

Fusionless Treatment of Scoliosis

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Scoliosis is a complex three-dimensional spinal deformity that results from both known and unknown causes in patients of all ages. Young children who present with large curves have a high tendency to progress as the child grows, but this progression can vary. More is known about the natural history of curve progression in adolescent idiopathic scoliosis, which is dependent on the patient's skeletal maturity, the curve pattern, and the curve magnitude. Children with congenital or neuromuscular forms of scoliosis can have an unpredictable course, with most being progressive. Curves that present in the growing child may be amenable to a variety of treatments to address curve progression during growth. The standard of care currently for skeletally immature patients with progressive scoliosis measuring greater than or equal to 25° is a thoracolumbosacral orthosis. These braces are used in an attempt to prevent curve progression, but the results can be variable.

Brace wear can be associated with many problems. As most braces exert their effect via pressure on the rib cage, their influence on the chest wall in the growing child creates concern. Some children have a problem with the stigma associated with wearing a brace, especially children who have to wear a brace for many years.

Also, while brace treatment is noninvasive and preserves growth, motion, and function of the spine, it does not correct an established deformity. While most orthopaedists, families, and patients agree that it is reasonable to wear a scoliosis brace for 1 or 2 years if it means preventing an operation, a more difficult situation is encountered in the very young child who faces the prospect of wearing a brace for many years with no guarantee of a favorable outcome. It is in these children that fusionless treatment options hold the greatest potential.

To date, most fusionless treatment options have centered on addressing a progressive scoliosis in the growing child. The fusionless treatment of an established larger curve in the patient who is skeletally mature or is nearly so has been limited, but may hold some potential [1,2]. Fusionless scoliosis surgery may provide substantial advantages over both bracing and definitive spinal fusion. The goal of this procedure is to harness the patient's inherent spinal growth and redirect it to achieve correction, rather than progression, of the curve. Several methods of treatment of scoliosis without fusion have evolved and include (1) anterior vertebral body stapling, (2) anterior spinal tethering, (3) convex scoliosis tethering, (4) mechanical modulation of spinal growth, and (4) internal bracing. The anterior fusionless techniques are theoretically more advantageous than external bracing because they address the deformity directly at the spine and not via the chest wall and ribs, and because they eliminate problems with patient noncompliance.

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Furthermore, minimally invasive thoracoscopic access to the anterior thoracic spine is less extensive than that for posterior instrumented surgery.

For the purposes of this article the term fusionless scoliosis surgery is used to describe anterior spinal procedures that control the progression of scoliosis during growth, but other fusionless treatments are available. These more established fusionless procedures employ posterior implants (growing rods and the vertical expandable prosthetic titanium rib) that can control the progression of spinal deformity but do not correct an established deformity in the younger child. These posterior growing systems are fraught with complications and take a multi-year commitment of semiannual surgery from the family and patient to be successful. Single or dual growing-rod techniques and the vertical expandable prosthetic titanium rib are not only more invasive than anterior fusionless scoliosis surgery but are associated with higher rates of complications. Anterior fusionless scoliosis surgery avoids multiple procedures, as well as the requirement for an eventual fusion, by offering a single intervention that may provide a more permanent solution to the spinal deformity. Furthermore, correction of a spinal deformity in the absence of a rigid fusion mass spanning multiple vertebral motion segments may ameliorate some of the long-term problems related to spinal fusion with instrumentation, such as adjacent level degeneration.

To date, many models of fusionless surgery involving both the genesis of iatrogenic scoliosis and its treatment have been studied [3–10]. A review of the recent literature shows a marked increase in interest in the topic and number of publications on this subject in the past 2 years [11]. However, much of what has been done has involved experimental methods in animal models, with no transition to the clinical realm or a patient series. The authors first discuss the advent of anterior vertebral body stapling and its clinical experience, followed by experimental works on other fusionless scoliosis treatment options.

Anterior vertebral body stapling

The first recent study of a large patient series is that of Betz and colleagues [12], who reported on the Philadelphia Shriners Hospital experience with anterior vertebral body stapling in patients with adolescent idiopathic scoliosis. This is a landmark study in that previous attempts to correct scoliosis with anterior fusionless techniques had

been disappointing [13,14]. Convex apical vertebral body (hemiepiphyseal) stapling theoretically affords immediate and possibly reversible cessation of growth of the anterior vertebral physes [15,16]. Animal studies using a rat tail model confirm its ability to modulate vertebral growth plates with skeletal fixation devices [17–19].

