

# Validation of A New Classification System For Surgical Planning of Vertebral Body Tethering (VBT)

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## Research Article

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# Abstract

**BACKGROUND:** Vertebral body tethering (VBT) may represent a paradigm shift in the management of adolescent idiopathic scoliosis (AIS). However, the ideal candidates, who may profit the most from this technique, have not yet been identified. We evaluated patients based on their curve type and on the potential benefits of VBT over fusion and developed a new classification to guide decision making for VBT, evaluating 5 different curve types (lumbar, double, long thoracic, short thoracic, presence of high thoracic curve). This study analyzed the inter- and intrarater variability of this new classification.

**METHODS:** 11 spinal deformity surgeons contributed to the validation. Four radiographs (p. a., lateral, right and left p. a. side bending) were prepared for 27 patients. Two sets of the patients' images were sent to each participant, with identical radiographs but in different order. Each participant was given instructions on how to employ the classification and was asked to apply it to the radiographs. The inter- and intra-observer reliability was assessed evaluating the kappa coefficient ( $k$ ).

**RESULTS:** The overall inter-observer reliability was  $k = 0.84$  (confidence interval: 0.76 to 0.91). The overall intra-observer reliability was  $k = 0.88$  (confidence interval 95%: 0.68 to 1.00). All  $k$  values were statistically significant and indicated an excellent inter- and intra-observer reliability of the classification.

**CONCLUSION:** The newly developed classification for VBT planning showed an excellent reliability.

## Background

Vertebral Body Tethering (VBT) is increasingly being considered as an alternative treatment option to spine fusion for selected patients with Adolescent Idiopathic Scoliosis (AIS) [1–6]. VBT is an anterior, fusionless surgical technique in which the screws are inserted in the vertebral bodies on the convex side of the curve, and then connected with a flexible tether that, once tightened, allows for curve correction [5, 7, 8]. In patients with considerable growth potential, curve correction occurs by growth modulation following the Hueter-Volkman principle [9, 10]. For patients approaching skeletal maturity, and thus with limited residual growth, curve correction may be driven by remodeling of bone and soft tissue mediated by Wolff's law [11, 12].

When introducing novel treatment approaches, medical ethics expects them to either entail a lower complication profile or an additional benefit for the patient compared to what is considered the established standard treatment, thus resulting in an improved risk-benefit-ratio [13]. Preservation of spinal flexibility, which is achievable with VBT [14–16], is currently being considered as a significant additional benefit when compared to spinal fusion. Furthermore, VBT seems to prevent disk and facet joint degeneration two years after surgery [17, 18].

Compared to spinal fusion, several studies have observed only few perioperative complications after VBT but more implant-related complications within the first five years after surgery [19, 20]. Patient selection seems to exert a marked influence on implant-related complications: most surgeons primarily base their

decision making on skeletal maturity, but published studies almost exclusively focus on patients with thoracic AIS [1, 3, 4].

In our current practice, we observed that available classifications [21, 22] were not directly applicable to the surgical planning of VBT. Following our experience with more than 250 surgically treated scoliotic curves by VBT in more than 170 patients, we have produced a classification that includes five fundamental curve types and that aims to highlight our thought process on defining risk-benefit-ratios and surgical treatment for patients with AIS, ranking curve types from type 1 (most favorable risk-benefit ratio) to type 5 (least favorable risk-benefit ratio).

An ideal classification is supposed to guide the thought process of a medical care provider while being both simple and reproducible [23]. Therefore, this study aims to evaluate the reproducibility of our classification as the initial step of a complex validation process.

