1. Can you tether left thoracic curves thoracoscopically?

Newton-Yes, but the distance of the aorta to the rib head can be small. I think left thoracic is a relative contraindication.

Lonner-I have done a two or three as well as one spinal fusion thoracoscopically years ago. More difficult and certainly not one to do early on in your learning curve.

Samdani- We have done left thoracic curves, but agree that should not be done early in learning curve.

2. What levels can you see adequately / instrument adequately with thoracoscopic approach? What about selection of VBT levels?

Lonner-T4 to L2. T4, possibly T3 can be done although I have never gone to T3 as more difficult due to smaller vertebrae and vascular anatomy. L1 and L2 requires dissection of diaphragm, segmental vessel can get away from you in that dissection and may require a small open thoracotomy to gain control so need to be meticulous and slow and steady. L2 more difficult but still doable.

Miyanji- T3 to L1 - distally diaphragm needs to be retracted

Newton-T4 to T12 (L1 if you split the diaphragm insertion, careful of the segmental)

Samdani- Cranially getting up to T4 is usually possible as long vascular anatomy does not preclude. Inferiorly, we can get to L1 with a small dissection of the diaphragm. L2 is possible but requires more dissection.

3. Have you experienced any clinical lung function issues after thoracoscopic approach?

Newton-Modest if any. However patients will report some pleuritic pain on occasion after intrathoracic surgery, presumably due to pleural adhesions.

Lonner-Not after recovery complete

Samdani- Have not noticed any issues other than occasional pleuritic pain in a rare patient.

4. What is the learning curve with thoracoscopic technique, especially without an access surgeon? Any specific recommendations?

Lonner-about 30 cases. May be helpful to start with mini-open and scope to assist. Need to place screws perfectly and avoid aorta on contralateral side so best to have help of thoracic surgeon to help diminish the learning curve. Also recommend fluoroscopy intraoperatively.

Miyanji- Learning curve can be steep - would recommend visiting center for exposure and being comfortable with open thoracotomy

Newton-Not well documented for these cases, 30 for anterior discectomy. Best if you can enlist help of thoracic surgeon. Visit centers doing this. Get some lab experience.
Samdani- 30 cases for anterior surgery with discectomy, tether technically easier and likely closer to 10-15.

5. **Curious as to the panelists’ thoughts on growth modulation / VBT in the congenital and neuromuscular population.**

Lonner-Less predictable but certainly can be done. Need to educate families as to the tradeoffs and unknowns and early impact on pulmonary function would make this unacceptable for any with significant pulmonary compromise.

Newton-not the place to start. Much more variable deformity and growth potential.

Samdani- We do not have much experience in this cohort. I would start with AIS.

6. **How do we know if the tether has broken? Are the tethers radiopaque? What should be our approach in such a situation?**

Lonner- Not radiopaque. Look at distance between screw heads from one x-ray to the next, if distance increased by 5 degrees or more, cord likely broken.

Miyanji- Tether not radiopaque; need to look at splay of tulips

Newton-we found an increase of screw angulation between any 2 time points of more than 6 degrees was indicative of tether failure. The increase can be slow and hard to recognize unless plotting each level over time. We found this to be a common occurrence and one that is easy to miss if it's not being serially measured.

Samdani- Peter has done nice work in this and looked at splay angle. Typically this occurs in at least half of patients with vast majority of little clinical significance.

7. **Do the faculty find patients or their families pushing for a tethering technique over a selective fusion as a 'modern technique'?**

Lonner-In my practice yes although I always tell them that selective thoracic fusion is an excellent operation with excellent outcomes and good return to function including sports.

Newton-Yes. Patients that have been to the internet before coming are often preconditioned into believing fusion is a procedure associated with a life of disability and tethering is the only option. I find patients who present with a thoracic curve I consider candidates for tethering based growth modulation choose such about ⅓ of the time based on the evidence.

Samdani- Absolutely. We always tell them selective thoracic is an excellent option, discussing the potential risks and benefits of both approaches.
8. Should we be tethering skeletally mature patients (Risser > 2, Sanders bone age over 5)?
Newton- Absolutely not - based on current implants and current knowledge of biomechanics. There is not enough growth to result in a lasting correction and vertebral shape change. Depending on a non biological implant has not worked in other orthopedic ligamentous replacements and there is no evidence the spine will be any different.
Lonner- I think we may do this but we don’t have data on how long the corrections will hold particularly in the face of broken cords. We are using double cords in lumbar and some thoracic skeletally mature which will increase the longevity. Whether or not some bone remodelling muscle memory changes occur that will result in at least partial maintenance of correction in the face of broken tether remains to be seen. Partial loss of correction does not equate to need for re-operation.
Samdani- Skeletally mature in our experience has not worked well with respect to modulation of the vertebral bodies.

9. Can a posterior tether work as good as anterior?
Lonner- In my view that is not a good idea as the facet joints are disrupted and it will interfere with flexion although as Dr. Diab does, he cord can be removed after growth is complete.
Newton- Some folks trying this. The only experimental data I am aware of comes from a kyphosis study from Tom Lowe. I worry to posterior muscular intrusion will be counterproductive. Evidence remains to be created/presented.
Samdani- Posteriorly, facet disruption will likely lead to autofusion in my opinion.

