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Vertebral Growth Modulation with Pedicular Tethering for the Treatment of AIS: A Proof of Concept Report

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Introduction

For the adolescents with progressive Idiopathic Scoliosis and a Cobb angle beyond 25º, bracing is still the standard of care. However, many curves will continue to deteriorate due to refractory progression, refusal to accept this type of treatment or patient noncompliance. Surgery is required when nonoperative management fails, in order to prevent curve progression, correct the deformity and to minimize morbidity but at the costs of fusing a segment of the deformed spine and loosing spinal motion. For this reason, over the last decades, surgeons have been searching for other surgical alternatives to achieve the same objectives.

Vertebral growth modulation procedures are new techniques that are performed during the adolescent growth spurt and therefore should be looked at more closely and reported earlier. Posterior Vertebral Pedicular Tethering (VPT) is a new less invasive growth modulation technique used for the treatment of thoracolumbar and lumbar adolescent idiopathic scoliosis and stands as an alternative for the standard surgical posterior fusion for those progressive curves that fail conservative treatment. Spine tethering is a non-fusion approach that preserves motion and spinal growth, and may guide growth to correct vertebral deformity in the adolescent, therefore more likely to succeed if used in a certain phase of the growth spurt.

Although a 2-year follow-up data has been accepted as the standard for reporting clinical outcomes following surgical treatment of Adolescent Idiopathic Scoliosis (AIS), it has been shown not to provide much relevant information beyond data collected at 1y [1].

As reported earlier at 6/12 follow up of patients treated with VPT, there is a trend to improve the three-dimensional plane deformity in idiopathic scoliosis-the coronal plane by correcting the scoliotic curve, sagittal plane by restoring lordosis and axial plane by derotating the apical vertebrae [2].

If we focus on another form of spinal vertebral tethering through the front, anterior vertebral body tethering (VBT), convex compression with enhanced concave growth may be advantageous in the thoracic spine by inducing kyphosis but potentially disadvantageous in the lumbar spine, when instrumenting anteriorly the main single scoliosis curve was the technique to follow taking into account, that prior to selective fusion era, anterior instrumentation would require to fuse less vertebrae [3-8].

Assessing markers of skeletal maturity is not an easy task as we know, but it is a key issue for these growth modulation techniques. Although the most popular around the world, the Risser sign is easy to assess but very unreliable for different reasons. On one hand, despite being difficult to classify accurately on an AP pelvic Xray, the Risser zero can correspond up to Sanders 5 and on the other hand, Risser 1 comes after the peak height velocity, so we lose a very relevant information for decision making on the estimate of remaining growth and the growth dependent curve correction [9].

Sanders's simplified skeletal maturity scale (SSMS) was developed and derived from the original Tanner-Whitehouse-3 and has been proved to be the most accurate system to assess skeletal growth and with a strong correlation to the probability of curve progression in idiopathic adolescent scoliosis and although there are many other scales to assess skeletal bone age, SSMS is the only one that has been shown to have this correlation to curve aggravation [9]. However, at present we do not understand clearly, it's correlation to the outcome of spinal growth modulation techniques to correct AIS as we will see.

Study Design

This study is a proof-of-concept report where we present a prospective case series of six adolescent patients with progressive thoracolumbar Idiopathic Scoliosis (Lenke 5c) treated with VPT

with a minimum 1 year follow up. In order to investigate the outcome of these patients, operated on with this new vertebral growth modulation technique, hospital ethical review board approval was obtained.

Methods

We report the mean1,2y follow of the first six cases of AIS treated by posterior Vertebral Pedicular Tethering (VPT) and that three of them have been reported earlier at 6 months. Patients were reviewed on a regular basis and clinical and radiological parameters were assessed at 6 months intervals post-operatively (minimum 1y and maximum 2y in this particular series). Reoperation and complication rate were prospectively reported.

The inclusion criteria were boys or girls with the diagnosis of AIS,
- Aged 11 to 16 years old
- Severe progressive curves with a Cobb angle: >40° to 65°
- Curve Flexibility ≥50%
- Type 5C on the Lenke Classification
- Sanders Skeletal Maturity Scale: 2 to 6
- A minimum follow-up of 1-year post-op

The exclusion criteria are patients with scoliosis that are not idiopathic, other than Lenke 5C, cobb angle ≤40º or >65º, stiff curve (flexibility <50%), Sanders <2 or >6, main curve with 8 or more vertebrae, less than 1y of post-op FU and adolescents with other comorbidities.