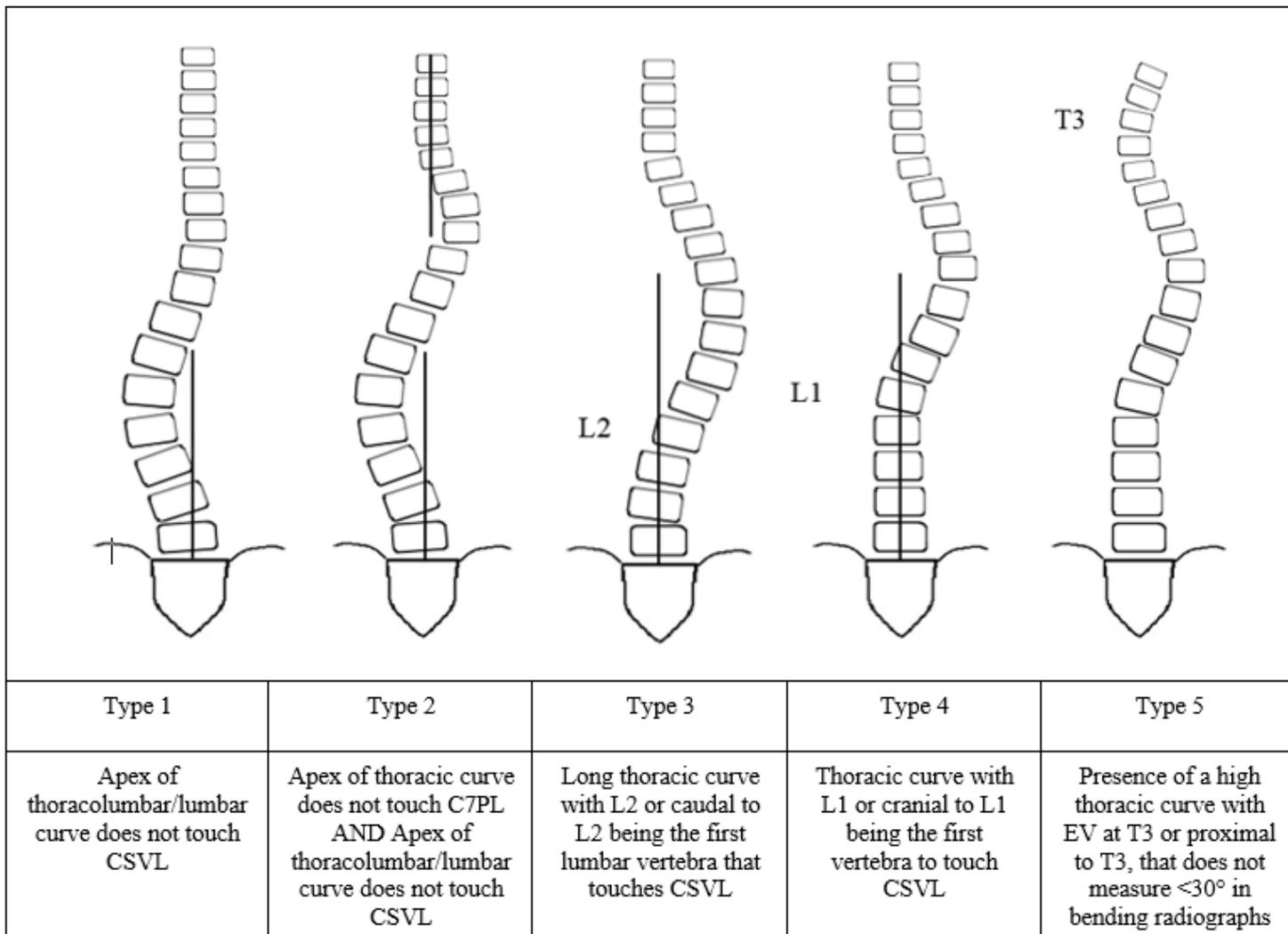
## Methods

The aim of this study was to evaluate the reproducibility of our newly developed AIS classification.

### Classification proposal

Our classification identifies five fundamental curve types and is based on the translation of the apical vertebra in relation to the C7-Plumbline (for thoracic curves) and to the Central Sacral Vertical Line (CSVL) for lumbar curves (**Table 1**).

