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Vertebral Body Tethering (VBT) in Pediatric and Adult Spinal Deformity

SRS Informational Statement on Vertebral Body Tethering (VBT) in Pediatric and Adult Spinal Deformity

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Since Hibbs first described spine fusion surgery in the early 1900s, there have been significant advances in surgical techniques that have led to improved fusion rates, greater three-dimensional correction of spinal deformities, lower complication rates and quicker post-operative recovery. However, improving spinal alignment with fusion occurs at the cost of permanent, iatrogenic stiffening of the corrected segments. Fewer motion segments, specifically in the lumbar spine, may lead to decreased function in high-level physical activity (e.g. competitive athletics) and increased risk of degenerative changes in the adjacent segments leading to secondary back pain, lower extremity radiculopathy or spinal stenosis symptoms. Hence, preservation of spinal motion, particularly in the lumbar spine, is a highly attractive goal.

This desire to maintain spine motion has fueled the development of various growth modulation procedures, whose goals are to correct the spinal deformity, maintain motion (without fusion) and have a low risk profile. One of these promising techniques which has gained traction in the last ten years is vertebral body tethering (VBT).

Vertebral growth modulation and “fusionless” surgical correction of skeletally immature spines in patients with idiopathic scoliosis is an evolving technique. The concept of growth modulation or arrest has been applied in the lower extremities for decades through epiphyseal stapling (asymmetrical growth arrest) for excessive genu varum and limb lengthening with distraction (Ilizarov technique).

The theory behind the use of VBT in spinal deformity is to alter the relative vertebral growth (right vs left) of the anterior spine in the coronal plane. This is accomplished by relative slowing of the vertical growth on the convex side (by tensioning of the tether) with unloading of the concave side of the vertebrae, to permit greater growth. For growth modulation to

occur, there needs to be sufficient vertical growth of the spine remaining to create a straighter spine.

At present, in the U.S., there is no FDA approved “fusionless”, growth modulation device for use on the anterior spine in a skeletally immature patient. The tether system most commonly used anteriorly is only approved for use in the posterior lumbar spine “to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatments of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment and failed previous fusion (pseudarthrosis)” (Zimmer Biomet). This means the application of this tether system to the anterior spine in the U.S. is an off-label use.

There are no published data (PubMed search) on growth modulation in adult (skeletally mature) spinal deformity. From a historical perspective, Dwyer, Zielke, Kaneda, Harms and subsequent anterior instrumentation techniques to correct scoliosis were used in conjunction with spinal fusion in children and adults.

Studies on VBT in animal models have demonstrated dynamic tethering of the immature spine can alter spinal alignment. In 2002, Newton et al reported the application of a VBT to create kyphoscoliosis in a bovine model, validating the concept that a surgically placed tether can modulate vertebral growth (Newton). Braun et al subsequently demonstrated that vertebral body staples on the convex side of the anterior spine can induce correction of experimentally created scoliosis (Braun). Changes in the intervertebral disc, specifically in thickness and the production of proteoglycan and type 2 collagen, have been demonstrated in a bovine model after placement of VBTs (Newton 2008). However, there were no changes in morphologic disc health or disc water content. In addition, the integrity of the vertebral growth plate appears to be preserved, even after placement of a VBT (Chay). These animal studies validate the concept that VBT can modulate spinal growth. However, the changes induced by VBT in these studies on the intervertebral and growth plate are of unknown significance to long-term function of the spine.

Anecdotal references have been made citing Hueter-Volkmann and Wolff’s Laws affecting asymmetric bone growth and diaphyseal remodeling as well as the ability of orthodontists to realign teeth in adults as possible mechanisms to achieve curve correction in the adult spinal deformity patient.

Aronsson, Stokes and McBride investigated the effect of asymmetrical growth and diaphyseal remodeling in rats in creating vertebral wedging and thereby, scoliosis. Their results showed that wedging was in large part due to asymmetrical growth (Hueter-Volkmann Law) in the 5-week-old rats and diaphyseal remodeling (Wolff’s Law) in the 14-week-old animals. They extrapolated that “if appropriate loads can be applied to human vertebrae, scoliosis and vertebral wedging can be corrected without a fusion in both adolescents and adults” (Aronsson).

The first description of VBT use in humans was a case report in 2010 by Crawford and Lenke (Crawford). Subsequently, Samdani et al (Samdani) reported on their first 32 consecutive patients treated with anterior VBT in the thoracic spine. The mean preoperative major Cobb angle was 43º which corrected to 21º on first erect radiographs. The curve showed significant

continued correction over the course of the 12-month follow-up period and measured 18º at the most recent time point (P<0.05). Overall, the lumbar curve demonstrated significant spontaneous correction as well, measuring 25º preoperatively, 18º at first erect and 13º at most recent follow-up (P<0.05). Importantly, thoracic axial rotation was modestly improved after VBT (mean preoperative 13 degrees to 7 degrees postoperative) in most these patients. Sagittal plane parameters remained stable and no major complications were observed. At present, there is limited data available on the clinical application of VBT from 2 institutions only.

Despite the above-mentioned studies, there remains a paucity of information/evidence on the use of VBT in skeletally immature patients with scoliosis. Animal studies have demonstrated VBT can modulate spinal growth with few changes to the intervertebral disc or growth plates. Early, short term, single institution series have been encouraging with few reported serious complications. More research is necessary on VBT safety, timing of VBT placement, VBT tensioning, intervertebral disc health and long-term patient reported and radiographic outcomes of VBT.

While research in animals may provide future opportunities for VBT in adult spinal deformity, it is important to emphasize that no data has been published to date confirming the safety or efficacy of this technique in adults. Any use of tethers for scoliosis correction remains experimental and without FDA approval in the United States.

The Scoliosis Research Society recognizes that the FDA regulatory policies are specific to the United States. Every member nation of the SRS has its own regulatory agency whose policies may differ from those of the FDA.

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