Quantifying Tension in a Vertebral Body Tethering System for Scoliosis Treatment

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Disclosures: Mannen, EM (8-Journal of Biomechanics), **Brink, IB** (None), **Cain, P** (None), **Farnsworth, CL** (None), **Caffrey, JP** (3B-Daedalus Medical Solutions), **Olmert, T** (3A-Daedalus Medical Solutions, Inc.), **Upasani, VV** (1-OrthoPediatrics; 3A-Daedalus Medical Solutions, Inc; 3B-DePuy, A Johnson & Johnson Company, Orthofix, Inc., OrthoPediatrics, Pacira, Stryker; 3C-Indius; 4-Imagen; 5-nView, OrthoPediatrics, ZimVie; 7B-Wolters Kluwer Health, Lippincott Williams & Wilkins; 8-Spine; 9-Pediatric Orthopaedic Society of North America, Scoliosis Research Society)

INTRODUCTION: The gold standard surgical treatment for children with adolescent idiopathic scoliosis is deformity correction with spinal instrumentation and fusion. Pain, inflexibility, and degenerative arthritis are possible sequelae of the surgery due to fusion site immobility [1], and longevity of the metal rods and screws may be a long-term concern. A medical device using an innovative approach, vertebral body tethering (VBT), was recently approved by the FDA and provides an alternate treatment option. VBT takes advantage of the natural growth of a child's spine to modulate spinal growth and correct the deformity over time without spinal fusion. A flexible polyethylene tether is affixed across multiple spinal segments to apply compressive forces on the vertebral growth plates. Using a tensioner device, the amount of tension applied in the tether at each vertebral level is controlled so that the surgeon may provide a desired amount of initial deformity correction, which is then followed by further correction as the patient grows (spinal growth modulation). Recent data shows 74% of patients treated with VBT achieve clinical success [2]. The tensioner device has six tension settings (0 to 5), though no data is available to correlate this ordinal scale with the amount of tension generated in the tether. This limits the understanding of how surgical treatment choices may influence clinical success. Furthermore, it may be surgically indicted to add an extension spring tube to the tensioner device for access to the spine, especially since these cases are often performed via a thoracoscopic approach, and it is unknown whether the addition of the extension tube alters the tension applied to the tether for each tension setting. Therefore, the purpose of this study was to quantify the force generated by the tensioner without the extension spring tube (method T1) and with the extension spring tube (method T2) at six categorical tension levels using current VBT instrumentation.

METHODS: We created mechanical fixtures (**Fig. 1**) with a titanium bone screw inserted into two polyethylene blocks to mimic implantation into vertebral body cortical bone. The screws were set apart at a distance of 45 mm. These fixtures were rigidly mounted to a mechanical testing frame (MTS 858 MiniBionix) to allow continuous uniaxial force measurement through the tether at each tensioner setting. We first affixed the tether to the bottom bone screw with a titanium set screw, then applied tension using either the tensioner and counter-tensioner alone (method T1, **Fig. 1A**) or with an extension spring tube (method T2, **Fig. 1B**). Eight orthopedic surgeons used methods T1 and T2 at each of the six tensioner settings (0 to 5) in a randomized order. After the desired level of tension was reached, each surgeon secured the top set screw, and the test machine recorded force from the load cell at 128 Hz for two minutes. One surgeon completed three total trials of every setting for use in intra-rater reliability assessment. We imported raw data into MATLAB R2023a to visualize the data and calculate means, standard deviations, and confidence intervals of force during the 90-120 second intervals for all trials. Intra- and inter-rater reliability were calculated using an intraclass correlation coefficient (ICC) method where ICC>0.90 is considered excellent agreement. Tension values from T1 and T2 were compared using two sample t-tests to determine if there was a significant difference between the two methods at each tensioner setting ($p<0.05$).

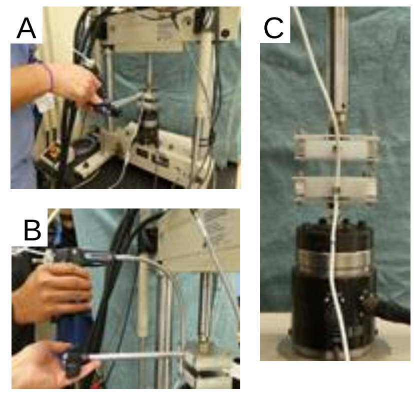

Figure 1:* (A)** *Photos of tensioner method T1.* ***(B) *Photo of tensioner method T2.* ***(C)*** *Photo of mechanical testing setup.*

RESULTS: The total range of tension values for both tensioning methods was 39 ± 13 N to 334 ± 26 N. Tensioner methods T1 and T2 exhibited linear relationships of the tension and setting number, with high coefficients of determination ($R^2 > 0.95$). Tensioner method T2 consistently produced higher forces in the tether with 62.1 N/tension setting, compared to tensioner method T1 with 50.6 N/tension setting. Intra-rater reliability between the three trials completed exhibited excellent agreement with an ICC coefficient of 0.971. Similarly, the inter-rater reliability between all surgeons exhibited excellent agreement with ICC coefficients of 0.951 and 0.943 for tensioner methods T1 and T2, respectively.

DISCUSSION: In this study, we quantified the tensile forces generated in a VBT system through the full range of tensioner settings using two different tensioner methods. Establishing the VBT forces may be useful to surgeons for targeting patient- and level- specific tension targets. Furthermore, the higher tension generated with the extension spring configuration (T2) may have significant clinical implications. Inter- and intra-rater reliability scores indicated that the tensioner had good repeatability and reproducibility, generalizing these findings to other surgeons using this VBT device. As a simplified benchtop study, the complex biomechanics of the *in vivo* spine are omitted, which likely affect the forces across the vertebral growth plates.

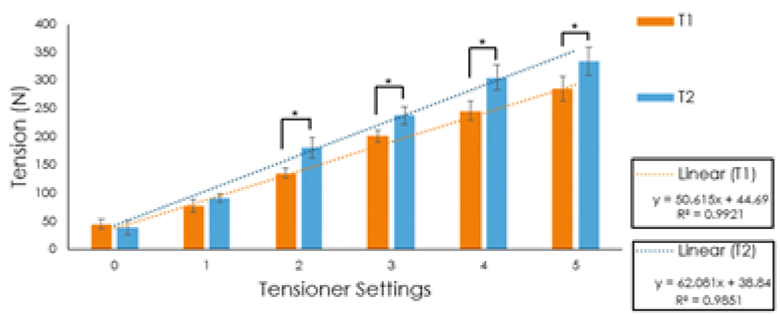

Figure 2: *Comparison of the two tensioning methods T1 and T2 for tension settings 0 to 5. Linear regressions fitted for each tensioner method with corresponding equations. *p<0.05*

SIGNIFICANCE/CLINICAL RELEVANCE: This study quantifies the tension by two tensioner methods used in VBT for adolescent scoliosis treatment. Understanding the forces created by the tensioner will allow surgeons to more accurately interpret their clinical outcomes and aid in planning of future surgeries, which may lead to improved spinal deformity correction.

REFERENCES: 1. Hoernschemeyer DG et al. J Bone Joint Surg Am. 2020 Jul 1;102(13):1169-1176. 2. Newton PO et al. Spine Deform. 2022 May;10(3):553-561

ACKNOWLEDGEMENTS: The Scoliosis Research Society Biedermann Innovation Award supported this work. We thank ZimVie Spine for use of the set.