All patients were consented, knowing the pros and cons about this new fusionless technique for the treatment of scoliosis, with no mid or long term follow up yet.

Results

We present the follow up of the first 6 cases with a minimum of 1 year (mean follow up 14,4 months). These are all female adolescents, post menarchal, with a mean age of 12y (11 to 16y). From a radiological perspective, all six cases were Lenke 5C scoliosis, three right sided, mean cobb angle of 51,6° (46° to 60°), flexible (> 50%), with an apex 2-T12, 3-L1 and 1-T10. Regarding the skeletal growth phase three were Sanders 3A, two Sanders 4 and 1 case Sanders 2. Concerning the number of instrumented vertebrae, there were 6 levels in 4 cases and 7 levels in the other two cases.

Upon reviewing our 6 cases with a minimum of 1y follow up, looking at the three different parameters of the scoliotic spinal deformity, our main concern was in the sagittal plane. Although there was a better sagittal alignment with 60% of the lumbar lordosis in the lower lumbar spine (34,6º) and an improvement in thoracic kyphosis from 35,5º to 39,2º, there was a theoretical risk of developing segmental hyperlordosis but this was not seen in any of the latest radiographs – mean upper lumbar lordosis was 18,8º pre-op and improved to 20,6º at 1y follow-up. As far as the Cobb angle (coronal plane) is concern (51,6º pre-op), there was improvement of 89% (5,8º post-op) at follow-up and regarding spinal lengthening within the instrumented segment, it increased from 183mm to 198mm during the same time period (table 1).

Parameters	Pre Op	6 Months FU	12 Months FU
Global LL	54.2	61.3	55.2
Proximal LL	18.8	26.8	20.6
Distal LL	35.3	34.5	34.6
Pelvic Index	40		
Sacral Slope	35.2	36.7	40
Spinal Length (mm)	183	190	198
Thoracic Kyphosis	35.2	36.8	39.2
Scoliosis Cobb Angle	51.6	16.7	5.8
Rotation (Nash & Moe Classification)	2.25		1.2
Wedge ratio	0.85		0.95

The third parameter that was assessed was vertebral apical rotation using the Nash and Moe Classification [10]. The mean Nash-Moe Index was +2,25 pre-op and +1.2 at 1y FU, showing a vertebral apical derotation of 47% (figure 1). This gradual improvement of axial vertebral rotation had been already pointed out in our previous article2 using the same surgical technique

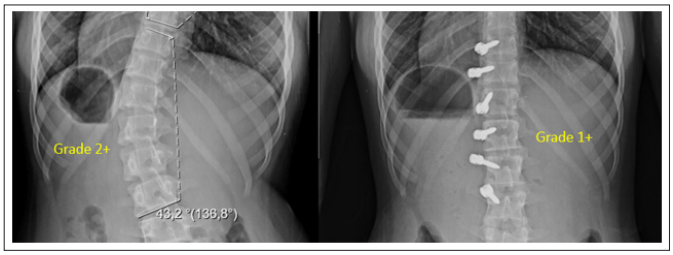

Figure 1: Axial Apical Rotation A. pre-op and B. at FU

As a growth modulation technique, it is important to look at the remodeling process of the apical vertebrae, assessing the coronal wedging ratio pre-op and at FU. This ratio improved from 0,85 pre-op to 0,95 at FU (figure 2), which shows that remodelling of these vertebrae with modulated growth is occurring, decreasing the abnormal wedge shape of the apical and of the adjacent vertebrae.

