Joint SRS/POSNA Position Statement on Payor Coverage for Anterior Fusionless Scoliosis Technologies for **Immature Patients with Idiopathic Scoliosis**

I. Background

An anterior instrumentation system designed to correct idiopathic scoliosis without spinal fusion (The Tether™ - Vertebral Body Tethering System by Zimmer Biomet) was approved by the FDA for use on August 16, 2019.

This technique has several benefits compared to spinal fusion with instrumentation

1. Growth modulation.
   Anterior instrumentation without fusion was first reported to change vertebral growth in an immature patient by Drs. Crawford and Lenke in 2010, followed by subsequent larger retrospective series by other centers [7-10].

2. Motion preservation.

   Significant progress has also been achieved in the treatment of spinal deformity in the past 50 years, allowing deformity to be corrected safely in all three planes. However, the standard of care currently requires that spinal instrumentation results in spinal fusion. It is known that if the sagittal plane is restored according to physiologic contour and the instrumentation is limited to the upper lumbar vertebral levels, excellent functional capacity is preserved for many years and quality of life is comparable to healthy individuals. However, this does not change the fact that fusion surgery is against the nature of human biomechanics and that it does cause some limitation of motion. The loss of motion may not affect daily activities of living, but still negatively impacts neighboring spinal segments over the long term. Undoubtedly, an alternative treatment that corrects deformity without the need for spinal fusion, preserving motion and not increasing the stress on neighboring segments, has created great excitement. In this context, VBT is a newly FDA approved treatment method that has great potential to correct scoliosis without the negative impacts of spinal fusion.

3. Less morbidity and costs.

   Reported evidence is summarized below. Clinical reports indicate a potential for 1) decreased length of stay 2) decreased narcotic use, 3) decreased blood loss, and 4) decreased operative time compared to fusion surgery. Revision rates are reported at 5-40% at 1 to 3 years of follow-up[7-10]. A wide variety of centers and surgeons across North America have reproduced clinical results demonstrating safety and efficacy of Anterior Vertebral Body Tethering (AVBT). Additionally, there

are four surgeon-sponsored IDE studies (NCT03506334, NCT03194568, NCT04119284, NCT03802656).

Based on physician directed use of the Dynesys System and an industry sponsored FDA IDE retrospective study, The Tether™ - Vertebral Body Tethering System by Zimmer Biomet received Humanitarian Device Exemption (HDE) approval by the FDA in August 2019.

The potential for anterior non-fusion devices to improve scoliosis patient outcomes under the principles of beneficence means that this device needs to be made available to those patients that meet FDA approved treatment indications and show interest in a new technology.

II. The Position of SRS/POSNA

Indication: The FDA approved Anterior Vertebral Body Tethering (AVBT) system is appropriately restricted under the terms of the HDE approval as being indicated for curves between 30 to 65 degrees in skeletally immature patients with idiopathic scoliosis and limited to use by surgeons with active IRB approval. Although the FDA did not require a more specific definition of "skeletal immaturity", we believe the definition should be similar to those used for bracing indications. Scoliosis Research Society defines skeletally immature as patients Risser 2 and under OR Sanders 5 and less, as under current understanding, growth modulation depends on meaningful remaining skeletal growth. AVBT is NOT indicated in the following circumstances: Skeletally mature patients, Congenital scoliosis or cases with vertebral or chest malformations, Non-ambulatory patients or patients with altered muscle function or control.

Billing/coding: due to lack of appropriate descriptive billing codes, billing this procedure as "anterior spinal fusion and instrumentation surgery with reduced services" is a reasonable coding approach as this best describes the amount of work, skill, and RVUs associated with this procedure. Current CPT code for spinal instrumentation are listed and valued as "add-on" procedures to be listed in addition to the spinal fusion CPT codes. As such the RVU values of the instrumentation codes are not subject to multiple procedure modifiers as the reductions in value have are been taken into account. We believe the fusion codes should receive a "reduced services" modifier and the instrumentation codes should be valued normally.