**Table 1:** Schematic representation of the different curve types.



**Figure 1:** Clinical examples of the different curve types (1-5).

Following our classification, we suggest thoracolumbar/lumbar VBT for type 1 patients, as these subjects would benefit the most from motion preservation and degeneration prevention. Similar consideration apply for type 2 patients, who also present a thoracolumbar/lumbar curve. However, these subjects require bilateral VBT. Type 3 patients can be instrumented with a long thoracic VBT, allowing to preserve mobility of the upper lumbar spine. In type 4, VBT is a relative indication: thoracic VBT can be performed, however there does not seem to be any benefit in performing thoracic VBT over thoracic fusion. VBT is contraindicated in type 5 patients, as rigid high thoracic curves cannot currently be instrumented with this technique.

### Study design

The present study was conducted following the design of Lenke's classification study [22] to allow direct comparability of the results. Eleven experienced spinal deformity surgeons from nine different countries participated in this study. Two of them had been involved in the development of this classification (developers: PDT and AB), whereas the other nine had not been involved (non-developers).

All participants received two sets of anonymized radiographs from 27 patients. Four radiographs (posteroanterior, lateral, left and right posteroanterior side bending views) were provided for each patient, resulting in a total of two sets, each containing the same 108 radiographs, but in a different sequence. The participants were asked to classify the given curves into type 1 through 5 according to the instructions provided. To limit recall confounding errors, the participants were asked to classify the two sets of radiographs on two subsequent days.

The images that were used had been previously marked with the Cobb angle in the anteroposterior and bending views. The radiographs were extracted among the images of all patients that visited the outpatient office of the developers for scoliosis consult.

The retrospective use of anonymized patients' images was authorized by the local ethics committee (EK 130/19).

## Statistical analysis

The statistical analysis was performed by one other author (FM), who has a master in data analysis. The software STATA/MP version 16 (StataCorp, College Station, Texas 77845 USA) was used. To assesses inter- and intraobserver reliability of multiple raters on a target, the kappa-statistic ( $k$ ) measure of interrater agreement was evaluated. The  $k$  evaluates the balance of agreement that would occur by random chance subtracted from the actual agreement. To allow a direct comparison with previously published scoliosis classifications, all  $k$  coefficients were evaluated according to Landis and Koch [24]. The strength of the  $k$  coefficients was evaluated as follows:  $0.01 < |k| < 0.20$  slight;  $0.21 < |k| < 0.40$  fair;  $0.41 < |k| < 0.60$  moderate;  $0.61 < |k| < 0.80$  substantial;  $0.81 < |k| < 1.00$  almost perfect. Values for  $p < 0.5$  were considered statistically significant.

## Result

### Interobserver reliability

For the two developers of the VBT classification concept, the mean inter-observer reliability for determining the curve type was 100% ( $k = 1.00$ ). For the non-developers, the mean interobserver reliability for determining the curve type was 92.2% (54.5 to 100), with a mean  $k$  value of 0.81 (0.73 to 0.91;  $p < 0.0001$ ), indicating excellent reliability. The overall interobserver reliability for determining the curve type was 93.6% (54.5 to 100), with a mean  $k$  value of 0.84 (0.76 to 0.91;  $p < 0.0001$ ), indicating excellent reliability. A detailed overview of the interobserver reliability by curve type for the non-developers is shown in **Table 2**.

**Table 2.** Non-developers interobserver reliability by curve type.

Curve Type	<i>k</i>	Agreement (%)
1	0.9130	98.5
2	0.7978	92.4
3	0.8818	90.9
4	0.8025	89.1
5	0.7582	97.7
Overall	0.8384	93.6

### Intraobserver reliability

The mean developers' intraobserver reliability for determining the curve type was 100% ( $k = 1.00$ ). For non-developers, the mean intraobserver reliability for determining the curve type was 88.1% (55.8 to 100), with a mean  $k$  value of 0.84 (0.54 to 1.00;  $p < 0.0001$ ), indicating excellent reliability. The overall intraobserver reliability for determining the curve type was 92.3% (74.1 to 100), with a mean  $k$  value of 0.88 (0.68 to 1.00;  $p < 0.0001$ ), indicating excellent reliability. A detailed overview of the non-developers intraobserver reliability is shown in **Table 3**.