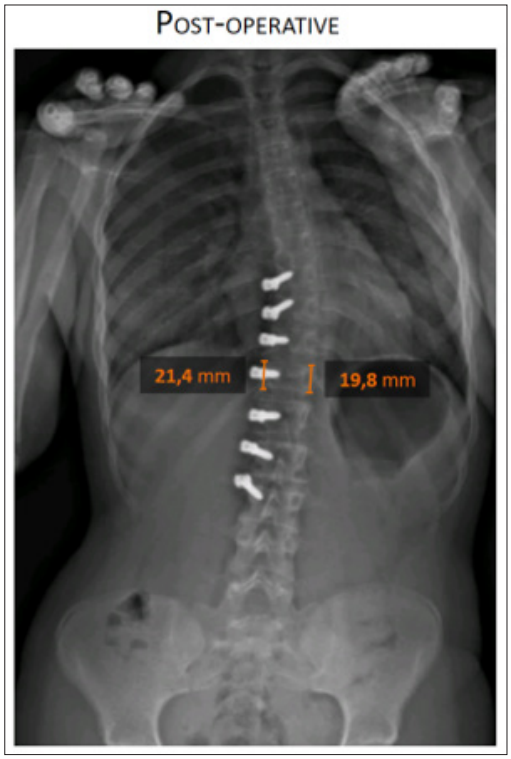

Figure 2: Coronal apical wedging A. pre-op and B. at F

From these six cases, no intra-operative neuro-monitoring issues or complications occurred but post-operatively, two required a minor procedure under local anaesthetic to release the tether (one proximal and one distal), due to overcorrection and this was the only type of complication (figure 3 and 4). None of the patients were braced or had a restricted physical activity post-operatively.

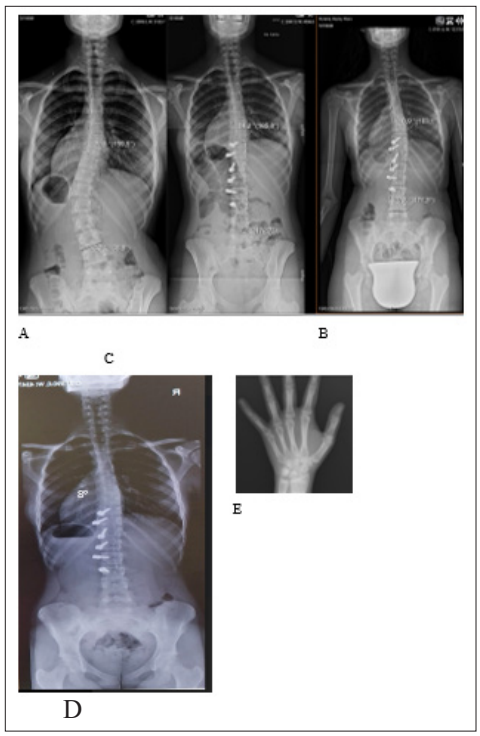

Figure 3: Despite being 13yo and a Sanders 6 / Risser 3, she developed proximal overcorrection at 1y post-op (shoulders unbalanced) AP spinal radiographs: A.pre-op, B post-op, C. 1y FU, D.post-tether release (shoulders balanced), E. Hand X-ray Sanders 6

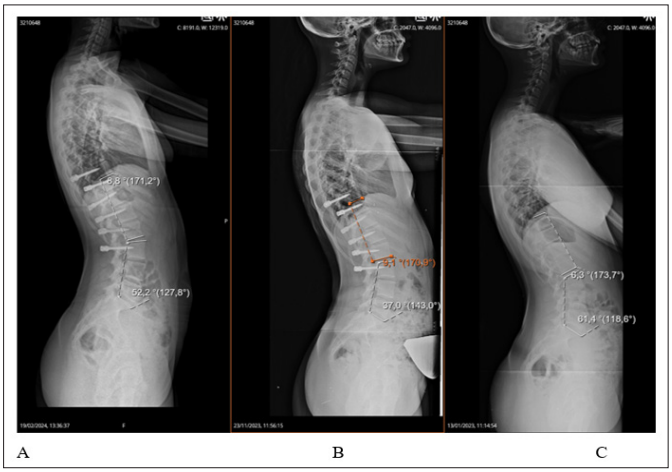

Figure 4: Lateral radiographs : A.1y FU, B. 8months FU, C. pre-op Regarding lumbar spinal range of motion (ROM) 1y post-operatively, it is definitely preserved but reduced to approximately 50%, when compared to pre-op figures, based on clinical grounds (figure 5).

Figure 5: Lateral bending standing at 2y post-op – flexible and sym

As this is a preliminary study (proof of concept report) on the 1y FU of this new spinal growth modulation technique for correction of certain AIS, with low numbers a statistical analysis on these figures would be underpowered and therefore not worthwhile.

