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Vertebral Body Stapling Procedure for the Treatment of Scoliosis in the Growing Child

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Thirty-nine consecutive patients have had vertebral body stapling of 52 curves (26 patients with one curve stapled and 13 with two). For the group with patients who were 8 years or older with less than 50° preoperative curve and a minimum 1-year followup, coronal curve stability was 87% when defined by progression less than or equal to 10°. Fusion was necessary in two patients. No curves less than 30° at the time of stapling progressed greater than or equal to 10°. Major complications occurred in one patient (2.6%, diaphragmatic hernia) and minor complications occurred in five patients (13%). Further followup of the patient cohort and further research into efficacy and indications are warranted.

Level of Evidence: Therapeutic study, Level IV (case series—no, or historical control group). See the Guidelines for Authors for a complete description of levels of evidence.

The current standard of care for immature patients with adolescent idiopathic scoliosis (AIS) and a curve of 20 to 40° is a cervicothoracolumbosacral orthosis (CTLSO) or a thoracolumbosacral orthosis (TLSO). These braces are used to control progression, but authors report that 18 to 50% of these curves will progress in spite of bracing.[1,8,12,14,18,22–24]

The results of bracing are better than the natural history studies reported. Lonstein and Carlson[15] found that in skeletally immature patients (Risser 0–1), 68% of untreated curves measuring 20° to 29° progressed greater than 5°, and 60% to 90% of untreated curves greater than 30° progressed. However, brace wear is often necessary for 14 to 23 hours per day for 4 to 5 years.[1] Poor self image may result in adolescents who are braced for scoliosis, and brace compliance is often poor.[2,3,9–13,16,20] With bracing's modest results at preventing progression and the associated psychosocial problems, a search for an alternate treatment option seemed prudent.

The concept of stapling the anterior vertebral spinal growth plates for growth modulation and curve stabilization seems sound. Stapling across physes of the long bones has long been accepted as a predictable method of treating limb malalignment in young children.[5,6] Animal studies using a rat tail model confirm the ability to modulate vertebral growth plates with skeletal fixation devices.[17,26] In 1951, Nachlas and Borden[19] did vertebral interbody stapling across the physeal end plates and discs in a canine scoliosis model. Correction was seen in many dogs, and in some the curve progression was arrested. Some staples failed because they spanned two interspaces instead of one and because of the mechanical design of the staples.

Results for humans with congenital scoliosis were presented as early as 1954,[25] 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 deformity. 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 specific staples using Nitinol, a shape memory alloy, which have 510K approval from the Food and Drug Administration 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, providing secure fixation.

This newly-developed Nitinol staple has been tested in the spine in a goat scoliosis model by Braun et al[7] and was shown to be safe and have utility for arresting the iatrogenic curves of less than 70° in the goat.

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Each author certifies that he or she has or may receive payments or benefits from a commercial entity related to this work. RRB is a consultant for Medtronic; Shriners Hospital receives royalties.
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The feasibility, safety, and utility of vertebral body stapling for treatment of AIS have been reported previously.[4] Our purpose is to describe the procedure and to discuss considerations of vertebral body stapling without fusion as a means of stabilizing the curves in patients with scoliosis.

MATERIALS AND METHODS

To date, we have stapled patients with idiopathic or syndromic scoliosis but have not done the procedure on patients with paralysis who are nonambulatory. The age in those who have had the procedure ranges from 4 to 14 years. It is recommended that the preoperative curve falls between 20° and 45° and that curves less than 25° have at least 5° of progression within a 6-month period.

If the patient has two curves, any curve greater than 25° should be stapled. We have not stapled the proximal thoracic spine (T1 to T3) or the lumbosacral spine (L4-5 or L5-S1) to date. The early failures of stapling in our experience occurred in those patients with preoperative curves greater than 50° (3 of 4 progressed) and in those in whom the second curve (> 25°) was not stapled.

