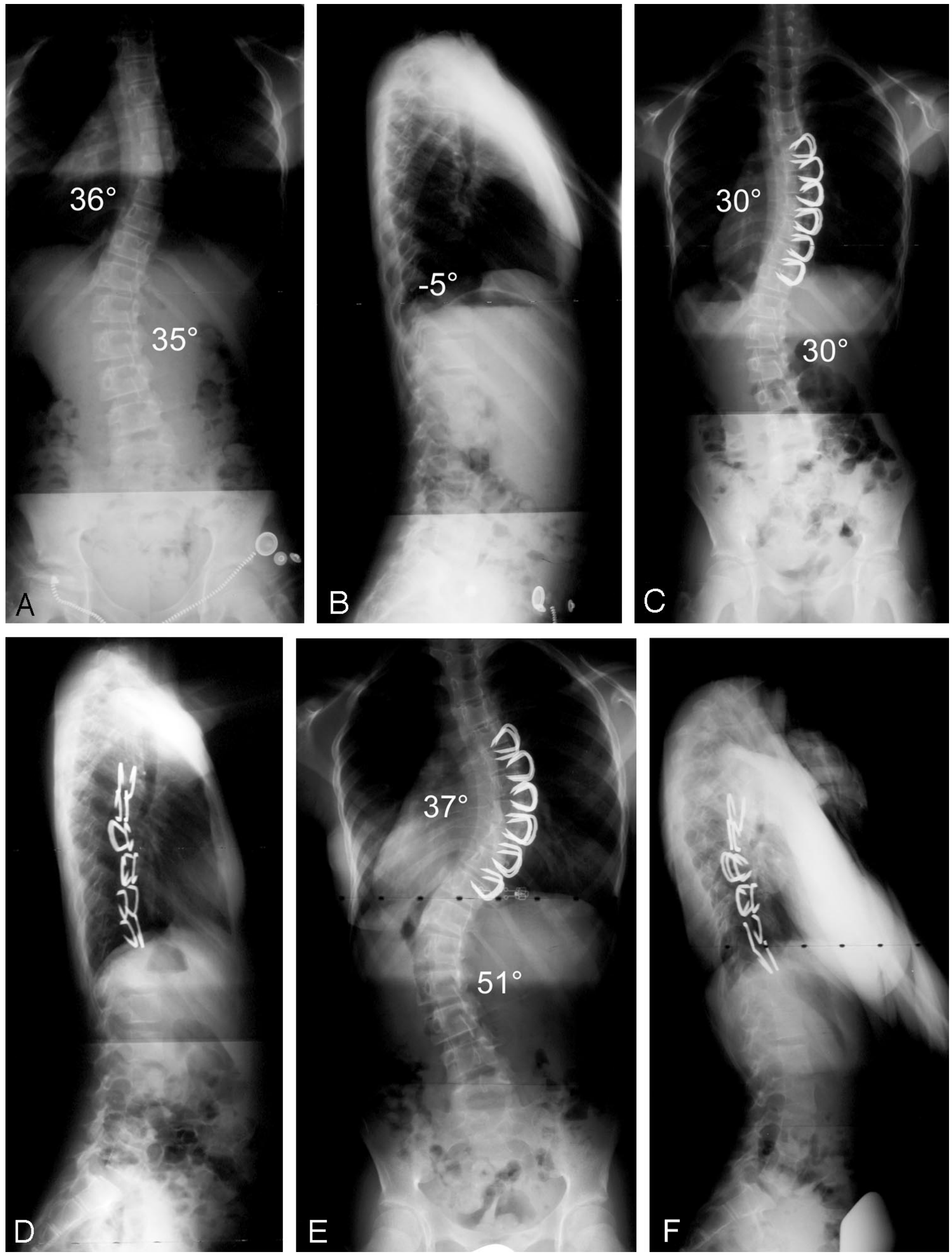

Figure 10. Case 4. This is a 10-year-old female who presents with idiopathic scoliosis. Magnetic resonance imaging is normal. She has open triradiate epiphyses and is premenarche. On the posteroanterior film (**A**), her scoliosis measures 36° thoracic, 35° lumbar, and on the lateral (**B**) her kyphosis from T5 to T12 is −5°. The patient underwent vertebral body stapling from T5 to T11. The initial erect postoperative film (**C**) shows the scoliosis to measure 30° thoracic, 30° lumbar. The lateral radiograph (**D**) shows two staples at each interspace. By the time the patient was 2 years poststapling, her lumbar curve (**E**) had increased to 51°. The thoracic curve (**F**) was still stable at 37°. The patient had a significant cosmetic deformity with trunk shift and asymmetrical hips. A fusion was recommended because of the progression in the lumbar curve, the fact that she was still premenarche, and she refused to wear a brace. **G**, This is the immediate anteroposterior prefusion film which is 2.5 years poststapling. The thoracic curve now has increased to 55° and the lumbar to 67°. Without control of the lumbar curve, the thoracic curve may have had to increase.[46] Preoperative left (**H**) and right (**I**) bend films. The left bend film shows the scoliosis to increase no further than what it does in the erect position, suggesting a successful tether on the convexity from the staples. However, on the right supine bend film, the scoliosis reduces to 33°, suggesting preserved motion. Postoperative anteroposterior (**J**) and lateral erect (**K**) films show excellent correction in both the coronal and sagittal planes. There was no restriction of motion on distraction between the spinous processes, and the staples do not appear to have inhibited the postoperative correction.

