



# The timing of tether breakage influences clinical results after VBT

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## Abstract

**Introduction** Tether breakage is a frequent mechanical complications after vertebral body tethering (VBT), but not all patients with a breakage show loss of correction. The reason of this clinical finding has not yet been clarified. We hypothesized that the integrity of the tether is relevant only in the early stages after VBT, when it drives growth modulation and tissue remodelling. After these mechanisms have taken place, the tether loses its function and a breakage will not alter the new shape of the spine. Thus, tether breakage would have a greater clinical relevance when occurring shortly after surgery.

**Methods** All consecutive patients who underwent VBT and had a min. 2-year follow-up were included. The difference in curve magnitude between the 1st standing x-ray and the last follow-up was calculated ( $\Delta$ Cobb). For each curve, the presence and timing of tether breakage were recorded. The curves were grouped according to if and when the breakage was observed (no breakage, breakage at 0–6 months, 6–12 months, > 12 months). The  $\Delta$ Cobb was compared among these groups with the analysis of variance (ANOVA).

**Results** Data from 152 curves were available: 68 with no breakage, 12 with a breakage at 0–6 months, 37 at 6–12 months and 35 > 12 months. The ANOVA found significant difference in the  $\Delta$ Cobb among the groups (Sum of square 2553.59; degree of freedom 3; mean of square 851.1; Fisher test 13.8;  $P < 0.0001$ ). Patients with no breakage or breakage at > 12 months had similar  $\Delta$ Cobb (mean 4.8° and 7.8°, respectively,  $P = 0.3$ ), smaller than the 0–6 or 6–12 groups (15.8° and 13.8°, respectively).

**Conclusion** Tether breakage leads to a consistent loss of correction when occurring within the first 12 months, while it has limited clinical relevance when occurring later on.

**Keywords** Adolescent idiopathic scoliosis · Vertebral body tethering · Fusionless anterior scoliosis correction · Tether breakage · Tether breakage timing

## Introduction

Vertebral body tethering (VBT) is increasingly employed for the management of selected patients with adolescent idiopathic scoliosis (AIS). This fusion-less technique maintains spine mobility [1], and patients showed a quick return to daily life activities and sports [2]. Furthermore, it allows for a good correction on the sagittal plane [3] and it may prevent adjacent segment degeneration [4, 5], a common downfall of spine fusion. VBT can be employed both in its growth-modulating

form for skeletally immature patients (VBT–growth modulation, VBT-GM) and as a tissue remodelling technique in patients who are approaching or have reached skeletal maturity (VBT–anterior scoliosis correction, VBT-ASC) [6–8]. Growth modulation is regulated by the Hueter-Volkman principle [9, 10], while tissue remodelling follows the principles of Wolff's law. Irrespectively of the underlying biomechanical driving force, it can be hypothesized that, once a corrective mechanism has taken place and the spine has obtained a new shape, the tether loses its function. Thus, a tether breakage occurring a long time after surgery would not have detrimental effects on the correction of the curve. Under the same hypothesis, a tether breakage occurring early on after surgery would lead to worse outcomes on the long term, as the scoliotic curve would lose the remodelling mechanisms driving its correction.

As tether breakage is one of the most common mechanical complications after VBT [11, 12], it is fundamental to be aware of its effects to provide adequate counselling and plan

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follow-up and management more accurately. Thus, we analysed the effect of tether breakage at different timepoints to investigate whether the timing of the breakage has any effect on the mid-term results of VBT.

## Materials and methods

### Patients' recruitment

The study was conducted following the Strengthening the Reporting of Observational Studies in Epidemiology: the STROBE Statement [13] and was approved by the local ethics committee (EK 130/19). A retrospective analysis of prospectively collected data was performed.

All consecutive patients who underwent VBT for AIS between June 2017 and March 2020 and who had a minimum follow-up of two years were included in the study. Patients who lacked a min. two year follow-up or whose imaging was not of sufficient quality were excluded from the study. The radiographic requirement for sufficient quality was the availability of whole spine anteroposterior and lateral x-rays. All surgeries were performed by one author as previously described [14, 15].