Functional benefit: Clinical reports (below) indicate a potential for 1) decreased length of stay 2) decreased narcotic use, 3) decreased blood loss, and 4) decreased operative time compared to fusion surgery. Revision rates are reported at 5-40% at 1 to 3 years of follow-up[7-10]. Additionally, POSNA and the SRS believe that non-fusion technology provides significant functional promise. It is difficult to put a price on spinal motion, but many patients and families place a high value on retaining spinal motion to support their wide variety of sports, activities, and everyday movements.

Conclusion: The FDA has deemed the device to be safe and of probable benefit. Thus, the Pediatric Orthopaedic Society of North America (POSNA) and the Scoliosis Research Society (SRS) firmly concur that payors should provide coverage for any FDA approved devices under FDA stated clinical indications and requirements (*limited to surgeons with active IRB approval*) at the same level as traditional spinal instrumentation/fusion and growing rod procedures for management of skeletally immature patients (Risser ≤ 2 or Sanders ≤ 5) with idiopathic scoliosis (as defined above, 30 to 65 degrees Cobb angle). For those patients who meet criteria for use of The Tether™ or other similarly FDA approved growth modulation systems, the decision for fusion versus growth modulation is best made between the patient, guardians, and treating physician - accounting for individual needs, values, and perspectives.

III. Detailed Review of Scientific Evidence on Anterior Vertebral Growth Modulation

Scientific Theory

Growth modulation operates under the principles of the Hueter-Volkmann Law, which describes the physiological response of growing bones under mechanical compression[11]. Compressive instrumentation of only the convex side of a scoliotic curvature inhibits growth on the convex side while permitting the concave side to lengthen with growth. As the patient approaches skeletal maturity, the lengthening of the concave side of the curve progressively straightens the spine in accordance with the Hueter-Volkmann Law[12,13].

Pre-Clinical Research on Anterior Vertebral Body Tethering

AVBT is a surgical technique that utilizes an implant system consisting of flexible tethers anchors to the anterolateral vertebral body that apply compressive force across the vertebral endplates (growth area) and discs without fully arresting spine mobility.

Early research on AVBT was conducted in skeletally immature non-scoliotic animal models. In 2002, Newton et al. showed that asymmetric flexible tethering was able to induce a spinal curve at the tethered levels in a rapidly growing bovine model[14]. This landmark study was followed in 2008 by a study utilizing an immature porcine model[15]. The investigators found that mechanical tethering during growth altered spinal morphology in the coronal and sagittal planes and produced vertebral and disc wedging proportional to the duration of tethering[15]. The generation of scoliotic curves in non-scoliotic animals was evidence that AVBT had the ability to modify spinal growth and curvature.

In 2013, Moal et al.[16] modified the design of the prior animal studies to further substantiate the findings that tethering can affect the instrumented spine in the coronal, sagittal, and axial planes. They conducted a biphasic study where they first used AVBT to induce scoliosis in a non-scoliotic animal[16]. They then removed the AVBT in the now scoliotic spines and switched the tethers from the concave side to the convex side to test if AVBT could treat the tethering-induced scoliotic curve[16]. The secondary corrective tether successfully created 3D realignment of the scoliotic curves and the observed corrective

process was not only a product of the mechanical tether, but also altered bone growth secondary to Hueter-Volkmann principles[16].

Subsequent animal studies were then conducted to examine the impacts of tethering on the cellular and structural integrity of spines post-treatment with AVBT[17,18]. Newton et al.[17] followed up on their bovine study and observed that tethering decreased spine motion by approximately 50% in lateral bending, flexion, and extension. Following the removal of the tether, motion returned to normal control values[17]. Biochemical and histologic analysis showed no change in gross morphologic disc health or disc water content[17]. Proteoglycan synthesis was significantly greater in the tethered discs and there was a trend toward increased type 2 collagen on the tethered side of the disc[17]. This was further substantiated in a more recent study that found these changes likely represent metabolic responses to the compressive loads generated by the flexible tether[18].