In 1951, Nachlas and Borden [13] were initially optimistic about their ability to create and correct lumbar scoliosis in a canine model using a staple that spanned several vertebral levels. Many of the dogs exhibited some correction, and some of the animals exhibited arrest of their curve progression. Some of the staples failed because they spanned three vertebrae. The enthusiasm for this new treatment was lost after the application of their stapling technique in three children with progressive scoliosis yielded poor results. Other investigators have also been dissatisfied with convex stapling as a means of controlling progressive scoliosis. In 1954, Smith and colleagues [14] presented disappointing results for human patients with congenital scoliosis. 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 loosened, possibly because of motion through the intervertebral discs.

James M. Ogilvie, MD, reported (personal communication) that in 1997 he began performing anterior vertebral body stapling with thoracoscopic assistance in six patients: three with infantile scoliosis, two with juvenile scoliosis, and one with spina bifida. Preoperatively, the patients' curves had progressed despite bracing for the previous year. At 2-year follow-up, four of the six curves stabilized following the procedure. In two patients the staples partially dislodged, requiring another operation to replace the staple.

A likely cause of disappointing results in previous series and experiments was the implant (staple). While the concept of stapling the anterior vertebral endplates/physes for growth modulation and curve stabilization seems sound, the staples designed for epiphyseal stapling about the knee are prone to dislodge in the spine because they are not designed for movement in the spine. To address this concern, Medtronic Sofamor Danek (Memphis, Tennessee) has designed a specific spine staple called the Nitinol (Nickel Titanium Naval Ordinance Laboratory) staple, which has 510K approval from the US Food and Drug Administration 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, when warmed to body temperature, clamp down in a “C” shape in the bone for secure fixation. Before its use in humans, the Nitinol staple had been tested in a goat model by Braun and colleagues [10] and was shown to be safe and have utility for arresting iatrogenic scoliosis in the goat.

In 2003, Betz and colleagues [12] reported on the use of the Nitinol staple in 21 skeletally immature patients with adolescent idiopathic scoliosis. Indications for the procedure were either brace noncompliance or the inability of the brace to prevent progression of the curve. They found the procedure to be safe and effective, with the results comparable with that of what would have been expected from bracing. In 2005, this group reported on 39 patients and their increased experience with the procedure [20]. Eighty-seven percent of those patients older than 8 years at the time of stapling who had a curve of 50° or less with at least 1 year of follow-up had stabilization of their curve. No curve less than 30° at the time of stapling progressed more than 10° at follow-up [20]. Experience from more than 80 patients to date has taught that the entire Cobb angle of all of the curves needs to be stapled (Figs. 1 and 2), and staple implants with tines proportional to the length of the staple (Fig. 3) have yielded better results than previous designs. Relative contraindications include curves above T2 or below L4, very small vertebral body size, thoracic kyphosis greater than 40°, and coronal curves above 45°. MRI scans of several of these patients have shown that the intervertebral discs remain hydrated and are normal in appearance (Fig. 4). The technique of anterior vertebral body stapling has been published [12,20,21].

Tethering procedures

Braun and colleagues [6,7,13] have done much work with the goat model in the creation of experimental scoliosis with a posterior tether of the ribs, and correction of this deformity with an anterior fusionless technique using bone anchors with ligament tethers. Braun’s group and Newton and colleagues [22,23] have also shown that if the bone-anchor–ligament-tether does not fail, it causes vertebral body wedging and scoliosis correction via growth modulation. Lowe and

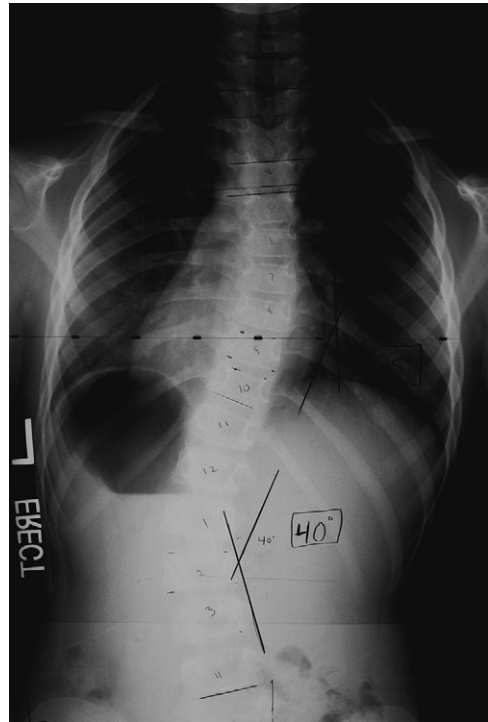


Fig. 1. Posteroanterior radiograph of a 7-year-old girl with idiopathic scoliosis having a 25° thoracic and 40° lumbar curve.