### Data extraction

Baseline data such as age, gender, skeletal maturity, pre-operative curve type, magnitude and flexibility and curve magnitude at the 1st standing x-ray were collected. The difference in curve magnitude between the 1st standing x-ray and the last available follow up was calculated ( $\Delta$ Cobb). For patients who had required revision, the  $\Delta$ Cobb was calculated between the 1st standing x-ray and the largest curve magnitude prior to revision. The curve type was determined according to a previously published classification [14].

### Outcomes of interest

For each curve, the presence or absence of a tether breakage was recorded. A breakage was considered a change in the angulation of  $\geq 5^\circ$  between two adjacent screws in two successive x-rays. In case of breakage, the timing was recorded. The curves grouped according to when the breakage was observed (0–6 months, 6–12 months, > 12 months). The  $\Delta$ Cobb was compared among these three groups and the group of the curves that did not present a breakage.

### Statistical analysis

The statistical analyses were conducted using the IBM SPSS version 25. For descriptive statistics, continuous data were

expressed as mean  $\pm$  standard deviation; qualitative data were expressed as percentages.

To investigate possible difference in the  $\Delta$ Cobb according to the timing of the breakage, the analysis of variance (ANOVA) was conducted between the four groups (no breakage, 0–6 months, 6–12 months, > 12 months). Sum of square (SS), degree of freedom (DoF), mean of square (MS), and Fisher (F) test were used to statistically validate the equality of the means. The confidence of interval (CI) was set at 95% in all comparison. The head to head Honestly Significant Difference (HSD) post hoc test was conducted to investigate which groups were significantly different. Values of  $P < 0.05$  were considered statistically significant.

## Results

### Patient recruitment

During the observation period, 125 patients underwent VBT for AIS and were screened for inclusion. Nine of them lacked a min. two-year follow-up and 12 did not present imaging of sufficient quality (e.g. only thoracic or lumbar x-ray instead of whole spine). Thus, 104 patients and 152 curves were available for the study.

### Baseline data

The mean follow-up was 27.4 months (range 24–48 months). The baseline data of the entire cohort are shown in Table 1. Overall, the preoperative mean Cobb angle of the instrumented curves measured  $58.2 \pm 12.1^\circ$ , bending down to  $38.8 \pm 15.8^\circ$  in side-bending x-rays. The instrumented curves measured  $25.6 \pm 11.4^\circ$  at the 1st standing x-ray and  $34.1 \pm 9.9^\circ$  at the last follow-up. The mean  $\Delta$ Cobb was  $8.5 \pm 8.7^\circ$ .

**Table 1** Overview of the baseline data of the included patients. Age, Risser and Sanders values are expressed as mean  $\pm$  standard deviation

Baseline data—entire cohort			
		N	TOT
Age		14.9 $\pm$ 3.9 years	
Risser		3 $\pm$ 1.8	
Sanders		6.1 $\pm$ 1.8	
Sex	F	93 (90%)	104
	M	11 (10%)	
Curve type	Type 1	21 (20%)	104
	Type 2	48 (46%)	
	Type 3	24 (23%)	
	Type 4	8 (8%)	
	Type 5	3 (3%)	

## Outcomes of interest

Among the 152 observed curves, 68 showed no sign of tether breakage at the last available follow-up. Twelve curves presented a breakage in the 0–6 month timeframe, 37 in the 6–12 month period and 35 after 12 months. Clinical examples are shown in Figs. 1 and 2. The mean Risser stage was 2 in the 0–6 group and 3 in all other groups. The evolution of the Cobb angle in each group at different follow-ups and the revision rate is shown in Fig. 3 and Table 2.

The ANOVA found significant difference between the four groups (SS 2553.59; DoF 3; MS 851.1; F 13.8;  $P < 0.0001$ ). Table 3 shows all the head-to-head comparisons in greater detail.