**Table 3.** Non-developers intraobserver reliability.

Rater	<i>k</i>	Agreement (%)
1	0.9213	92.6
2	0.9213	92.6
3	0.9213	92.6
4	0.9213	92.6
5	0.8182	88.9
6	1.0000	100.0
7	0.9213	92.6
8	0.6849	74.1
9	0.8328	88.9
Overall	0.8825	92.3

## Discussion

The results obtained show a very high inter- and intraobserver reliability when categorizing curves according to the AIS classification for VBT. Reliability was excellent also in the non-developers group, who

had not previously seen or used the classification. These data suggest that, for experienced scoliosis surgeons, the classification is easy to understand and applicable in a reproducible and reliable fashion.

The analysis of the identification of different scoliosis types yielded excellent results for curve types 1 to 4, while type 5 showed satisfactory results. Considering that type 5 patients may need to be treated with spinal fusion, particular care should be taken in the analysis of the bending radiographs of high thoracic curves, to identify patients in whom VBT is not indicated.

The results obtained in the present study compare favorably with the reliability outcomes of the Lenke classification, which represents the gold standard when planning fusion for AIS [22]. In the present study, we observed higher inter- and intraobserver  $k$  values in the developers group ( $k = 1.0$ ) than the values observed by Lenke's group ( $k = 0.92$  and  $k = 0.83$ , respectively) [22], but this may result from the smaller number of developers included in our study. Another explanation is the simplicity of our classification based on the fact that modifiers to evaluate flexibility and maturity should only be added as an adjunct and have not been included into the primary classification. Considering the non-developers group, the interobserver values were still higher in our study than in Lenke's ( $k = 0.84$  vs  $k = 0.74$ , respectively), while the intraobserver values were similar ( $k = 0.88$  vs  $k = 0.89$ , respectively) [22].

The rationale for a new classification is partially based on the difficulties that we observed when trying to form indications for VBT procedures using existing classification systems (e.g. King or Lenke). A Lenke type 1C curve, that many surgeons would treat by selective thoracic fusion (for example) should not be treated with a selective thoracic VBT given the risk of add-on scoliosis (meaning the progression of the lumbar, not instrumented curve). Also, our type 3 and type 4 both represent Lenke type 1 curves, but with clinically important differences. Type 3 patients usually require fusion to the mid lumbar spine. Additionally, the apex in type 3 curves is typically located in the lower thoracic spine and frequently is much more flexible than in type 4 patients. For this reason, VBT – at least from a theoretical and biomechanical point of view - offers clear advantages over fusion for these patients. Conversely, type 4 patients would typically only require a selective thoracic fusion, which would have only limited effects on mobility. Thus, in type 4 curves, the choice between fusion and VBT is often based on other factors such as skeletal maturity. VBT for structural high thoracic curves (Lenke 2 or 4) is technically not feasible with the currently available instrumentation, also, the benefits of preserving motion in the upper thoracic spine are questionable at best. We therefore would typically recommend spinal fusion for these curves.

VBT is expected to play a significant role as an additional treatment option for patients with AIS in the future. This surgical technique has been shown to have an acceptably low perioperative complication profile and a relatively short learning curve even for surgeons not previously familiar with anterior spinal surgery [11, 25, 26]. Although promising results are increasingly being reported, little is as yet known about the ideal candidate, the optimal surgical planning and the best surgical technique [8, 25, 27, 28]. In our own clinical experience, we noticed that skeletal maturity and curve flexibility may not be the most important parameters for our decision making, as good results have been obtained both in growing patients and in patients approaching skeletal maturity [1, 20]. Instead, we believe that curve type and

curve location are much more important. As a recent study showed that VBT has no kyphotic effect on the lumbar lordosis [29], we would not hesitate to offer this surgery to a suitable patient with a lumbar curve to preserve the mobility of this segment.