10. Baron, do you tell your patients that this is human experimentation?
Lonner- I think this question goes for all of the panelists. They are told this is not FDA-approved, this is experimental, we don’t have longterm or even intermediate term follow-up, etc. I tell the patients about our current experience and early recoveries and complications and that we will look back at our cases over time to determine outcomes. AT the present time, prospective research not permitted except under IDE.

11. Can tethers be used in patients with neuromuscular deformities due to syringomyelia?
Lonner- I have used them in this setting, yes.
Newton- Maybe. The less thoracic kyphosis the better. Some of these patients are hyperkyphotic and would be contraindicated.
Samdani- For me it is about ambulation and trunk control (assuming radiographically meet criteria). If both present then can be considered.
12. What are your thoughts and experiences on the effect of lumbar tethering on the sagittal alignment - kyphogenic?

Lonner- Could be kyphogenic if screws placed too anterio. I am very diligent about posterior placement of screws in the lumbar spine as I do for anterior fusion.

Newton- I have limited lumbar experience. Many idiopathic lumbar curve are in fact hyperlordotic in 3D. I worry more about the durability in this region where more motion and load are likely to result in an earlier tether failure.

Samdani- We try to place the screws in the posterior half of vertebral body to perhaps minimize kyphosis. When we have looked at in 2D have not found them to be kyphogenic, 3D analysis needed.

13. Do you recommend Schroth therapy post-surgically to help correction of untreated curves and modulating growth overall?

Lonner- I am not sure if growth modulation is assisted by this but I do feel Schroth therapy is helpful in the postoperative setting to help with secondary curve correction or at least postural re-alignment.

Newton- I’m unaware of evidence to suggest exercise changes growth.

Samdani- No evidence to support, but I am very open to this concept.

14. (Stephen Eckrich) Have you used bone age of the hand to help determine growth remaining?

Lonner- Can use hand x-rays, I now use the Proximal Humerus Ossification STaging system of Smith. PHOS of 2 or less are likely to growth modulate, I believe but would have to be studied.

Newton- the hand X-ray has the most data to predict remaking growth at this point and I do believe this should be used to predict remaining growth understanding the error of prediction is substantial.

Samdani- We use the Sanders stage routinely.

15. It is in plan retirement of material at some point?

Lonner- I assume you are referring to breakage of cords and whether newer material or different geometries may be beneficial. All of this will require further study under a regulatory pathway.

Newton- I don’t fully understand the question. I do not routinely plan removal, but do anticipate implant failure particularly in the more mobile segments distal to T9. Current implants that are under load begin to fail at roughly 2 years.

Samdani- Not sure of question, but foresee newer materials in the future with greater durability and retaining flexibility.
16. Is elevated BMI a contraindication?

Lonner-Same as for anterior fusion but perhaps even more important given limitations of cord strength. Moderately overweight not likely problematic. Bone density must be adequate.

Newton-Not clear. If the weight leads to increased kyphosis, then yes.

Samdani- Not clear for us, we have done a few patients with higher BMI and so far appear similar.

17. Thank you for the presentations. You have shown curve correction can occur- just like a fusion. However, please provide some data about the motion preservation - does it really remain mobile?

Lonner-Thank you Tim. We have seen excellent curve correction, much like a fusion, in moderate or even moderately severe curves, especially thoracolumbar curves that are flexible. Different from a fusion, we do not know the longevity of the cord and hence curve correction. Further followup and time will determine this. Difficult to say how much motion is present at the instrumented segments as we have not studied this. I would state anecdotally that our patients are highly flexible and appear to be more mobile than our comparable fusion patients with similar curve types.

Miyanji-

Newton-the data on motion is limited and anecdotal. I have bend films on cases revised to fusion that remain mobile and correction in revised cases (without tether removal) seems to correct typically.

Samdani- We have been looking at motion analysis and will soon have some data from this perspective.

18. Do you need to cut the tether to get motion?

Lonner-I don’t believe so. The only limitation in motion is lateral bend to the contralateral side in the tethered segments.

Newton-to restore complete motion the tether would have to be cut or break. I have only cut the tether of over correction a problem (and prefer removal or replacement looser in those cases)

Samdani- Complete motion would recover a cutting of the tether, but we don’t routinely do unless over correction.

19. Are there any commercially available systems for tethering or are they all off label with intra-op modifications by the surgeon

Lonner-Currently all off label in the United States

Newton-there are only posterior systems with the PET cord cleared for use. At this time all cases are “physician directed use”. There are no FDA cleared systems for anterior use.

Samdani- No FDA cleared systems.
20. For Dr. Lonner- As in case of Dr. Moh Diab, can a posterior tether work as good as anterior? Also, which vendor supplies tether?