Discussion

The continuous search for an alternative method to treat AIS that progress and failed conservative treatment, draw the attention to the effects of the Hueter-Volkmann Principle if used in the scoliotic adolescent spine [11,12]. The use of this principle in lower limb deformities has been validated by different series as pointed out by Blount and used by Paediatric Orthopaedic surgeons for decades [13]. However, in order to achieve the expected result, these techniques of gradual correction of the deformity by hemiepiphyseal arrest have to be timed to take into account not only the size of deformity but also the remaining growth available for correction by guided growth. The pre-op planning requires the use of growth charts to assess bone age, in order to calculate the right time to operate on these knees but even so, some error is inherent in the process and subsequent over or under-correction may develop [14,15]. According to Anderson et al, those who were within six months of skeletal maturity (14 years of bone age for females and 16 years for males), were considered unsuitable for this technique [16].

In the growing spine we lack a lot of information that is already available for correcting the lower limb deformity. Taking into account that this new phase of growth modulation in the spine is recent, we have to accept that some errors are inherent in the developing process and therefore we need to progress step by step, assessing frequently the results of our procedures [17]. If in the valgus or in the varus knees we are planning to correct the coronal plane deformity, without disturbing the sagittal plane alignment, in the scoliotic spine our objectives are more demanding, as we are aiming to improve the three-plane deformity – coronal, sagittal and axial.

The growing vertebrae have more endplates than the knee and they are structured in a different way. There are primary and secondary ossification centres–the primary ossification centres form the ventral 2/3 of the vertebral midbody and the secondary ossification centres cover the entire canal and caudal ends of the vertebral body. The body and the arch ossification centres meet on each side at the neuro-central synchondrosis (NCS). The bipolar distribution of these cartilaginous centres of growth (NCS on each side of the vertebra), contribute to the growth of the vertebral body, spinal canal and posterior elements of the spine. These NCS close simultaneously on both sides, but at different ages according to the different segments of the spine, the ones in the lumbar segment closes around 11y of age and in the thoracic segment, the last one to close at 17y approximately [18]. Acknowledging this structure and process helps a great deal to understand spinal growth modulation and to act at the appropriate time if we want to make the most of our procedure.

By inserting one screw through the convex NCS it blocks and closes this cartilaginous growth centre, but according to the Hueter-Volkmann principle it stimulates the growth on the opposite side, the concave side and we believe this is the reason why the continuous growth of the concave NCS will contribute to the derotation of the apical vertebrae and improvement of the coronal wedge ratio that we have seen in all our cases (figure 1 and 2). However, as growth is a complex ongoing process with many different components-age, hormonal, mechanical, etc …, the diversity of factors acting at the same bony age may explain why the progress may be different even in the same stage of known skeletal growth markers. In this preliminary study we present the mean figures of the six cases that have reached more than 1 year FU, but what has puzzled our minds is why some patients do better than other, despite all of them fulfilling the inclusion criteria and following the guidelines for treatment. As skeletal growth marker we used SSMS because it has been shown to be the more closely related to the progress of AIS but even so, we do need more accurate technique to assess growth stages in a more global reliable way. We believe this "locking" effect of the convex side NCS, is the main cause for derotation in our cases and improvement of Nash-Moe index at the apical vertebrae from +2,25 pre-op to +1,2 at FU in these growing adolescents may also be related.

Vertebral spinal tethering implants are now being used as an internal mechanical restraint to limit the progression of the scoliosis, in adolescent spines with certain characteristics and hopefully, reducing the deformity by harnessing the remaining spinal growth of that particular patient. Despite one of the components being a flexible cable it does not mean that it is a mobile instrumentation for the spinal deformity in general. Guiding growth of a flexible lumbar scoliosis of moderate magnitude (40 to 65º of Cobb angle) in a growing spine, ideally Sanders 3 to 6, is not the same as using the same cable in a rigid curve or in an adolescent spine close to the end of growth, where the remaining growth available for curve correction is almost none. These are stiff or less flexible curves where the whole concept is different and this technique of growth modulation is not appropriate in our opinion. For these cases this particular implant is not suitable because it breaks (either the screw or the cable) as shown in the literature, no matter if you use double cable or double screws. Trobisch et al in 2023 reported on the 2-year FU of a group of adolescents with thoraco-lumbar and lumbar scoliosis with a mean age of 14,3y, where they used a double tether technique in anterior vertebral body tethering. At FU, the average curve correction was 50% but there was a tether breakage in 90% of the cases despite the fact that only two cases required revision surgery [19]. However, if you look into the demographics in detail, 60% of the patients were Risser 3 or higher or Sanders 6 or higher. So, patients were operated on far beyond the Adolescent Rapid (Early) phase of the growth spurt when the peak height velocity (Sanders 3) occurs, operated later than the Adolescent Steady (Late) phase of growth (Sanders 6). At this stage most of the curves are less flexible and the expected remaining growth is short for subsequent scoliosis curve correction. In these cases, in order to reduce the curve magnitude at the end of the procedure, you have to apply an excessive power to tension the cables that subsequently will not decrease, because there is little growth modulation, and end up breaking the implants, no matter if the cables are single or double.