40% progressing). Specifically, Lonstein and Carlson[40] found that in skeletally immature patients (Risser 0–1), 68% of curves measuring 20° to 29° progressed 5° or more. Skeletally immature children with curves >30° progressed in approximately 60% to 90% of cases.

The current standard of care for immature patients with AIS and a curve of 20° to 40° is a CTLSO or a TLSO. These braces are used to control progression, but 18% to 50% of these adolescents will progress in spite of bracing.[1–4,6–9] Noonan *et al*[41] in 1996 re-

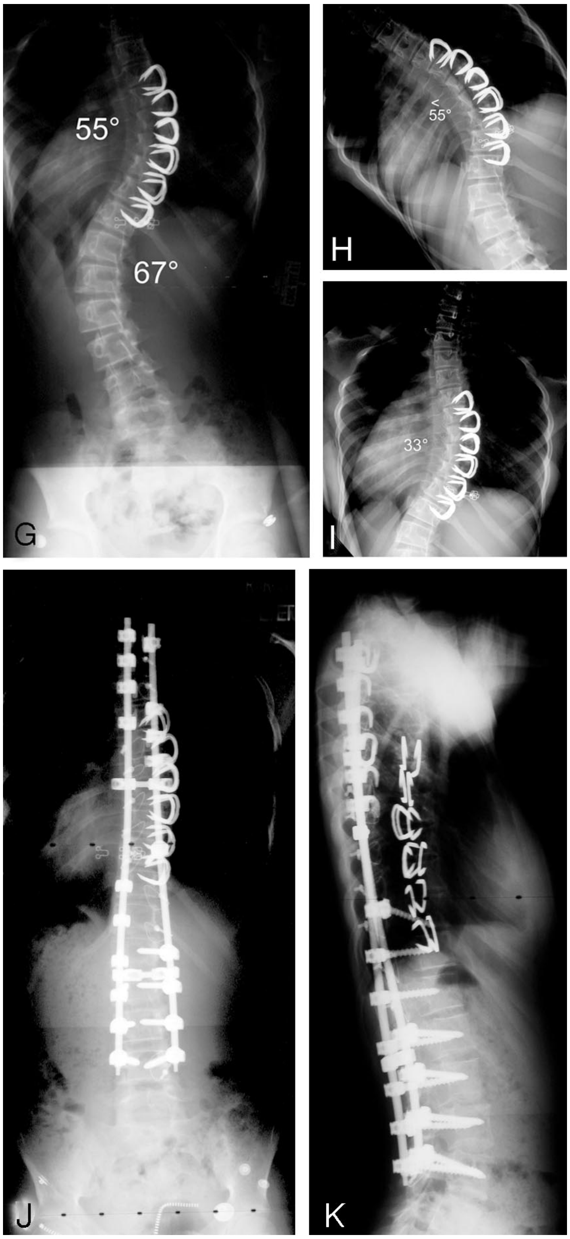

Figure 10. *Continued.*

ported on 102 patients using the Milwaukee brace for progressive idiopathic scoliosis, with an average follow-up of 6.3 years. They showed that nearly 50% of patients treated had progression of the curve beyond 5°.

Nachemson and Peterson,[7] in association with the Scoliosis Research Society, published the results of a prospective, controlled study comparing brace treatment, electrical stimulation, and observation only. Less than 6° of progression was noted in 74% of the brace-treated patients, in 33% of those treated with electrical stimulation, and in 34% of patients treated with observation only. However, there were a disproportionately high number of the more benign thoracolumbar curves in the braced group, likely resulting in a more positive outcome for the braced group. In addition, only curves measuring 25° to 35° were included, thus eliminating a large population of patients with curves between >35 and 45° (a category into which 5 of our 10 patients with >1 year follow-up fell). Patients with curves in this range (35°–45°) are usually indicated for bracing and are thought to have the largest risk for progression.

Comparison of curve stability using criteria of ≥6° change shows the results of stapling in controlling curve stability (60%) to be comparable or better than these brace series. Larger numbers of patients are needed to allow subanalysis of patients to decide who best benefits from a stapling.

In immature patients (especially females) with braceable curves, brace wear is often necessary for 14 to 23 hours per day for 4 to 5 years.[4] Poor self-image may result in adolescents who are braced for scoliosis, and brace compliance is often poor.[6,42–49] Stapling offers an alternative to possibly address these issues, but this needs to be studied further.

Using similar criteria for fusion (progression to >50°), the number of patients in the current study (1 of 10, or 10%) are in the range of other brace studies reporting progression to fusion in 18 to 42% of cases.[7,41,50] In this current study, 3 patients had preoperative curves >50°, and all 3 of these have progressed and required fusion: Case 12, Case 16, Case 18. We currently recommend vertebral body stapling for immature patients with AIS (Risser 2 or less) with curves between 20° and 45°.