Surgical Procedure for Stapling

General anesthesia is used. The patient is positioned in the lateral decubitus position with the convex side of the scoliosis in the up position. Observation with fluoroscopic imaging is confirmed. All the vertebrae in the measured Cobb curve are stapled. For thoracic curves, a thoracoscopic-assisted approach is preferable. Portals are made in the posterior axillary line for insertion of the staples. As an alternative to posterolateral portals, two mini thoracotomy incisions (< 5 cm) may be used (eg, one centered at T4-5 and the other at T9-10). A radiopaque trial instrument is used to determine the dimension of the staple (3 to 12 mm) and to create pilot holes. The smallest staple that spans the disc and growth plates is used. The staple, which has been cooled in an iced water basin, is inserted into the pilot holes. Two single staples (two-prong) or one double staple (four-prong) are placed laterally, spanning each disc of the measured Cobb curve (Figs 1, 2). In most cases, the parietal pleura is not excised, and the segmental vessels are preserved. If there is significant hypokyphosis (kyphosis < 10°) at the apex of the thoracic spine, the staples are placed more anteriorly to the mid-body of the vertebra, or a third single staple is placed along the anterolateral aspect of the vertebral body (Fig 3). Occasionally, at T4 and T5 the vertebrae are too small and can only accommodate a single 2-prong staple. Staples that cross the thoracolumbar junction require partial reflection of the diaphragm anteriorly off the spine to be applied in the proper position. The diaphragm then is repaired.

Lumbar vertebrae are approached with a mini-open retroperitoneal approach. The segmental vessels of one or two levels are

Fig 1A–B. (A) A posterior-anterior and (B) a lateral erect radiograph of a 7-year-old with a right thoracic curve demonstrating stapling with double single staples at each vertebral level are shown.