Lonner-I am concerned about the health of the facet joint with posterior tether. Furthermore, flexion is limited but can be restored with removal of tether after growth. Dr. Diab can be of more assistance. Currently there are no FDA-approved devices. Hopefully that will change in the months and years to come.

21. For Baron Lonner- how do you adjust the tether tension on the dual screw technique? Distal to proximal or apex to end vertebra? Also, what degree of correction do you shoot for on the table?

Lonner-Thank you Steve, I go for maximal correction on the table for skeletally mature and near complete correction at the apex for skeletally mature and less complete at the ends, especially distally where overcorrection most likely. I correct from proximal to distal with care not to plow the proximal screws in the relatively smaller vertebra. In dual screw technique. Correction is done through the posterior cord and the second cord is tensioned similarly to the same tension as the first, simply to take out the slack and as a protective cord against failure.

22. If the goal is correction and control of deformity over time, with or without growth modulation, why would it not be appropriate to correct a 50 degree curve to 25 degrees in a R=4 patient. Esp for a lumbar curve. And why is H-V the only method of modulation where changes according to Wolff may occur as well?

Lonner-Dr. Braun is credited with much of the early basic science work in this area and is one of the pioneers of this technique. I agree that Heuter-Volkmann may not be the only mechanism of correction and maintenance of curves, time will tell, future study will tell and I hope to be able to collaborate with Dr. Braun and others to learn more in the future.

Newton-The potential for shape change in the vertebrae is much greater due to Heuter volkmann compared to Wolff’s Law. The only experimental data I’m aware of on this in the spine is Aronson/Stokes’s rat tail experiments. The amount of change in shape required to Square up the vertebrae is commonly more than occurs even with a year of growth. Without growth the correction would be completely dependent on the implant compressing the disc and surviving for decades. Not the case with current bio materials available.

Samdani- We started our journey on tethering after a discussion with Dr. Braun at the SRS in Kyoto in 2010. He with Peter Newton did a lot of the early work. Greater potential with H V principles.
23. Is anyone within industry taking a lead role in establishing communication with FDA and educating them on tethering? If so, does anyone have a pulse on how long it will be before we see the first FDA cleared system?

Lonner- Industry is interested in seeing this technology and approach move forward with the FDA and is in conversations with the agency. The pace of that is really up to the FDA which in my opinion is an organization that is looking out for the best interests of the patients from numerous perspectives.

Newton- the SRS and POSNA have a joint task force that regularly communicates with the FDA and industry.

Samdani- FDA working closely with societies, study groups, and industry to bring this to market.

24. Does your evidence prove that tethering a 30 degree 13+6 Year old AIS patient is superior to that of traditional bracing with long term outcomes? Should you be doing a prospective randomized study?

Lonner- 30 degree curve too small, overcorrection and need for secondary surgery will be near 100% in that scenario.

Newton- I do not believe that an evolving surgery should replace a proven successful non operative treatment such as bracing. Continue to brace such patients assuming growth remains.

Samdani- Non op treatment always better, we try to tether curves when they are past 40 degrees or clearly heading there.

25. How much scarring/difficulty have you encountered on revisions?

Lonner- I have done three revisions, one early on to revise a screw with little difficulty, a second over a year after surgery for a thoracolumbar overcorrection which was a bit more tedious but total operative time was one hour and the patient did exceedingly well and has returned to full activities, now approaching a year since her revision. A final revision was for over correction of a thoracolumbar curve in another surgeon’s patient, who was one year postoperative, with little difficulty. She had a hospital length of stay of 3 days and returned to swimming within 4 weeks.

Newton- I found the pleural adhesions to be of variable severity and difficulty. I have always found some degree of lung adhesion. In one an open approach was required to release the adhesions. In all cases there has been at least a small air leak that resolved over several days of chest tube suction. It should be a real concern especially in the revision lumbar retroperitoneal (ureter, vena cava) approach.

Samdani- Generally, revision surgery has been a challenge. We have found the chest tubes stay in longer and patients stay longer in the hospital.

26. How do you define major curve if both thoracic and lumbar curves are similar in magnitude?
Lonner-The largest curve with similar rules as the Lenke classification. If we have a classic double curve, we tend to do both.

Newton-rotation and clinical appearance can help. I am not a fan of tether 2 curves at this point. Too unpredictable. On rare occasions I have fused the thoracic and tethered lumbar to “encourage” not so spontaneous lumbar curve correction. Very limited experience and too soon to know how it works.

Samdani- We tend to tether both curves if similar in magnitude.

27. Why is that so important to avoid overcorrection, we can still accept may be up to 25 degree of curve over correction

Lonner-I agree.

Newton-agree that 25 over is likely fine as long as it’s not adding to another 25 that was is a previously compensatory curve creating something bigger in total. Over correction seems to create adding on and other issues. At least one case is known to have over correction greater than 40 degrees...clearly too much. It is also unclear how much “rebound” occurs after loosening the tether in such a case.

Samdani- We have found that over correction of even 15 degrees if at the base of a thoracic tether, will lead to adding on and a clinically significant deformity. This is not always the case, but dependent on location of over correction