Additional histological studies have been performed evaluating the effects of growth modulation on the physis[19,20]. Chay et al.[19] conducted a comparative histological study of immature Yorkshire pigs that had only scoliosis-inducing AVBT versus pigs that had biphasic tethering with scoliosis-inducing AVBT followed by corrective AVBT. Between the two groups, they found no difference in hypertrophic zone height and cell height in the hypertrophic zone, concluding that growth potential is preserved with growth modulation.[19] These findings were substantiated in a more recent study that showed thinner physes on the tethered side without notable physeal closure[20].

Clinical Data

In 2010, Crawford and Lenke[9] published the first human trial of AVBT in a case report of an 8 year, 6 month old male with juvenile idiopathic scoliosis that underwent treatment by AVBT. The patient's preoperative curve improved from 40° to 6° at most recent follow-up, 48 months after the index procedure[9]. The patient's thoracic kyphosis changed from 26° preoperatively to 18° at most recent follow-up[9]. Furthermore, the patient grew 33.1 cm during this time.[9] Although this patient was without complication 4 years post-tethering, he remained skeletally immature at most recent follow-up in this report[9].

In 2014, Samdani et al.[7] conducted the first multiple patient study of AVBT in a case series of 11 patients with thoracic idiopathic scoliosis and a mean age of 12.3 years. All patients underwent tethering over an average of 7.8 levels[7]. Preoperative thoracic Cobb angle and compensatory lumbar curves corrected on average from 44.2° to 13.5° and 25.1° to 7.2°, respectively, at 2 year follow-up with approximately 70% correction on average for both curves[7]. Furthermore, scoliometer measurements improved from 12.4° to 6.9°[7]. No major complications were observed[7].

In 2015, Samdani et al.[8] expanded their sample size and reported results on their first 32 patients that underwent AVBT. The mean age was 12 years, mean Sanders score was 3.2, and all patients had minimum 1 year follow-up[8]. Thoracic curve correction improved from mean preoperative magnitude of 42.8° to 17.9° at most recent follow-up[8]. The mean compensatory lumbar curve also showed correction from 25.2° to 12.6°[8].

In 2017, Boudissa et al.[21] reported similar positive results and published their early outcomes of AVBT with minimum 1 year follow-up. Six patients underwent tethering of the thoracic curve at a mean age of 11.2 years and mean thoracic Cobb 45° and lumbar Cobb 33°[21]. At 1 year follow-up, the average thoracic Cobb corrected to 38° and lumbar Cobb 25° with no patients requiring fusion[21]. Additionally, no complications were recorded in this small series of patients[21]. These early human trials demonstrated the potential efficacy and safety of AVBT for the treatment of juvenile and adolescent socliosis[7-9,21], but were limited by small sample sizes and short follow-up timelines.

In 2018, Newton et al.[10] published a retrospective case series of 17 patients with 2-4 years follow-up. All patients underwent thoracoscopic tethering of the thoracic curve and mean age at surgery was 11.2 years[10]. Average preoperative thoracic curve was 52° and corrected to 27° at most recent follow-up[10]

In February of 2020, Newton et al. published a comparison of vertebral tethering and posterior spinal fusion[22]. They compared 23 VBT patients to 26 PSF patients at 2 and 5 years post-operative. They reported similar patient reported outcomes and a higher re-operation rate. However, they also found that VBT was successful at avoiding or delaying the need for fusion surgery in the majority of patients [22]

