Fusionless Surgery for Scoliosis

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Abstract
Scoliosis is a very common condition, affecting approximately 7 million children in the United States. Treatment of this condition in young children can be challenging. A variety of techniques that avoid spinal fusion have been developed to manage scoliosis in this patient population. This review article describes several of these methods, including growing rods, prosthetic ribs, vertebral stapling, and vertebral tethering. Particular attention is given to literature discussing each technique.

Scoliosis is a complex, three-dimensional deformity of the spine resulting from both known and unknown causes. The treatment of young children with early onset scoliosis presents a particular challenge. Traditionally, the surgical management of scoliosis has been focused on correcting the curvature and obtaining a solid fusion of the growing spine, thereby halting further progression of the deformity. However, it is estimated that in children who are 5 years old, there is up to 12.5 cm of vertical growth of the spine remaining. Furthermore, the lungs do not fully develop until the age of 8; the alveolar maturation process continues from birth, resulting in an increase in the number of alveoli, alveolar ducts, and terminal sacculles. Restricting growth of the thoracic cavity through spinal fusion can cause significant pulmonary issues later in life. Keeping this in mind, scoliosis in young children typically tends to progress. The pattern of progression is not nearly as predictable as that seen in adolescent idiopathic scoliosis (AIS); in AIS, progression is more reliably dependent on skeletal maturity, curve type, and curve magnitude. The surgical treatment of scoliosis in older children is, therefore, more straightforward and involves correction of the curve, instrumentation, and fusion of the spine. However, in young children with significant growth potential remaining, spinal fusion may not be the best option as it limits further longitudinal growth of the spine and consequently the thoracic cavity, potentially inhibiting pulmonary development and resulting respiratory dysfunction and in some cases premature death. In order to address these concerns, “fusionless” techniques have recently been implemented with varied success and are gaining increased interest. Various techniques have been utilized and have individual advantages and drawbacks.

Dual Growing Rods
Harrington is credited as the first to describe using instrumentation to correct scoliosis without attempting a concurrent arthrodesis. In the dual growing rod technique, instrumentation is placed in the vertebrae at the ends of the curved segment of the spine, and rods are then placed either subfascially or subcutaneously. The concept behind growing rods is to provide structural support to correct the deformity, maintain the correction, and permit continued axial growth of the spinal column. The rods are engaged by a connector that can be adjusted by loosening a set screw and distracting between two poles of the construct. The patient returns to the operating room at set intervals for lengthening of the growing rods. There are no formal guidelines as to when patients should return for growing rod lengthening; however, most surgeons recommend lengthenings be performed every 6 months until at or near skeletal maturity. Sankar and associates investigated the frequency and efficacy of lengthenings of dual growing rod constructs. They examined 38 patients from 5 centers who were followed for an average of 3.3 years (2 to 7 years); lengthenings occurred at an average of every 6.8 months. Cobb angles decreased from a mean of 74° to
36° immediately following growing rod implantation. They described that although the T1-S1 length improved with subsequent lengthenings, the amount of axial length gained diminished with each subsequent procedure. They purported that this decrease may in fact be due to autofusion of spinal levels that were within the spanned unfused segments and also alluded to the potential of eliminating lengthenings towards the end of the treatment duration.

Recently, a means of lengthening rods without a surgical incision has been developed utilizing electromagnetic current; however, these devices are not yet approved for use in the United States.7 There is no set criteria indicating a patient for treatment with growing rods; however, most investigators agree that patients must have 1. significant axial growth potential remaining, 2. progressive deformity, and 3. spinal deformity that is either flexible or can be made flexible with anterior releases.2,5,8,9

Akbarinia and colleagues9 described their results of a multi-centered study involving 23 patients at a minimum of 2 years follow-up. They noted an average pre-operative curvature of 82° was corrected to an average of 38° at the time of final follow-up. Furthermore, spinal growth averaged 9.6 cm (1.24 cm per year), and space available for the lung ratios increased from 0.87 to 1.0. The space available for the lung relates to thoracic morphology and the potential for lung development. It is obtained by measuring the height of the concave hemithorax and comparing it to the convex hemithorax; this parameter is then either reported as a ratio or multiplied by 100 and expressed as a percentage.10 In this series, 13 complications were reported in 11 patients, and 4 patients required unplanned procedures. The investigators concluded that the dual rod technique is safe and effective and had a complication rate comparable to that reported in single growing rod techniques.

