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Vertebral Body Tethering (VBT): Quantifying Tension in a VBT System for Scoliosis Treatment

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Abstract

The gold standard surgical treatment for children with adolescent idiopathic scoliosis is deformity correction with spinal instrumentation and fusion. However, there is associated significant, long-term morbidity in fusing multiple motion segments in a child. Pain, inflexibility, and degenerative arthritis are often sequelae of the surgery due to fusion sites being immobile [1], and longevity of the metal rods and screws is a long-term concern. However, an innovative approach, vertebral body tethering (VBT), was recently approved by the FDA and has since provided 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 to multiple spinal segments to apply compressive forces on the vertebral growth plates. Using a tensioner device, the amount of tension in the tether at each vertebral level is controlled, eventually correcting spinal curvature as the patient grows. Recent data shows 74% of patients treated with VBT achieve clinical success [2]. The tensioner device has tension settings of 0 to 5, though no data is available to correlate with the amount of tension generated in the tether at each setting. Furthermore, there are two different tensioner device designs that can be used in this medical device set (methods A and B), and it is unknown whether these different tensioners produce similar tension. Therefore, the purpose of this study was to quantify the forces generated with the two tensioner methods (A and B) at six categorical tension levels using current VBT instrumentation.

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.

Comments

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Vertebral Body Tethering (VBT)

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Quantifying Tension in a VBT System for Scoliosis Treatment

BACKGROUND

- Spinal Fusion is the current gold standard treatment for children with adolescent scoliosis.
- Vertebral Body Tethering (VBT) was recently approved by the FDA and has since provided an alternative treatment option.
- A tensioner device with setting 0-5 is used, but there is no public data on the amount of tension generated at each setting.
- Surgeons cannot fully analyze clinical data without access to and an understanding of the underlying biomechanical data

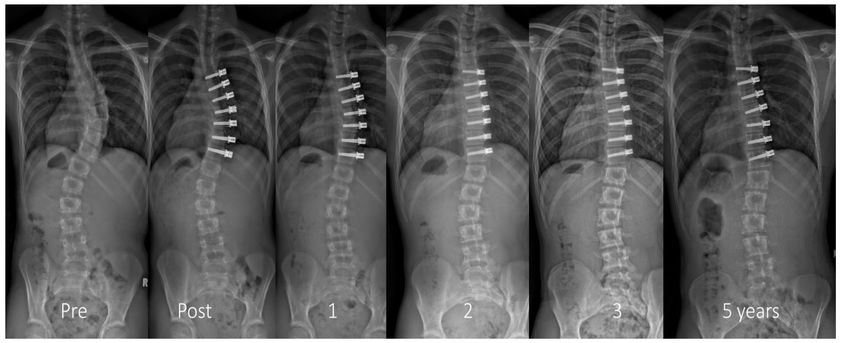


Figure 1: VBT success story from Rady Children's Hospital

PURPOSE: To quantify tension in a VBT system for scoliosis treatment.

METHODS

Eight surgeons tested two tensioner methods (A and B) each at settings 0 to 5, using a mechanical fixture we created.

Biomechanical Tensile Test System

- Records the amount of tension and displacement

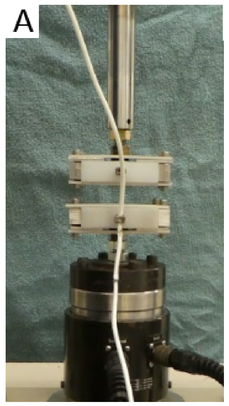
Tensioner (ZimVie)

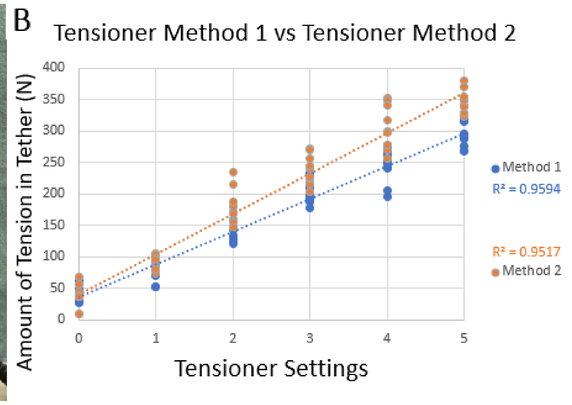
- Changes the amount of tension generated in the tether

RESULTS

Biomechanical Tensile Test System

- The data collected determined that both tensioner methods A and B exhibited linear relationships of the tension and setting number.
- Standard deviations were within 10% of the means.
- High coefficients of determination for both methods A and B.





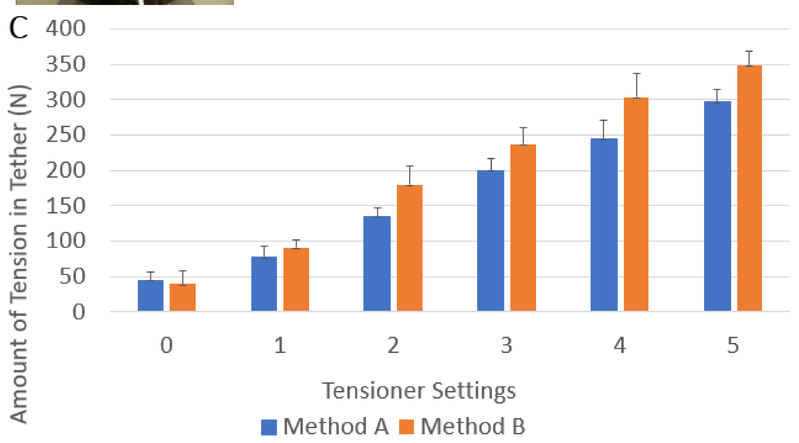


Figure 2: (A) mechanical fixture (B,C) Tension [N] at each tensioner setting for both methods

Tensioner

- The method B tensioner consistently produced higher forces in the tether compared to the method A tensioner.

CONCLUSION

- Tension in the tether of the VBT was quantified at each setting (0 to 5), finding that the relationship between tension and setting is linear for both tensioner methods.
- The method B tensioner resulted in greater force generation compared to method A in the tether at each setting which was unexpected since the settings (0 to 5) for each method were not different.
- This research will provide analytical data that may inform surgeons on how to specify VBT loads for each spinal segment and potentially allow patient specific VBT loading.

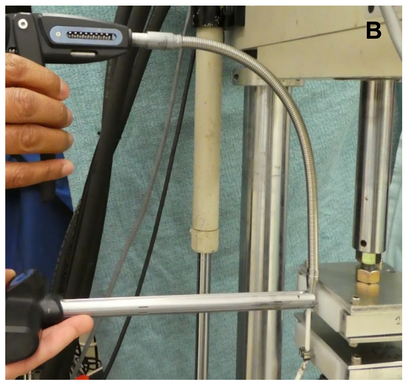


Figure 3: (A) Tensioner Method A (B) Tensioner Method B

IMPACT: Understanding the various unknowns involved with VBT surgeries can help overall scoliosis treatment. Additionally, better understandings and interpretations of clinical outcome data can be made.

FUTURE WORK

- Adding inter- and intra- rater reliability and statistical comparisons of the two methods to the novel data set
- Coding all of the stored data from the MTS machine

REFERENCES: [1] Newton PO et al. Spine Deform. 2022 . [2] Hoernschemeyer DG et al. J Bone Joint Surg Am. 2020 .

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