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eLetter in response to: "Anterior Spinal Growth Modulation in Skeletally Immature Patients with Idiopathic Scoliosis: A Comparison with Posterior Spinal Fusion at 2 to 5 Years Postoperatively"

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Dear JBJS Editor,

We read with interest the publication by Dr. Newton et al., May 2020, which complements a previous publication on anterior vertebral body tethering (AVBT) by this group (1,2). The 2020 paper provides data on 23 idiopathic AVBT patients with a mean 3.4 year follow-up (range 2 to 5 years), of whom 9 had a revision procedure. In the 2018 paper there were 14 idiopathic patients and 3 syndromic with a total of 7 revision surgeries, one of whom was syndromic, with a mean 2.5 year follow-up (range, 1.75 to 4 years). These early AVBT papers hold a significant amount of weight in the limited literature on this topic, and this data may be used in future meta-analysis. The 2018 paper notes one of the 7 revisions was in a syndromic patient, but it is unclear if the 14 idiopathic patients reported on in 2018 were also included in the 23 patients reported on in the recent publication. Furthermore, it would be important to understand whether the 6 revision surgeries described in 2018 were also included in the 9 revision surgeries outlined in the recent 2020 publication. From the two publications, were there a total of 37 idiopathic patients requiring 15 revision surgeries, or is there some overlap between the two cohorts?

Secondarily, we continue to be surprised by the high AVBT revision rate of 52-59% reported by this well-respected group (1,2). In 2018, it was thought that this was due to the longer term follow-up provided by Newton et al., since previous papers had only reported 2 year follow-up on only 11 patients. More recent reports, however, note more encouraging reoperation rate of 6-20% at a mean of 3.2 years and 2.3 year follow-up (4,5). Perhaps it is, as one of the authors recently points out, "a considerable portion of the

mechanical complications might be attributed to the learning curve, and can be lessened by optimizing patient selection and surgical planning." From that standpoint, we would ask that the authors of JBJS 2020 publication please provide insight into how the tether cord was tensioned. All surgeries in this report were performed prior to the 2019 release of the Tether system with a designated tensioning device. In our experience, twisting of the cord using a thoracoscopic grasper potentially holds the risk of damage to the cord, which could precipitate cord failure. Further, it is worthwhile to consider the amount of intraoperative correction obtained as a potential factor contributing to device failure. Reports with the lower failure rates report a 51-70% coronal correction at 1st erect imaging (4,5,6), whereas Newton et al. had a large preoperative Cobb angle (mean 52-53 degrees) and only 36-40% correction on 1st erect imaging (1,2). This left patients with a mean 31-34 degree Cobb angle on 1st erect imaging. Certainly, further data regarding growth modulation is necessary, but it is possible that with a large residual curve pattern, growth modulation does not occur and predisposes the device to failure.
Again, we are extremely appreciative of this group's effort to transparently document outcomes of AVBT surgery and hope that all parties performing fusionless surgery actively pursue evidence-based research to provide every AIS patient with the optimal care.

Sincerely,

Noelle Larson and Todd Milbrandt

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Conflict of Interest: None Declared

Article Author Response

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Article Author(s) to Letter Writer(s)

Dear JBJS editor,

On behalf of my coauthors, I thank Drs. Larson and Milbrandt for requesting important clarification regarding two of our JBJS manuscripts on the topic of vertebral body tethering with the goal of anterior spinal growth modulation published in 2018 (1) and 2020 (2). As they have noted, the first paper included patients with both idiopathic and syndromic scoliosis, while the second was limited to idiopathic scoliosis and included a posterior spinal fusion cohort for comparison. To answer the first question posed, there was overlap between the two cohorts. The original 14 idiopathic scoliosis patients (IS) from 2018 were included in the 2020 cohort of 23. Thus, 2020 had an additional 9 unique IS cases.

Drs. Larson and Milbrandt incorrectly quoted the revision rates of our 2018 and 2020 papers as 52%-59%. In fact, the rate of revision reported in the 2018 paper was 41% (7/17) and in the 2020 paper was 30% (7/23). The revision rate for the 2018 cohort when only considering IS patients was 36% (5/14), but increased for those original 14 cases to 43% (6/14) by the time of the 2020 paper. On the other hand, the subsequent 9 patients only reported in the 2020 paper had a revision rate of 11% (1/9). These rates are based on rates per patients, as 2 patients from the original 2018 cohort had undergone 2 revisions by the time of the 2020 publication. In summary, at the time of the analysis for the 2020 publication, there were

23 unique IS patients with a revision rate per patient of 30% (7/23) with a total of 9 revision surgeries. Table V in the 2020 publication details the reasons, procedure details, and timing for all 9 revisions in these 7 patients.