Two issues may improve the results of vertebral body stapling in the future. Early in the stapling experience, in an effort to make sure we did not invade the endplate, larger width staples were placed (average 8-mm to 10-mm), and the staples did not have proportional tines. Therefore, sometimes the tines extended more than 50% across the vertebral body width, and, in addition, there was significant space between the staple base and the growth plate (Figure 10C). Our current technique uses smaller staples (average 4-mm and 6-mm) instead, with proportionally smaller tines.

Not controlling all the curves may be a contributing factor. Recent evidence from brace treatment suggests that insufficient control of the lumbar curve can lead to curve progression.[51] Case 4, who went on to fusion, is an example of the thoracic curve remaining stable but the lumbar curve progressing, resulting in the need for a fusion.

Three patients had stapling of a second curve, because the untreated lumbar curve progressed. We now staple all potentially treatable (braceable) curves. Three of the 21 patients had this done as part of their index procedure (Figure 11).

Conclusion

These data demonstrate the feasibility, safety, and utility of vertebral body stapling for the treatment of scoliosis in the adolescent. Further follow-up of the patient cohort

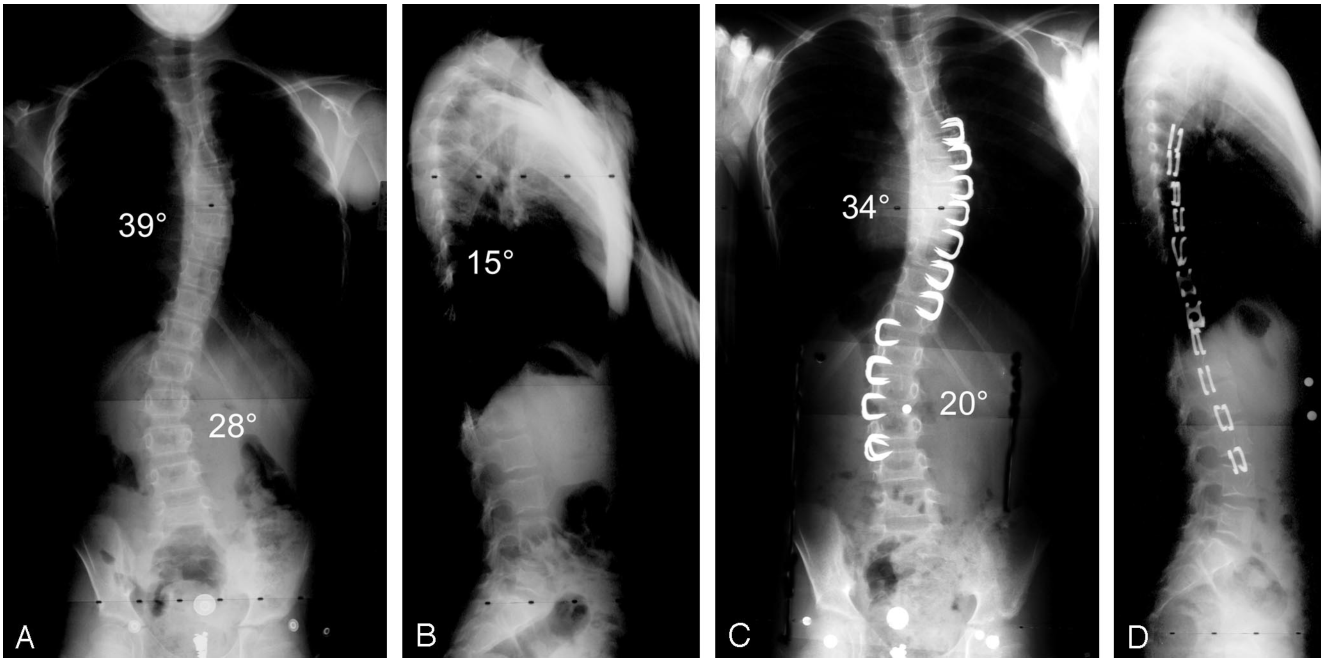

Figure 11. **A**, This is an 11-year-old female, premenarche, who presents with a 39° thoracic, 28° lumbar curve with open triradiate epiphysis. **B**, Her thoracic kyphosis measures 15°. Both the thoracic and lumbar curve need to be treated because of the patient's immaturity. **C**, The patient had a thoracoscopic-assisted stapling of the thoracic curve, from T5 to T12, and a stapling of the left lumbar curve through a mini-open incision just below the 12th rib, from T12 to L4. **D**, A four-prong staple was used at T10–T11 and T11–T12. The remainder of the levels had dual single staples, because double staples were not available in all sizes.

and further research into efficacy and indications are warranted.

Key Points

- The objective of this study was to retrospectively report the feasibility, safety, and utility of vertebral body stapling without fusion as an alternative treatment for adolescent idiopathic scoliosis.
- The concept of vertebral body stapling of the convex side of a patient with AIS is feasible. The procedure was safe, with no major complications and 3 minor complications in our group of 21 patients.
- In the short-term, stapling appears to have utility in stabilizing curves of progressive AIS.

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