## Discussion

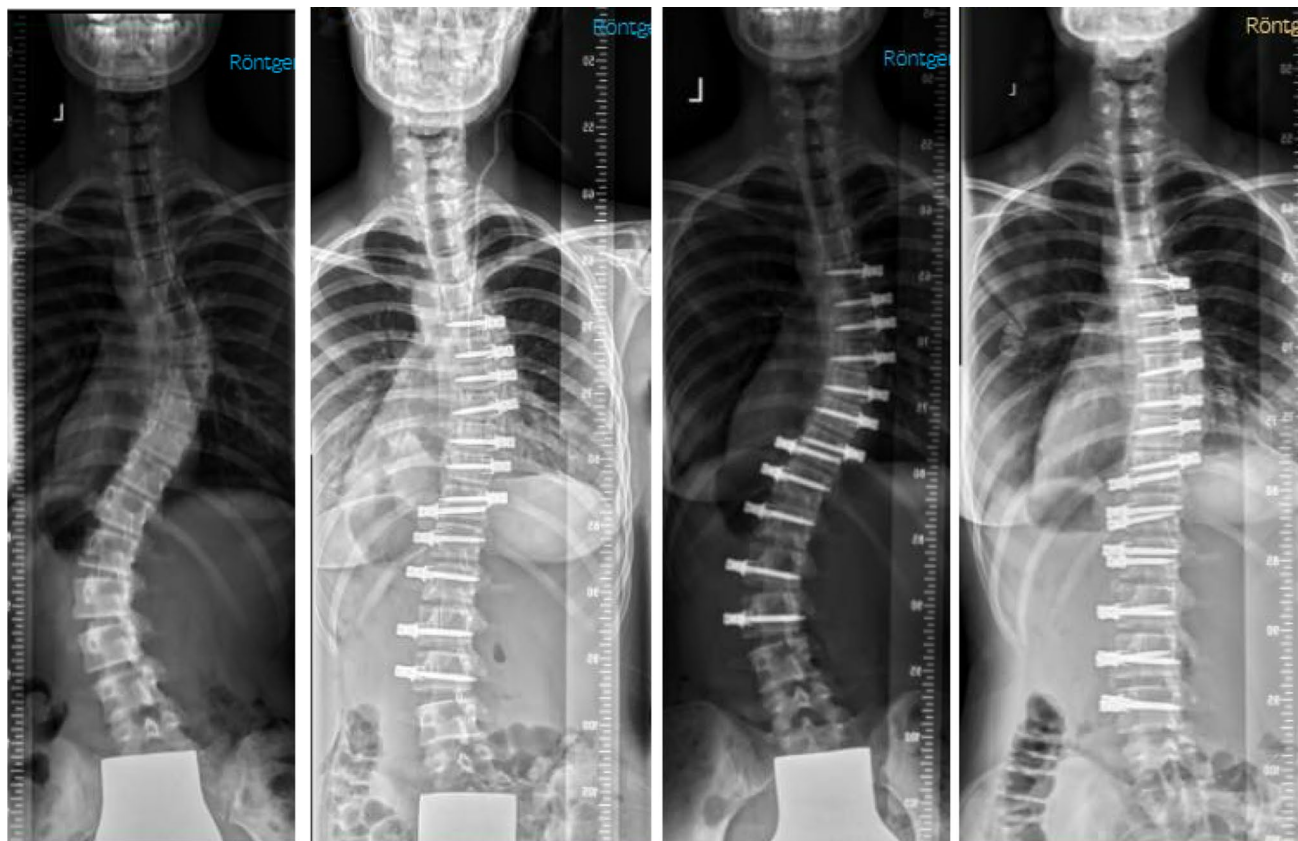
The main finding of this work is that a tether breakage occurring in the first 12 months after VBT leads to a significant loss of correction. When the breakage occurs after 12 months or does not occur, the mean loss of correction

is limited and less than  $4^\circ$ , which would imply a clinically relevant change [16].