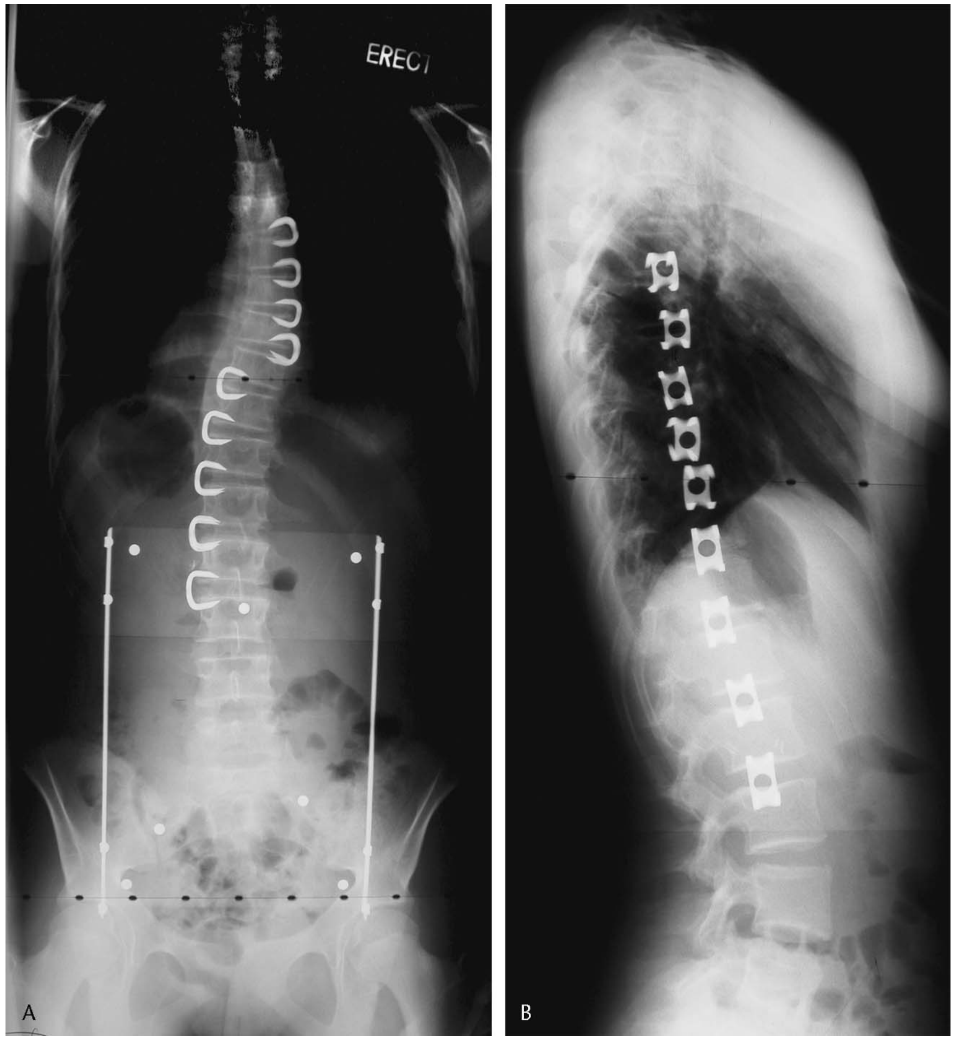

Fig 2A–B. (A) A 13-year-old girl had stapling of the thoracic and lumbar curves using the four-prong staples. (B) The lumbar staples are positioned in the posterior half of the vertebral body so they would not cause kyphosis of the lumbar spine.

ligated to allow posterior retraction of the psoas. Staples are placed in the posterior one-third of the vertebral body to allow normal lordosis (Fig 2).

The authors have used a minimally invasive psoas-splitting lateral approach (MaxAccess, NuVasive, San Diego, CA) after use of the Neurovision SE nerve locator (Neurovision Medical, Ventura, CA) to identify the nerves running in the psoas.

In all cases, maximum correction is obtained on the operating room table first by positioning but also by pushing with the staple trial instrument.

Postoperative Care

Early in the series, patients were asked to wear a custom non-correcting TLSO all the time for 4 weeks to allow scar tissue to stabilize the staples. After brace removal, there were no restrictions of activity. Currently, patients are not asked to wear a brace but only to modify their activities (restricting themselves by creating a mental image of themselves in a brace) for one month.

Authors' Experience

Of 31 patients aged 8 years or older at the time of surgery, 21 patients with 12 months or more of followup and a preoperative curve measuring less than 50° were reviewed (Figure 4). These 21 patients had 25 curves stapled. The average time of followup was 1.6 years, and the average preoperative curve measured 33° (range, 20°–41°). Three of the 25 (13%) of the curves progressed greater than 10°. None of the 8 preoperative curves less than 30° progressed, whereas three of 17 (18%) of preoperative curves greater than or equal to 30° did progress. Three of the 18 (16%) thoracic curves progressed, and none of the seven lumbar curves progressed.

Progression greater than or equal to 50° is the tidemark most surgeons use for surgery because of the risk of significant progression after maturity based on the work of Weinstein et al.[27] In this cohort, two of 21 patients (9%) who originally had a curve less than 50° progressed to greater than or equal to 50°. Both went on to have a spinal fusion.