While the stage of skeletal maturity does not, in our opinion, affect the indication for VBT or the extent of the instrumentation performed, this parameter needs to be taken in consideration when determining how much intraoperative correction is required. Patients whose triradiate cartilage is still open (typically Sanders  $\leq 2$ ) present a high risk of overcorrection [1], and surgery, when possible, should be delayed. However, we do consider earlier surgery in patients with severe curves of more than 60° or inclinometer reading of more than 20°. More studies on ideal timing and impact of curve flexibility are required. When continued skeletal growth for more than 2 years is expected, a residual curve of about 20° should remain intraoperatively to limit the rate of overcorrection. For some authors, this patient group is the ideal candidate for VBT [1], but, despite very good clinical results, the possibility of overcorrection must be taken into account [30]. When expecting less than 2 years of skeletal growth (e.g. Risser 2-4, Sanders 5-7), we try to achieve full or almost full intraoperative correction, as only limited growth modulation can be expected. Other groups have obtained satisfactory results, with a limited number of revision surgeries [30]. In particular, performing VBT in patients approaching skeletal maturity (e.g. Sanders 5) may allow for more predictable results [1, 3]. Currently, we do not routinely offer VBT for patient who already completed skeletal maturity.

Overall, flexibility and skeletal maturity may in the future become modifiers of the current classification. However, the available data do not yet allow to identify possible cutoff values for flexibility and/or skeletal maturity that would influence the feasibility of a VBT procedure. Furthermore, the technical advances in this technique such as the use of two tethers or the use of disk releases may limit the relevance of flexibility and skeletal maturity in the decision making for VBT in the future [11, 20].

## Conclusion

The presented new classification for AIS proved to have a high inter- and intraobserver reliability and it may represent a useful tool for the planning of VBT and for communication among different study groups.

## List Of Abbreviations

AIS: adolescent idiopathic scoliosis

CSVL: central sacral vertical line

VBT: vertebral body tethering

## Declarations

### **Ethics approval and consent to participate:**

The present study was approved by the Ethik-Kommission Uniklinik RWTH Aachen, Approval n. EK 130/19. The ethics approval includes allowance to use anonymized, retrospectively collected data without consent to participation and publication from the patients. The requirement of informed consent was waived by the RWTH Aachen University ethics committee (Ethik-Kommission). The research was conducted in accordance with the Declaration of Helsinki.

### **Consent to publication:**

Not applicable.

### **Availability of data:**

The datasets analysed during the current study are not publicly available due to limitations of ethical approval involving the patient data and anonymity but are available on reasonable request. Please contact Alice Baroncini (alice.baroncini@artemed.de) for data request.

### **Competing interest:**

PT: Globus Medical (Consultant, Speakers' Bureau, Grants/Research Support); PB: NuVasive (Grants/Research Support, Consultant, Advisory Board or Panel, Other Financial Or Material Support - royalties, patents, etc), Medacta and Alphatec (Consultant; DePuy Synthes, K2M: Grants/Research Support, Consultant); SH: Globus Medical (Consultant, Speakers' Bureau, Grants/Research Support, Other Financial Or Material Support.-royalties, patents, etc); CB: EOS Imaging (Stock/Shareholder-self managed); DL: Stryker Spine (Grants/Research Support, Consultant), Zimmer Biomet (Consultant); IH: Medtronic (Grants/Research Support, Consultant), K2M (Grants/Research Support, Consultant); SC: Globus Medical (Consultant, Other Financial Or Material Support-royalties, patents, etc), Zimmer Biomet (Grants/Research Support, Consultant), Medtronic and CGBio (Consultant; CGBio); AB, FM, NM, AC, EP, TB: none.

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none

### **Authors' contribution:**

PT: logistic support, data collection, critical manuscript revision; FM: statistical analysis, critical manuscript revision; AB: study design, data collection and interpretation, manuscript draft; PB, SH, CB, DL, IH, SC, AC, EP, NM, TB: data collection and interpretation, critical manuscript revision. The manuscript was approved by all authors. All authors have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated, resolved, and the resolution documented in the literature.

