In Vivo Measurement of Tether Tension in a Pig Model of Spinal Deformity

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INTRODUCTION: Ian Stokes [1] hypothesized that spinal deformity progresses as a "vicious cycle" due to asymmetric stresses/strains applied to the growing spine over time and space. Predicated on the Heuter-Volkmann principle [2] (i.e., tension applied to an apophysis/physis stimulates growth, while compression inhibits growth), interventions such as Vertebral Body Tethering [3] (VBT) attempt to correct scoliosis, while preserving spinal motion, by predictably modulating spine growth via mechanical manipulation of affected functional spinal units. Currently, it is unknown how asymmetric loading alters the growth of the developing spine. Previously, (**Fig. 1**) we created a reciprocal model of scoliosis by applying a posterolateral tether to a straight spine to induce an asymmetrical bending moment to provoke scoliosis in a growing pig. While a static tether tension is set during surgery, *in vivo* the loading environment is quite different: rather than a constant applied load/bending moment, there is great variation in applied stresses/strains in time and space owing to superimposed dynamic forces and moments generated during gait and changes in posture that result in stochastic loading which may be more influential in regulating the adaptive response of the growing spine. The purpose of this study was to determine the *in vivo* variation in tether tension and resulting forces/moments applied to the spine during gait and changes in posture in a swine model of spinal deformity induced by growth modulation.

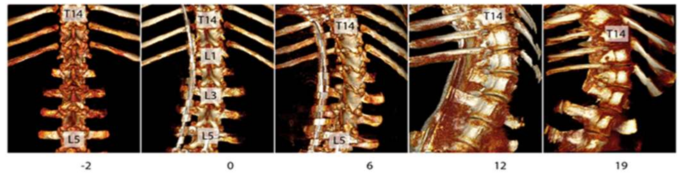

***Figure* 1** Asymmetric spine loading using a posterolateral cable tether provoked asymmetric spine growth. Initially deformity was localized to thoracolumbar and lumbar region, primarily through the IVD, reflecting viscoelastic CREEP. However, from 12 to 19 wks. anatomical change through the thoracolumbar vertebrae, indicate mechanical growth modulation of the bony vertebrae.

METHODS: Under IACUC approval, in a 6-week-old, 20 kg, female Yorkshire pig, a lateral bending moment was induced by tethering the thoracic to lumbar spine using a subcutaneous posteriorly placed, laterally offset stainless-steel cable spanning two posterior pedicle screw clusters with a lateral off-set at T9-10 and L4-5 respectively (**Fig. 2**). The applied *in-vivo* cable force was measured in real time using an in-line spring assembly a calibrated attached to a submersible load cell (50 lbf full scale capacity; 32Hz sampling rate). Cable force was recorded: during surgery, following recovery from general anesthesia at rest, during posture changes and ambulation in a 4x4 pen 3x/week over 7 days. Measured cable force values were synchronized with video recordings of the pig during representative activity states.

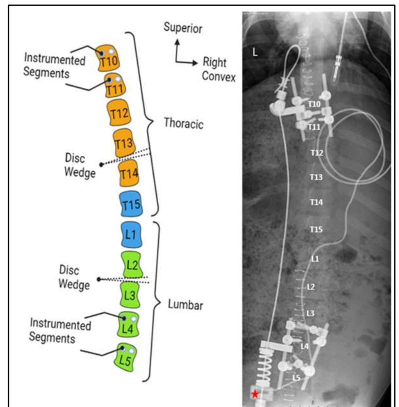

Figure 2. Radiograph and schematic illustrating placement of spinal anchors and interconnecting cable tethering the spine by anatomical region: thoracic (orange), thoracolumbar (blue), lumbar (green). The red star in the dorso-ventral radiograph at the lumbar cluster depicts load cell in line with the spring assembly to maintain tension on the tether construct.

RESULTS: During surgery, maintaining the spine in neutral position, ~40N of tension (**Fig. 3A**) was applied to the cable connecting the thoracic and lumbar vertebral anchor points. Immediate postoperative CT revealed a minimally induced scoliosis (Cobb angle = 2°). There was a progressive decline in cable force to ~15-20N over the ensuing 24hrs reflecting the viscoelastic stress relaxation of the connective soft tissues (**Fig. 3B**). Motion capture videos synchronized with cable force data revealed highly dynamic variation in cable force (and corresponding bending moment) associated with movement. *In vivo* cable force measured 7 days following surgery revealed that ambulation produced highly variable tether forces ranging in amplitude from 0 to 40N (**Fig. 3C**). CT imaging of the spine at postoperative day 7 with the pig positioned in neutral sternal recumbency demonstrated a natural kyphosis angle of 7° with an accompanying cable force of 7 N. Right and left bends obtained under general anesthesia demonstrated that a lateral bend of 8° away from the tether (convexity of scoliosis) produced a cable tension of 24N while a 35° lateral bend towards the tether (concavity of scoliosis) resulted in a cable force of 10N **(Fig. 3D-F).**

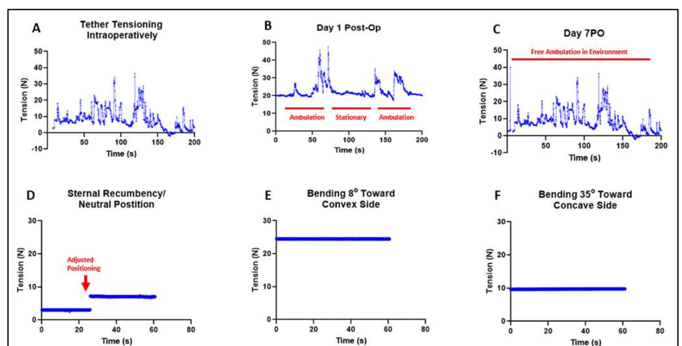

Figure 3. Measurement of tether tension *in vivo*. **A**) *In vivo* tensioning of the tether monitored during surgery - tension applied ~ 40N. **B**) Day 1 postoperative after the tether tension declined from 40 N to ~20N, due to viscoelastic stress relaxation. **C**) *In vivo* tether tension monitored during activities over next 7 day. Representative data shown here highlights variation in tether tension with activity and movement. (D-F) Day 7 postoperative, CT imaging and tether tension recordings in the anesthetized animal under 3 different postures: **D**) sternal/neutral, **E**) 8° bending away from tether (convexity scoliosis), **F**) 35° bending toward tether (concavity scoliosis).

DISCUSSION: Cable tether tension rapidly declined after it was set intraoperatively because of viscoelastic stress relaxation. Depending on the activity and movement, superimposed forces were highly dynamic, exhibiting a wide range of amplitudes and frequencies. Analytic models of mechanically induced growth modulation based on Heuter-Volkmann principle that assume static stresses and strains will need to be modified to incorporate the stochastic nature of applied *in vivo* forces and moments. Future work will focus on longer-term monitoring of the dynamic forces generated by the tether during controlled treadmill walking combined with real-time motion capture imaging to determine the kinematics and kinetics of spinal motion and develop stochastic models to predict the mechanical manipulation of spine growth.

SIGNIFICANCE/CLINICAL RELEVANCE: Tether based surgeries for correction of scoliosis in humans are increasing in prevalence and patient outcomes are predicated on growth modulation induced by tether forces/bending moments. Understanding the nature of stochastic *in vivo* tether forces will afford an enhanced understanding of short vs. long term tissue response and mechanobiological effect on the cells that modulate spine growth to improve outcomes.

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