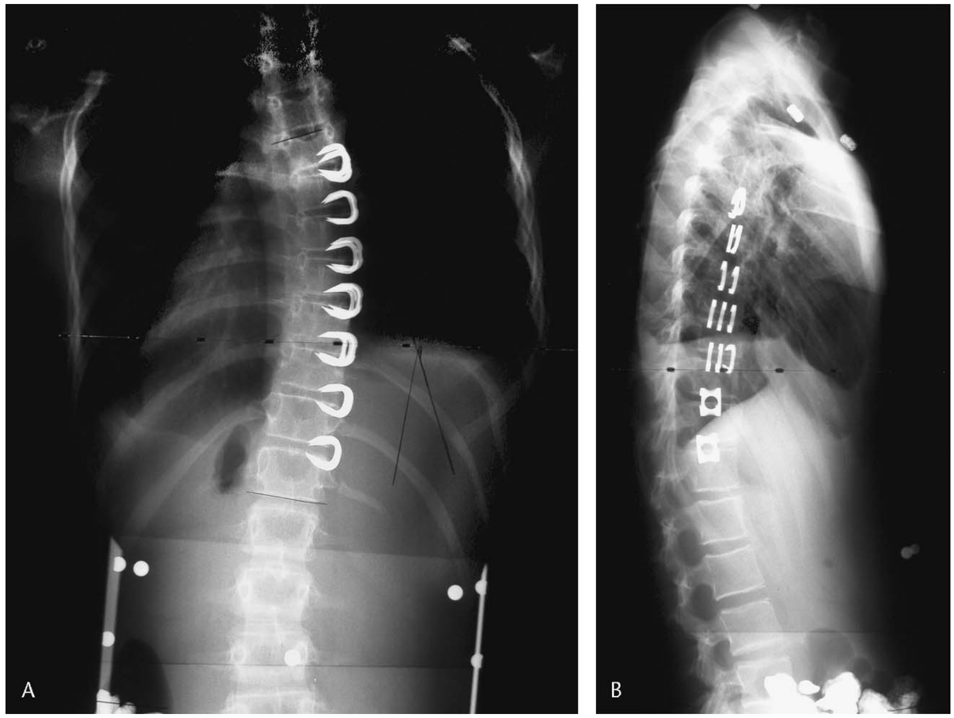

Fig 3A–B. (A) A posterior-anterior and (B) a lateral erect radiograph of a 13-year-old who had stapling of a right thoracic curve with three staples crossing the vertebral body at the area of hypokyphosis are shown.

Four patients 8 years or older who had vertebral stapling had a preoperative curve greater than 50° at the time of stapling. Three continued to progress and ultimately required a spinal fusion. The fourth is currently within 5° of her preoperative curve at 18 months of followup.

Eight patients younger than 8 years at the time of surgery had vertebral body stapling. Of these, four had idiopathic scoliosis. Followup on one of these patients is too short to report. Four patients had nonidiopathic scoliosis. Two of these had large curves (88° and 100°), and stapling was done as an alternative to apical fusion associated with growing rods. Followup of both is greater than two years; currently the curves measure 36° and 72°, respectively.

The procedure has been done on 39 patients (52 curves). Complications occurred in six of 52 surgical procedures. There was one major complication (2.6%) and there were five minor complications (13%). The major complication occurred in a 4-year-old patient with infantile idiopathic scoliosis who had an uncomplicated thoracoscopic stapling from T5 to T12. At 6 weeks postsurgery, she developed a rupture of a pre-existing, unrecognized diaphragmatic hernia that required emergency repair. Five patients had minor complications. One patient had a segmental spinal vein that was punctured by a staple prong and required conversion of the thoracoscopic portal to a mini-incision and ligation of the vein. This resulted in an estimated blood loss (EBL) of 1500 cc, which is considerably more than the 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. Another patient developed mild pancreatitis that resolved with a low-fat diet, and two patients had clinically significant atelectasis.

Two other patients had prolonged chest tube drainage beyond 4 days, which was considered to be an insignificant complication. A strict criteria of less than 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.

During followup averaging 12 months (range, 2–47 months), there has been no evidence of staple dislodgement nor migration in the group of 31 patients (600 staples). One four-prong staple (early design) fractured at the waist.

Pain has been reported by one child, whose preoperative curves were more than 50° when stapled. Her thoracic curve progressed, and she required fusion. The stapled lumbar curve actually corrected. Two distal lumbar segments that were stapled did not require fusion. Two months after fusion, she had pain in the lumbar spine, and a bone scan showed increased uptake at the staple-bone interface. Three weeks after removal of the two distal staples, the patient had no pain.

DISCUSSION

The results in this early cohort of patients showed curve stability after vertebral body stapling to be 87% when defined by progression less than or equal to 10°.

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 and, while the results still are better than those of the natural history,