Spinal tethering ideally should be done either during or immediately after the peak of the curve acceleration phase (Sanders 3). In these cases, the maximum tension on the cable is at the index procedure, because with subsequent guided growth the tension on the tether will progressively decrease due to the scoliosis curve correction and therefore, the likelihood of breakage will be minimal. This is probably the reason why we have not identified any broken tether or loose pedicular screws in this series.

Metaizeau and Denis in 2024 reported on the 2y FU of a group of adolescents with thoraco-lumbar and lumbar curves and a mean age of 14y [20]. In this series there was a 70% cobb correction

of the main curve post-op, but with a complication rate of 45% (overcorrection 18%, screw pullout/ breakage 18% and progression scoliosis 9%). When we look at the demographics, we can see that the mean Risser sign was 1,5 (from Risser 0 to Risser 3) and they did not use Sanders Skeletal Growth markers. However, we do know that often Risser 0 can go up to the stage of Sanders 5 and therefore we can understand the mixture of complications reported may be due to the fact that it does cover a wide range of characteristics of the growing adolescent spine, some were probably too young and other probably too old for this growth modulation procedure.

Siu and Diab in 2023 presented their series of 14 cases with a mean FU of 3years. When we look at the demographics there was a mixture of different types of curves Lenke type 1c, type 3C (43%) and also 6C (29%) [21]. From these, 10 patients presented with double curves (6 were 3C and 4 were 6C) that underwent a combined Anterior Thoracic Vertebral Body Tethering (ATVBT) and Posterior Lumbar Spine Tethering (PVST) which is exactly the same technique as posterior pedicular tethering (VPT). Mean preoperative curve magnitudes were 53° for the main thoracic and 49° for the thoracolumbar/lumbar curve. All double curves (3C and 6C) had AVBT for the thoracic curve and PVST for the lumbar curves. At FU, patients that underwent an ATVBT and PVST had an improvement of 43% of the thoracic cobb angle and 60% in the lumbar curves. Regarding skeletal maturity 10 patients (72%) were Risser 0, two (7%) were Risser 1 and another two (7%) cases Risser 2, but in 9(64%) of these cases the triradiate cartilage was still opened. Overall, 50% of the cases required a revision operation for overcorrection or cable replacement and despite a cable breakage of 43%, not all required revision. In this series there was a mixture of patient's characteristics which can also explain the wide range of complications from overcorrection to a high tether breakage.

In these two articles published using this posterior vertebral tethering technique, either as a standalone or associated to an anterior vertebral body tethering, most of the patients were older by skeletal growth markers, most likely less flexible and therefore growth modulation may have been compromised explaining the unsatisfactory results [20,21].