### **Aknowledgements:**

none

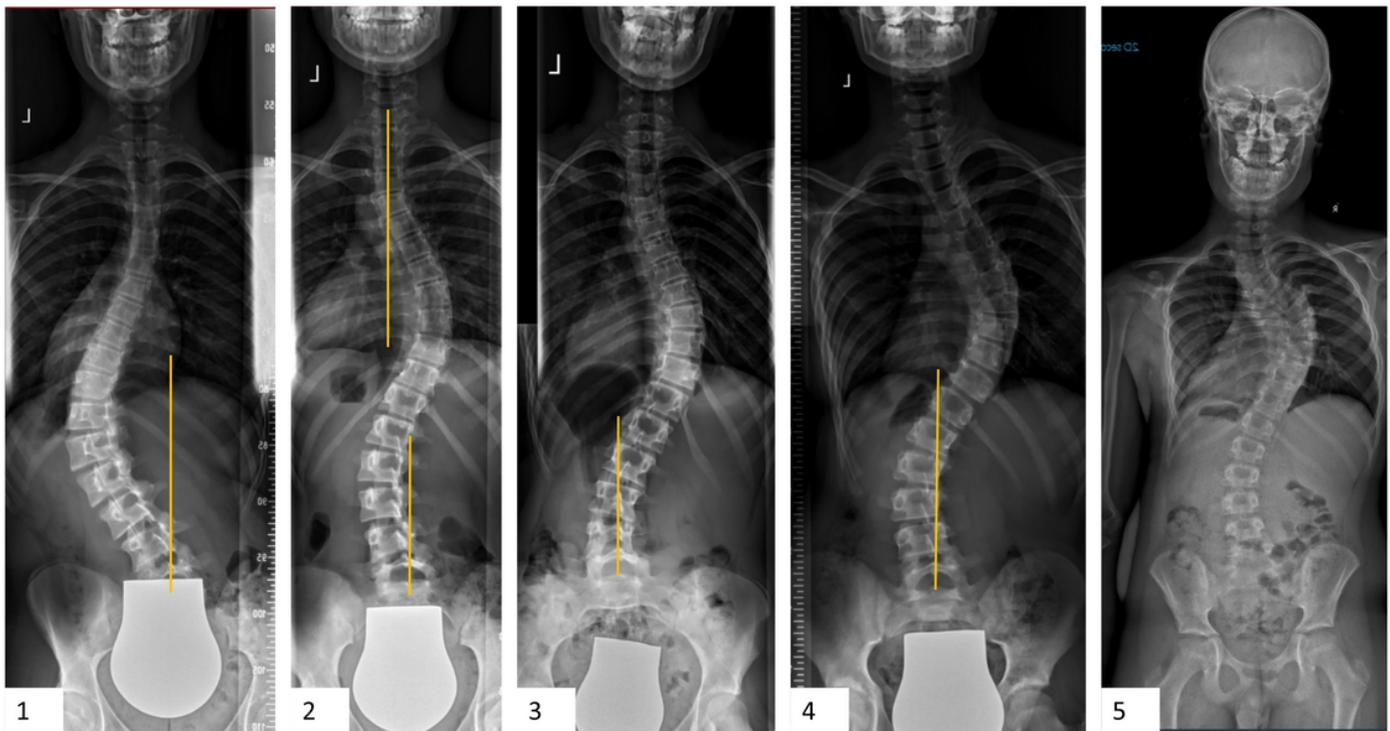
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## Figures



**Figure 1**

Clinical examples of the different curve types (1-5).

Following our classification, we suggest thoracolumbar/lumbar VBT for type 1 patients, as these subjects would benefit the most from motion preservation and degeneration prevention. Similar consideration apply for type 2 patients, who also present a thoracolumbar/lumbar curve. However, these subjects require bilateral VBT. Type 3 patients can be instrumented with a long thoracic VBT, allowing to preserve mobility of the upper lumbar spine. In type 4, VBT is a relative indication: thoracic VBT can be performed, however there does not seem to be any benefit in performing thoracic VBT over thoracic fusion. VBT is contraindicated in type 5 patients, as rigid high thoracic curves cannot currently be instrumented with this technique.