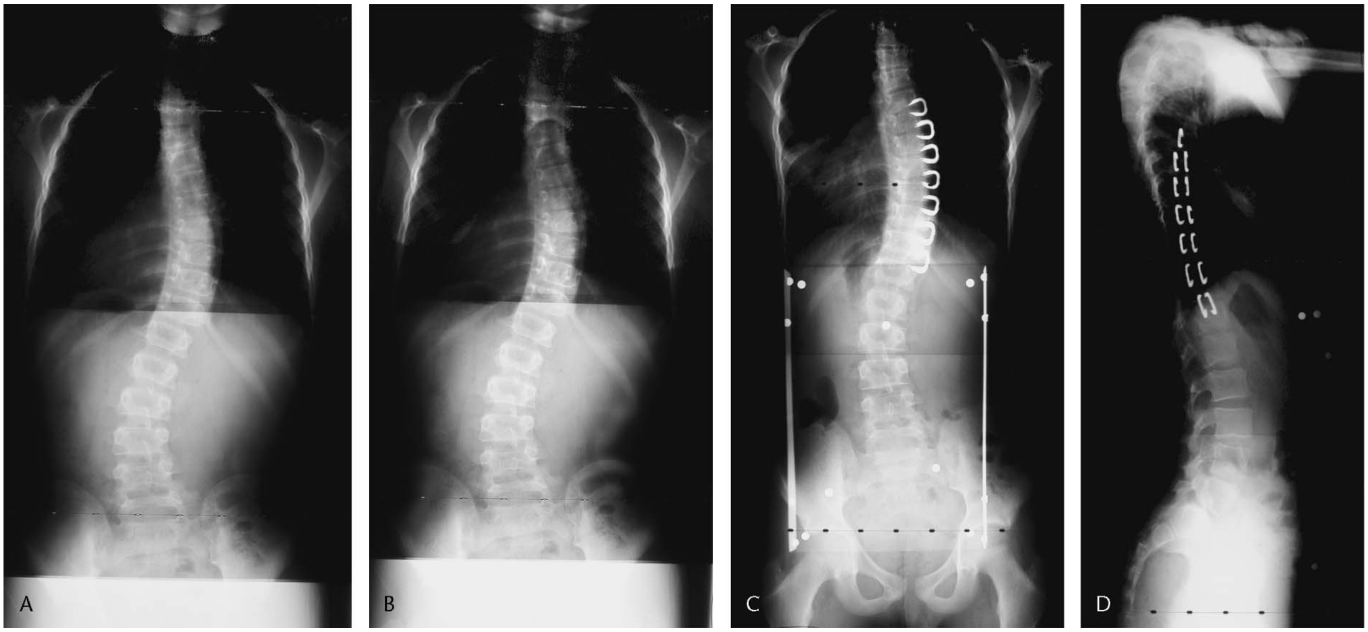

Fig 4A–D. (A) This patient is a 10-year-old male with open triradiates (Risser 0). He presents with a 35° right thoracic curve. Magnetic resonance imaging is normal. (B) The patient is placed in a TLSO and returned in 1 year with an xray out of the brace. He is now 11 years old with progression to 42°. Two years after the patient's vertebral body stapling of T6 through L1, (C) a posterior-anterior and (D) a lateral radiograph show the curve is maintained out of the brace at 28°. The patient wore a brace for 1 month postoperatively. Thereafter, no brace was required and there was no restriction of activities.

authors report that 18% to 50% of these adolescents will progress in spite of bracing.[1,8,12,14,18,22–24] In one classic reference, Noonan, et al[21] report that curves progressed greater than 10° in 33% of 102 patients using the Milwaukee brace for progressive idiopathic scoliosis. Our early results of vertebral body stapling (average followup of 1.6 years) for patients greater than or equal to 8 years showed 13% progressing greater than 10°.

In immature patients (especially females) with braceable curves, brace wear often is necessary for 14 to 23 hours per day for 4 to 5 years.[1] Poor self image may result in adolescents who are braced for scoliosis, and brace compliance often is poor.[2,3,9–13,16,20] Stapling offers an alternative to possibly address these issues, but this needs to be studied further.

Based on the failures in three of four patients with preoperative curves greater than or equal to 50°, we currently recommend vertebral body stapling for immature patients with AIS (Risser 2 or less) with curves between 20 and 45°, with 5° of documented progression for curves less than 25°.

During the course of this series, there were several changes in the staple design and in the technique. In the first case, the staple tines were too short and had to be imbedded into the disc to maintain stability. The next-generation staples had long tines in which the 4-mm, 6-mm, and 8-mm staples went past the midline of the body and would have penetrated the disc space. Therefore, larger staples (8 mm, 10 mm, and 12 mm) were used, but this left a larger gap between the staple base and the growth plate on the periphery, where growth retardation was needed. The later cases in the series were done with staples with proportional tines, such that the angle portion of the staple allowed the staple to be placed much closer to the growth plate.

This is a preliminary report on a retrospective review of a series of patients. A prospective study is needed to research the efficacy and indications of vertebral body stapling for immature patients with AIS.

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