To the best of our knowledge, this is the first study to investigate the effects of the timing of the tether breakage on the clinical results. These findings support the hypothesis that, while the tether has a fundamental role in the first year, which is likely the timeframe in which the growth modulating and/or remodelling processes take place, this function is lost over time. Once the remodelling processes have terminated, the spine can hold its new shape even if the tether breaks, at least in the mid-term.

The effect and relevance of tether breakage on the clinical results of VBT have been questioned [17, 18]. In fact, some authors have observed that not all patients requiring revision had a tether breakage [19], while others have shown that a breakage does not always imply the necessity of revision surgery [20]. The timing of the breakage may, at least in part, offer an explanation for these unclear findings, as only early breakages occurring within the first 12 months would lead to a significant loss of correction.

This finding has important clinical consequences. As early tether breakages present a higher loss of correction



**Fig. 1** Example of a 15 year old patient (Risser 1) with a type 2 curve measuring  $50^\circ$  at thoracic and lumbar level before surgery (A). After VBT, the curves corrected to  $26^\circ$  and  $17^\circ$  at thoracic and lumbar level, respectively (B). At the 1-year follow-up, however, a tether

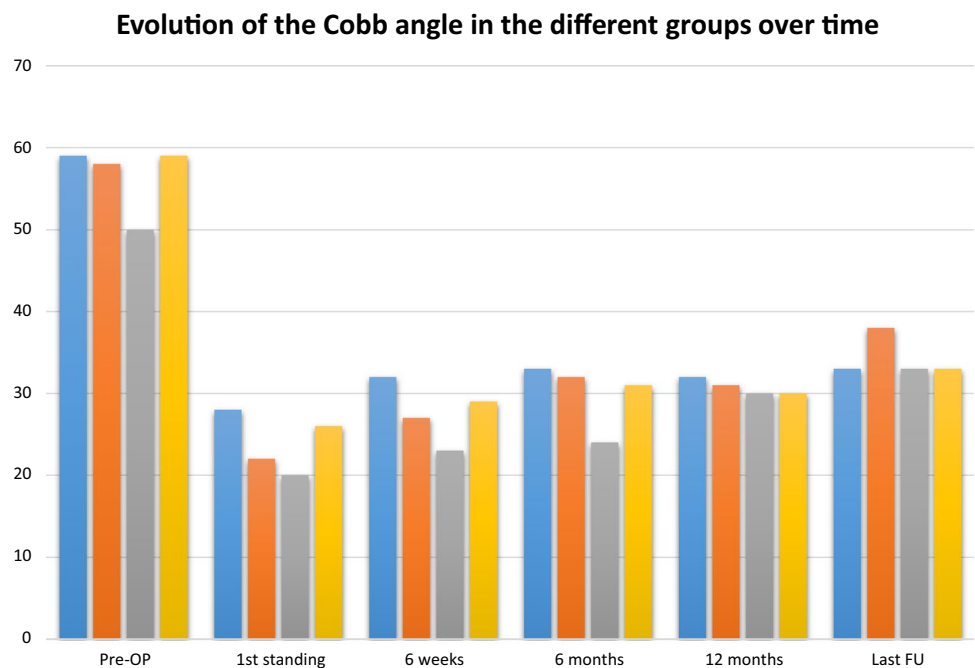
breakage at L2/3 was observed and, at the 2-years follow-up, both curves had increased to  $40^\circ$  (C). Thus, revision VBT was performed with a double tether in the lumbar spine and both curves corrected to less than  $10^\circ$  (D)



**Fig. 2** The images show a 16 year old curve (Risser 4, Sanders 7) with a type 1 curve measuring 45° (A). At the first-standing x-ray the curve corrected to 2° (B) and stabilized at 10° at the 1-year follow-

up (C). At the 24-months follow-up (D) a breakage between the two most caudal screws was observed (L2/3), however the lumbar curve still measured only 13°