Lower rates of revision certainly have been reported in the literature and understanding the differences in the age, curve magnitudes, and length of follow-up between the various series is important in understanding potential reasons for such variation. I would note an additional recent JBJS paper by Wong et al (3) that reports minimum 4 year follow-up on 5 patients with thoracic curve tethering with a 40% revision rate. The revision rate in the 2020 Hoernschemeyer et al (4) paper was 20%. However, if one looks at the first 23 IS cases in that paper (similar to the number of IS cases we reported in 2020) the rate of revision was 26% (6/23). This is very similar to our 2020 report limited to IS patients with a rate of 30% (7/23), both papers being initial cases with 2-5 years of follow-up. I would still consider these high rates of revision for tethering, and we will have to do better in the future. However, the rates reported in the literature are not as strikingly different as suggested.

Drs. Larson and Milbrandt also requested information on the details of how the tether was tensioned, suggesting the technique may result in a high rate of cord failure. The Zimmer Biomet Dynesys posterior spinal instrumentation was utilized in all of the cases reported in both our papers, utilizing the tensioning device that come in that set. The tensioning was done from proximal to distal, locking the proximal set screw and bringing the distal extent of the cord outside the chest around the screw counter torque tool. Tensioning was with the Dynesys system tensioner. The cord was then replaced into the chest and brought out the next most distal portal and tensioned on the next screw in a similar manner until all levels were tensioned. The cord was not tensioned by “twisting with a thoracoscopic grasper”, but rather tensioned with the device designed to tension the cord via the open posterior approach. The device to redirect the cord out of the chest to accommodate the tensioner was modeled after the open tool to allow use through 15mm thoracoscopic portals and is similar in concept to the tool in the current Zimmer Biomet, The Tether product set. Time will tell if the newer tools for tensioning will impact cord failure rates.

Cord failure has been a major issue with the current reports (1,2,4) and detecting cord failure requires careful sequential measurement of the angulation between each pair of adjacent screws at all visits. The increase in angulation (>5 degrees) between screws over time is what we have suggested represents evidence of cord failure. Without these sequential segmental measurements and analysis, cord failure detection can easily be overlooked. Of the references Drs. Larson and Milbrandt have quoted regarding lower cord failure rates, Hoernschemeyer et al (4) reported a cord failure rate of 48% in patients with 2-5 years of follow-up, while Alanay et al (5) and Samdani et al (6) have minimum follow-up of just 1 year. These later two studies do not have sufficient minimum follow-up to report comparable cord failure rates.

We reported a cord failure rate of 52% in the IS cohort in 2020, similar to Hoernschemeyer et al, both with minimum of 2 year and >3 year average follow-up. Cord failure seems to be related to the time of follow-up, longer follow-up results in higher rates of failure. The question raised by Drs. Larson and Milbrandt regarding an effect of residual curve magnitude on cord failure is certainly an area to investigate further. However, one must consider that the degree of residual curve should also likely be dictated by the remaining growth of the patient in order to limit the incidence of over-correction. Younger patients may require slightly larger first standing post op deformity than those with less growth remaining, in order to avoid over-correction of the curve requiring a secondary procedure. The differences between the 2020 papers of ours and Hoernschemeyer et al with regards to curve/tether locations (thoracic vs thoracic and/or lumbar, respectively) and skeletal maturity (96% open triradiate cartilage vs. 38% open triradiate cartilage, respectively) make direct inferences regarding this possible effect on cord failure difficult, especially given the similar rates between the 2 groups' initial cases. There is questionable homogeneity of patient characteristics, surgeon experience, and surgeon technique in all of the current existing studies on vertebral body tethering, making direct comparisons of results very challenging.

Prospective longitudinal data from a large number of patients and surgeons will be required as we strive to glean the features of the ideal patient. While there will be continued improvement in surgical technique, the true "learning curve" for this procedure will be related to a better understanding of the optimal surgical timing, curve magnitude and curve type. I trust this will occur while we work to identify improvements in the flexible tethering materials used to limit spinal growth while allowing some motion. The perceived benefit of spinal motion amongst patients appears to be driving demand for such technology, but advancements in this method that we must ultimately deliver, are required for the approach to have true lasting value.

Most sincerely,

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