Lastly, Thompson and coworkers11 compared the results obtained with dual rod constructs versus single rod constructs. Lengthenings were performed every 6 months regardless of curve progression. They separated 28 consecutive patients into 3 groups: 1. single rod only with short apical fusion, 2. single rod only, and 3. dual rod implantation. Group 1 was found to have the worst results with an average correction of only 23%, and group 3 was found to have the best results with an average of 71% correction. They also noted a 12.1 cm gain in axial length in the dual rod construct versus 6.4 cm in the single rod design. They concluded that dual rod constructs were stronger and provided better curve correction and maintenance. They also commented that apical fusion did not appear to be effective over the course of treatment.

**Shilla Procedure**

The Shilla procedure employs principles similar to growing rods; the advantage, however, is that the technique attempts to obviate the need for lengthenings. In this system, the apex of the curve is instrumented, corrected, and fused. Non-traditional, “sliding” poly-axial screws are then placed at the ends of the construct, allowing the rods to engage them while permitting axial sliding and growth of the unfused spine to occur.

Due to the novelty of the procedure, there is a paucity of literature reviewing this technique. McCarthy and associates12 studied the technique in an immature goat model and found an average of 4.8 cm of length was obtained after a 6-month period. Most notably, as predicted, the growth occurred at the cranial and caudal ends of the fixation. Though none of the implants failed, his group noted a high rate of fretting at the sliding screws and also reported a significant incidence of rod breakage.

At the Second International Congress on Early Onset Scoliosis and Growing Spine, McCarthy and associates13 described their results with the Shilla procedure on 10 patients with scoliosis of varying diagnoses. Data was recorded at a minimum of 2 years of follow-up. The mean pre-operative curve measured 70.5° and was corrected to an average of 27° immediately postoperatively. At the time of final follow-up, the curves averaged 34°. The space available for the lung improved an average of 13%, and the truncal height was noted to have increased an average of 12%. Of note, the investigators highlighted the fact that assuming returns for lengthenings would have occurred at an average of every 6 months using traditional growing rod systems, and the Shilla technique saved the 10 patients a combined 49 returns to the operating room over the course of treatment.

**VEPTR (Vertical Prosthetic Titanium Prosthetic Rib)**

Thoracic development can be significantly compromised in the setting of congenitally fused ribs (rib synostosis). This condition can lead to thoracic insufficiency syndrome, which is defined as the inability of the thorax to support normal respiration and lung growth. The classic indication for VEPTR as described by Campbell and colleagues10 is for rib synostoses often associated with congenital spinal anomalies. The VEPTR is a procedure that avoids spinal fusion by utilizing an opening wedge thoracostomy and placing the device between the ribs or between the ribs and the spine or pelvis. Like growing rod systems, the patient is periodically brought back to the operating room for repeat lengthenings.

Campbell and Hell-Vocke15 investigated the results of VEPTR implantation in 21 children with congenital scoliosis and fused ribs; three of the children had already had a posterior spinal fusion procedure performed. Of the 18 who did not have prior spinal procedures done, the average age at VEPTR placement was 3.3 years, and they were followed for an average of 4.2 years. Axial spine growth was seen in all patients; an average of approximately 8 mm of growth per year was seen on both the concave and convex sides of the curve despite congenital failure of segmentation (fusion). In those patients who had already had spinal fusions...
performed, an increase of only approximately 4 mm per year on either side was seen. They concluded that the VEPTR device allowed for continued growth of the thoracic spine and provided the lungs with more growth potential.