In our present series the Cobb angle improved 68% (to 16,7º) at six months and 89% (to 5,8º) at final FU (table 1). This may be not be a linear progressive improvement of the main curve taking into account that two cases overcorrected and therefore final figures may be distorted by this fact. As far as the spinal growth of the instrumented segment is concern, there was an increase of 15mm but as pointed out earlier, it is difficult to know how much is due to the curve correction under this growth modulation technique and how much is real spinal growth being aware that this is an ongoing process in an adolescent spine. Concerning the axial plane deformity, at FU there was a 47% improvement in the Nash-Moe index of apical vertebral rotation which we believe can be due to the stimulation of the concave MCS and locking the ones on the convex side with pedicular screws. Our main concern was the possible development of hyper lordosis in the upper lumbar / thoracolumbar segment of the spine which can be a severe and difficult deformity to handle. For this reason we have looked at the progress of the upper lumbar segment, from the upper endplate of L1 to the lower endplate of L3 (the distal lumbar segment from upper endplate of L4 to the endplate of S1), but as we can see from table 1, that did not happen in the proximal lumbar segment and from 18,8ºpre-op it progressed to 26,8º at six months and to 20,6º at FU, with 60% of the global lumbar lordosis(55,2º) at the lower lumbar spine(34,6º) as expected. If we take as reference normal figures reported by Pierre Stagnara we can see that the hypo lordosis/kyphosis of this segment pre-op has improved to normal figures of alignment at FU, although only one girl is reaching the end of growth now [22]. As the tether becomes slack with the correction of the cobb angle in this technique, we do not believe that this complication may occur with the remaining slow skeletal growth.

Regarding vertebral remodelling the best method to assess the vertebral deformity without further radiation exposure is by using the coronal wedging ratio [23]. Within a year of FU, apical vertebrae show the tendency to remodel towards a normal "square" format on the coronal view, instead of a wedge shape typical at the apex of AIS. We believe this is an effect of the Hueter-Volkmann principle, stimulating the growth at the concave side of the vertebrae in the main curve of the scoliosis and that is the reason why in this series it improved from 0,85 to 0,95 at FU. For this reason, we believe that none of the reported cases are fused, otherwise the spine would not have grown or corrected the deformity.

Concerning sagittal alignment in thoraco-lumbar AIS, we do know that these adolescents usually present a hypo kyphotic thoracic spine. As pointed out earlier the same realignment in the thoracic spine occurs during this year post-op, just by correcting the deformity in the thoracolumbar segment of the spine [2]. Thoracic kyphosis gradually improved over these 14 months post-op, increasing from 35,2º pre-op to 39,2º at FU, closer to normality [24]. We believe that the hypo kyphotic thoracic spine is a consequence of the Euler Critical Load theory/ mechanism and also as a proximal spinal sagittal compensation of the thoracolumbar kyphosis [25]. If we correct the more distal deformity, there is a tendency for the spine to realign its proximal curvatures but we need longer FU to assess how it progresses until the end of growth. These findings are in agreement with R. Castelein study that demonstrates that an intervention in one plane in scoliosis leads to a response in the other planes and also to Virgine Lafage findings that patients with flexible thoracic spines were able to fully respond to the lumbar-induced changes from lumbar procedures [26,27].

Recently, Trobish et al reported on the 1 year followed of a group of adolescents with thoracolumbar scoliosis (either Lenke 5C or 6C) treated by two different anterior growth modulation techniques-15 underwent a standard VBT (patients with a mean Sanders 5.3) and the other group of 10 patients had a combined VBT and an apical fusion with a cage and bone graft (older patients mean Sanders 6.7), but only patients Risser 5 or Sanders 8 were excluded [28]. For the ones that had an apical fusion with a cage, the far concave annulus was released. At FU the thoracolumbar curve correction was 87,8% in the VBT and only 67% in the VBT with apical fusion. But when we look at the sagittal profile, lumbar lordosis was decreased in both groups but worse in the VBT group and the thoracic hypokyphosis was aggravated in the VBT group and remained the same in the one with apical fusion. Early tether breakage was seen in 60% of patients in the VBT group and in only 10% of the ones that also had an apical fusion. These findings reinforce the principle pointed out by Zielke and Dwyer in the seventies and eighties that anterior instrumentations of the thoracolumbar / lumbar spine were kyphotic and therefore in order to gain lordosis, Kaneda added anterior cages [29-32]. It also draws the attention that most of these patients are too old

for the remaining growth to correct the deformity but even so, the ones that had apical fusion, correction was worse (arthrodesis is against the principles of growth modulation). Another key issue is that instrumentation was used as mobile instrumentation for the treatment of AIS and as expected, the ones that had associated fusions had a much lower rate of tether breakage.