colleagues [24] looked at the role of posterior tethers in sagittal plane (kyphotic) deformities in sheep. While the posterior tether resulted in less kyphosis, this was accompanied by significantly less motion from heterotopic ossification. The authors are unaware, however, of any published series on the use of bone-anchors–ligament-tethers in human patients.

Braun and colleagues [22] recently compared shape memory staples with bone-anchors–ligament-tethers in the fusionless treatment of iatrogenic scoliosis in the goat. Results of this study demonstrate greater efficacy and integrity of a bone-anchor–flexible-ligament-loop-tether compared with a more rigid shape memory alloy staple in the fusionless treatment of a progressive experimental scoliosis. In contrast to the more rigid staple base, the ligament loop used with the bone anchor provided a more flexible tether spanning the disc space. This increased flexibility was likely associated with decreased forces during spinal motion. This decrease in force potentially protected the bone anchor from loosening. Whereas the staple demonstrated no significant

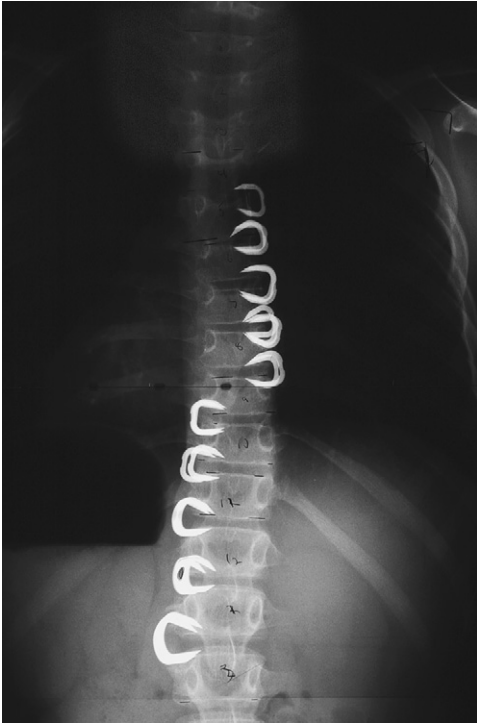


Fig. 2. At the age of 12 years, both curves completely corrected in girl shown in Fig. 1.

change in axial pullout strength between the two time-points, the bone anchor showed a significant increase in pullout strength. It is postulated that this difference was related to two factors: (1) the rigidity of the portion of the implant spanning



Fig. 3. Intraoperative fluoroscopy image showing ideal placement of the proportional-sized staples.



Fig. 4. MRI of the patient in Fig. 2 showing normal-appearing well-hydrated discs.

the motion segment and (2) the quality of the fixation to bone. The staple, though made of shape memory alloy, has a relatively rigid base spanning the disc space compared with the ligament-loop-bone-anchor construct. Additionally, the smooth tine is suboptimal for fixation to bone and relies primarily on the mechanical “crimping” effect of the deployed shape memory alloy staple. The authors do not necessarily believe that the lack of rigid fixation seen with staples is bad. The associated halo that is seen around the tines on radiographs in long-standing cases shows that there is motion, and perhaps this is why there is such a low rate of staple failure and why patients are able to maintain spinal mobility.

Summary

The recent investigations of convex anterior vertebral body stapling, both in animal models and in juvenile and adolescent scoliosis have offered promising early results with use of improved implants and techniques. The use of a shape memory alloy staple tailored to the size of the vertebral body, the application of several staples per level, the instrumentation of the Cobb levels of all curves, and the employment of

minimally invasive thoracoscopic approaches all offer substantial improvements over previous fusionless techniques. Patient selection may also play a role in the current success of these fusionless treatments, with perhaps the ideal candidates for this intervention possessing smaller and more flexible curves. Still, reports on the clinical success of these stapling procedures are based on short-term results. Long-term results of the effects on the instrumented motion segments and adjacent spine are not yet available.

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