Indications for VEPTR have expanded to include various types of early onset scoliosis without intrinsic chest wall deformity as a means of providing extra-spiral correction and avoiding stiffening of the spine and autofusion. Shulz and coworkers\textsuperscript{14} retrospectively reviewed their results of eight patients treated with VEPTR; all were diagnosed with idiopathic infantile scoliosis. The average age at the time of surgery was 45.8 months, and the mean pre-operative Cobb angle was 84°. A 35% correction was obtained over the course of an average of 32 months, and spinal height increased an average of 7.1 cm. Three of the eight patients experienced minor hardware complications. They concluded that the use of VEPTR was safe and effective for the unique patient population with rib fusions.

Ramirez and associates\textsuperscript{15} reviewed their results of 17 VEPTR implantations. They noted a mean pre-operative curve of 59° and reported a final curve average of 35°. Similar to other groups, they reported a 13% complication rate, including infection, device migration, and rib fracture. Lastly, Smith’s\textsuperscript{16} group reviewed their experience treating 31 children with infantile idiopathic scoliosis. Treatment modalities included bracing, casting, and VEPTR. Of the 10 patients treated with VEPTR, an average pre-operative Cobb angle of 90° was reported, and a mean correction of 33.8% was obtained.

Recently, Akbarnia and Emans\textsuperscript{17} reviewed the literature regarding the complications seen in the use of VEPTRs. Reports of infection were quite common, with some investigators noting a risk of 1.9% per procedure (initial VEPTR placement as well as subsequent lengthenings). Other noted complications included issues with the anchor points, brachial plexus injury, chest wall scarring, rib fusions, shoulder stiffness, and the iatrogenic creation of a sagittal imbalance.

**Vertebral Stapling**

The Heuter-Volkman law states that a growth plate under pressure will grow more slowly than one that is subjected to less pressure. Using this principle, the concept of vertebral stapling was developed. The idea was first tested in 1951 when Nachlas and Borden\textsuperscript{18} were able to create, and subsequently correct, a scoliosis by placing wire staples across the disc spaces adjacent to the endplates of immature canines. Following their work, Smith and colleagues\textsuperscript{19} attempted the technique in three humans, which was unsuccessful due to implant migration. Subsequently, the procedure was abandoned until recently. New “memory shape alloys,” surgical techniques, and implant designs have breathed new life into this procedure, and we have seen a resurgence of its use. The shape-memory metal, Nitinol, is implanted into the spine in a cooled state such that the metal prongs of the staple retain a perpendicular posture in relation to the bone. Once they warm to body temperature, they clamp down in an acute angle to the bone and endplate providing a gentle compressive force and minimizing the risk of device pullout.

In 2003, Betz and coworkers\textsuperscript{20} described their results in 21 skeletally immature (Risser ≤ 2) patients with AIS. In their series, a thoracoscopic approach was used to access the vertebral bodies; three minor complications were reported. They then examined a subset of this study to evaluate curve stability; the 10 patients with at least 1 year follow-up (mean 22.6 months) were reviewed. The group defined clinical failure as curve progression of 6° or more from the index procedure or a curve that progressed to a minimum of 50°. Using these criteria, 6 of the 10 patients remained stable, and 4 of the 10 progressed. Only one of the 10 patients went on to receive a spinal fusion procedure.

Two years later, Betz’s\textsuperscript{21} group reported on 39 consecutive patients who had undergone vertebral stapling. In this study, the group defined curve progression as 10° or more progression from the index procedure. The study noted that 87% of patients older than age 8 and whose curves were less than 50° were successfully treated using the stapling procedure; this result was seen at a minimum of 1 year of follow-up. None of the curves of 30° or less progressed after stapling. There was one major complication and five minor complications reported by the group. Though their preliminary results looked promising, the group conceded that longer follow-up was necessary.