As far as preservation of motion in the lumbar spine is concern, our Institutionary Review Board did not allow to take further radiographs in this paediatric group of patients just for the sake of research purposes (4 extralong film radiographs at pre-op, post-op and at FU visits). Therefore, we had to base our opinion on clinical grounds, although we realize how unreliable it can be. However, if we look at the literature, Mathiew et al pointed out that their series of 13 patients that had anterior VBT for thoracolumbar and lumbar curves followed up for 1year, presented a decrease in the coronal plane motion to approximately 50% compared with preoperative values and a much better-preserved flexion and extension motion in the sagittal plane at FU [33]. In their short FU there was no evidence of auto fusion in the instrumented segment and so, a functional motion of the lumbar spine was preserved compared to a standard posterior spinal fusion where no motion is retained. If we look at the clinical images (figure 5) of one of our operated girls with a 2y FU, we can see that the coronal range of motion of the lumbar spine is flexible and very symmetrical. We believe that by performing a posterior atraumatic approach for a VPT, through the "corridor" between the Multifidus and the Spinalis, no bleeding, without touching the periosteum except for pedicle insertion and no post-op immobilization, we create all conditions to avoid autofusion and therefore we believe that the same preservation of lumbar functional motion does occur [2].

In order to understand and use growth modulation procedures in the spine we require more information on the behaviour of the growing spine to this type of fusionless procedures. Skeletal Growth is a complex process that cannot be assessed purely/accurately on a skeletal bony scale and we believe this is one of the main reasons to explain why similar cases at the same skeletal growth stage reacted and progressed in a different way. Some errors are certainly related to the unpredictability of the curve behaviour after the procedure and therefore will for certain decrease with experience and more accurate indications for surgery. However, we need to preserve a very narrow and clear indications for the type of growth modulation procedure. The lack of a table for decision making for growth modulation procedures in the spine, as exists for correction of the knee coronal deformities, is the reason why the few series published show a wide range of inclusion criteria for the procedure and consequently a wide range of complications and outcomes.

Based on our experience and on our low complication rate, when we consent patients with a Lenke 5C scoliosis for a VPT, we tell parents that this may be a two-stage procedure. Within the following 18 months post-op, there is a very high chance that the adolescent may require a minor procedure (second stage), under local or general anaesthetic to release the tether in case of overcorrection and this will help to realign and rebalance the spine. At the mid or long term, this stage will for certain be avoided but at present we believe it is an acceptable risk to take for such a procedure that is performed in a much less invasive approach through the "corridor" between the multifidus and the spinalis, no intra-op blood loss, a procedure that corrects the complex spinal deformity in the different planes, preserves spinal growth and functional lumbar motion and allows patients to resume normal full physical activity. For the ones that eventually may fail, a posterior spinal fusion can be performed through the same posterior midline incision and instrumenting only the concavity of the scoliosis in the standard way.

Looking into the future and being aware that the segment we need to preserve motion is in the lumbar spine, we think that this growth modulation technique may be combined with a selective fusion in the thoracic spine for certain double curves that progress despite conservative treatment. At present, we feel that this technique is only appropriate for thoracolumbar or lumbar scoliosis (Lenke 5C), but we do know that they only account for approximately 40% of AIS cases that require surgery and within this group, only a small % of patients fit the criteria for VPT [34].

This preliminary study has obvious limitations, including the small patient cohort that was followed for a short follow-up period. Furthermore, none of the patients have not reached the end of growth (older one is now close to 17y) and therefore, as a growth modulation procedure we cannot rule out that other deformities may arise until the very end. However, it is still rather unpredictable how to correlate Sanders Skeletal Stage, the effect of the Hueter-Volkmann principle in the growing spine and the remaining spinal growth after this procedure, as we can see from case described in figure 3, the more mature the skeleton the more difficult it is to predict the outcome.

Conclusion

Posterior Vertebral Pedicular Tethering (VPT) is a growth modulation technique that can be used successfully for Lenke 5C idiopathic scoliosis in adolescents that fail conservative treatment or in those that refuse this type of management.

This is a fusionless technique that should be used ideally in cases that are Sanders 3 to 6 in order to be successful. In this case series, there was an improvement is all parameters analysed like Cobb angle, lumbar lordosis, thoracic kyphosis, spinal growth, coronal vertebral wedging with no intraoperative problems and a low complication rate. It does preserve motion where movement is relevant.

Although with a short FU, the results of this technique are encouraging but we do need series with larger number of patients and longer FU in order to validate this technique.

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