Ongoing AVBT research has demonstrated some additional patient selection criteria that may help refine surgical indications. At the SRS 2018 annual meeting, Yilgor et al. presented their results of a single surgeon experience of 19 thoracoscopic AVBT cases with minimum 1-year follow-up[23]. The average age at time of surgery was 12.5 years with mean follow-up of 17.6 months. Patients were divided into Rapid Growing (Sanders <5; mean height gain 8.1 cm) and Steady Growing (Sanders 5-7; mean height gain 2.6 cm). The average preoperative main thoracic Cobb was 45° and thoracolumbar/lumbar Cobb of 30° in the Rapid Growing cohort, and 44° and 30°, respectively, in the Steady Growing cohort. At most recent follow-up, the Rapid Growing cohort achieved 75% total correction and the Steady Growing cohort achieved 62% total correction. In the Rapid Growing Cohort, 2 patients developed atelectasis, 1 patient had a screw loosen, 1 tether release due to over-correction, and 2 more patients are candidates for tether release, but have yet to undergo surgery. No complications were reported in the Steady Growing cohort. Based upon these findings, the authors concluded this is a promising technique and may be safely performed in Steady Growing patients, but longer follow-up is needed.

At the POSNA 2019 Annual Meeting, Hoernschemeyer et al. presented their results on which curves may respond to AVBT with 2 years of follow-up[24]. All patients were diagnosed with adolescent idiopathic scoliosis and categorized into 5 groups: main thoracic (Lenke 1A), thoracolumbar, long thoracolumbar, Lenke 1B/1C, and Lenke 3 curves. 31 skeletally immature patients (mean Sanders 4.2; Risser 1.8) were reviewed: 11 main thoracic curves (mean preoperative Cobb 48°; mean post-operative Cobb 22°), 8 Lenke 1B/1C curves (mean preoperative Cobb 48°; mean post-operative Cobb 24°), 4 long thoracolumbar curves (mean preoperative Cobb 54°; mean post-operative Cobb 27°). There were 4 patients with Lenke 5 curves and 2 patients with double tethers that showed no significant change at most recent follow-up. The authors concluded Lenke 1A, 1B, 1C, and long thoracolumbar curves appear

to be effectively treated with AVBT with low complication rate and low rate of revision surgery at 2 years post-operative.

At SRS 2018, Turcot et al. presented their results of a prospective developmental study of 23 patients with 2 years follow-up[25]. The average age at time of surgery was 11.8 years. Mean thoracic Cobb 53° improved to 27° at most recent follow-up. Thoracic kyphosis was found to be unchanged from preoperative radiographs and most recent follow-up. Apical vertebral rotation corrected on average from 14° to 11° at most recent follow-up. This abstract showed there is progressive improvement of coronal and rotational deformity.

At POSNA 2019, Miyanji et al. presented an AVBT study with the largest patient cohort to date[26]. They conducted a prospective multicenter database study of AVBT with minimum 2-year follow-up in 57 patients who underwent a total of 63 procedures. The mean age at time of surgery was 12.7 years and mean follow-up was 29.2 months. Mean preoperative curve improved from 51° to 23° and mean compensatory curve improved a mean 31% at most recent follow-up. In this review of 57 patients from 2 centers, the authors concluded AVBT is an acceptable treatment option being effective at preventing and obtaining curve correction in most patients.

IV. Summary

In summary, a wide variety of centers and surgeons across the US, Canada, and outside North America have reproduced clinical results demonstrating acceptable safety and efficacy of anterior vertebral body tethering (AVBT) in skeletally immature patients. The FDA has judged this treatment as 'safe' and with 'probable benefit', and given this FDA approval the SRS and POSNA support insurance payor coverage for FDA approved usage of such devices. There have been no published scientific reports to support the use of vertebral tethering or other non-fusion anterior instrumentation in treating scoliosis in skeletally mature individuals. **The SRS and POSNA do not support the use or reimbursement for anterior non-fusion instrumentation in skeletally mature individuals for the management of scoliosis or other spinal deformities**. For skeletally immature patients with idiopathic scoliosis who, with their parents/guardians, have selected this approach via shared decision making with their health care professionals considering the risks (including higher rate of reoperation) and the motion preserving benefits, the SRS and POSNA recommend such treatment as an insured covered benefit.

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