Recently, Betz’s\textsuperscript{22} group reported the results of a minimum of 2 years of follow-up on 28 of 29 patients with AIS treated with vertebral stapling. Follow-up averaged 3.2 years. They again used a threshold of 10° of progression as the tidemark to determine whether treatment was successful. All patients were either Risser 0 or 1, and all curves measured between 20° and 45° on Cobb angle measurement. Thoracic curves measuring 35° or less had a success rate of 77.7%; those whose Cobb angles measured 20° or less on the first postoperative erect x-ray had a success rate of 85.7%. Flexible curves which corrected greater than 50% on bending x-rays had a success rate of 71.4%. The group also reported that there were no neurologic or hardware related complications. Two major complications (rupture of a diaphragmatic hernia and curve over-correction) and two minor complications (SMA syndrome and atelectasis) were reported. They concluded that in patient population with idiopathic scoliosis who are at high risk for progression, vertebral body stapling provided curve stabilization in 87% of all lumbar curves and 79% of thoracic curves that were 35° or less. Thoracic curves measuring 35° or more were not successfully treated using vertebral stapling and should be treated using different means.

**Vertebral Tethering**

At the present time, there are no reports in the peer-reviewed literature of tethering procedures having been performed in humans. Several investigators have performed such
techniques on animal models with varying success. The tethering procedure uses a segmental bone anchor construct with a polypropylene ligamentous tether spanning adjacent anchors. Multiple investigators21-25 have successfully demonstrated the creation of a scoliosis model in animals using this technique.

In 2006, Braun and colleagues26 compared the use of a memory shape alloy staple and a flexible ligament tether in a goat model. A flexible tether was successfully used to create a scoliosis model in 20 out of 24 immature goats. The goats were then divided into three groups: no treatment (N = 6), vertebral staple (N = 7), and ligamentous tether (N = 7). The six levels of maximal curvature were instrumented in groups 2 and 3, and the goats were then observed over a period of 12 to 16 weeks. At the conclusion of the observation period, radiographs were obtained, and an overall deformity score was calculated consisting of the degree of scoliosis, lordosis, and rotation. The figures were then compiled and analyzed for each group. They concluded that the tether possessed a modest ability to correct the spinal deformity in the coronal plane but failed to improve the sagittal or rotational deformities. They also noted that the final deformity in the ligamentous tether group was significantly less than either the staple or the no treatment groups after implantation of the devices.

Due to the novelty of these devices and techniques, long-term data regarding adjacent segment disease and spinal mobility are not available. Additionally, current investigations using these techniques have only been studied in animal models, and findings do not necessarily translate to the human spine. Newton and colleagues27 examined the effects of tethering procedures on the overall health of the disc and vertebral body. Using a calf model, a kyphoscoliotic deformity was created. Four consecutive levels in 36 animals were instrumented; 17 animals were instrumented and tethered and the remaining 19 were instrumented only. After 6 months, the spines were harvested and underwent radiographic, biochemical, histologic, and biomechanical analysis. Disc thickness was noted to be significantly decreased in the experimental group versus the control. Additionally, the tether significantly increased spinal stiffness in lateral bending, as well as flexion and extension. There was no difference between groups in morphology of the disc or water content of the discs. Interestingly, proteoglycan synthesis was noted to be significantly higher in the tethered discs compared to the controls.

Conclusion

Scoliosis in the young patient poses a treatment challenge for the orthopaedic surgeon. Currently, there is no gold standard option, either surgical or non-surgical, to manage patients with this condition. Bracing and physical therapy have not been particularly successful at halting progression, and spinal fusion procedures can cause limitations on the space available for the lungs, as well as the axial growth of the spine and ultimately, the height of the patient. Fusionless surgery of the spine offers both patients and surgeons another option in the treatment of scoliosis. Currently, neither stapling nor tethering techniques are FDA approved for treating scoliosis. Companies and institutions considering obtaining investigational device exemptions to study these constructs will certainly be faced with considerable costs. Whether the procedure provides a benefit, a definitive treatment, or merely temporarily maintains correction of the deformity until a fusion procedure can be performed remains to be tested.

Disclosure Statement

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