**Fig. 3** Schematic representation of the evolution of the Cobb angle in the different groups over time. Blue: no breakage; red: breakage at 0–6 months; gray: breakage at 6–12 months; yellow: breakage > 12 months



( $\Delta$ Cobb), adequate counselling should be provided for the patients and their families along with regular follow-ups. Patients who show sign of tether breakage after 12 months, on the other hand, present the same amount of loss of

correction as patients without breakages and should be reassured that this mechanical complication is unlikely to have any consequence. While 11% of the patients who presented a breakage after 12 months required revision surgery, two of

**Table 2** Summary of the Cobb angle of the treated curves at the different timepoints and for each group with rate of lumbar curves and revisions

Group	N	Pre-OP	1st standing	6 weeks	6 months	12 months	Last FU	Lumbar curves (%)	Revisions (%)
No breakage	68	59 ± 12.8	28.8 ± 10.7	32.6 ± 13.3	33.6 ± 11.8	32.5 ± 11.2	33.6 ± 10.3	10 (14%)	0 (0%)
0–6 months	12	58 ± 14.9	22.5 ± 14.4	27.5 ± 12.1	32 ± 9.4	31.7 ± 10.2	38.3 ± 9.2	11 (91%)	2 (16%)
6–12 months	37	50 ± 10.1	20.5 ± 9.8	23.2 ± 9.2	24.8 ± 10.5	30.5 ± 9.9	33.8 ± 9.6	27 (73%)	5 (13%)
> 12 months	35	58.9 ± 11.9	26 ± 11.9	29.7 ± 10.9	31.5 ± 9.8	30.2 ± 10.2	33.7 ± 9.6	18 (50%)	4 (11%)

**Table 3** Head to head comparisons of the  $\Delta$ Cobb in the different groups

Group	Means	MD	95% CI	P
0–6 vs > 12	15.8, 7.8	– 8	– 14.61 to – 1.39	0.01
0–6 vs 6–12	15.8, 13.4	– 2.4	– 8.97 to 4.17	0.8
0–6 vs No breakage	15.8, 4.8	– 11	– 17.19 to – 4.81	0.00005
> 12 vs 6–12	7.8, 13.4	5.6	0.85 to 10.35	0.01
> 12 vs No breakage	7.8, 4.8	– 3	– 7.21 to 1.21	0.3
6–12 vs No breakage	13.4, 4.8	– 8.6	– 12.74 to – 4.46	<0.0001

them had unsatisfactory results at index surgery and the loss of correction after the breakage, albeit only of a few degrees, lead to an increase of the curves to  $> 40^\circ$ . Thus, only two patients with successful index surgery required revision after a late breakage and consequent loss of correction.

It may be argued that the follow-up is too short to highlight possible detrimental effects of breakages occurring after 12 months from VBT. Surely a longer follow-up will be required to better assess the effects of late breakages on curve correction. However, observing the evolution of the Cobb angles in the different groups, the loss of correction always seems to rapidly follow the breakage and the available follow-up should thus be sufficient to observe any change. Furthermore, the evolution of the Cobb angle and  $\Delta$ Cobb in patients who showed a breakage after 12 months resembles the ones of the patients without breakage. For these reasons, we do not expect a loss of correction in patients who showed signs of breakage over 12 months from VBT.

This study does not come without limitations. Tether breakage is a complex topic, and specific timing analysis divided by curve type and by level of skeletal maturity will be required for a deeper understanding of the effect of rupture timing in different patient populations. In particular, regarding skeletal maturity, the average Risser grade of the patients requiring revision in the 0–6 and > 12 months groups was the same of those who did not require revision, while in the 6–12 months group patients requiring revision were more skeletally immature than those who did not (data not shown). However, the number of involved subjects is too

small to reach any conclusion on the effects of skeletal maturity on curve progression after tether breakage. A longer follow-up will be required to confirm whether patients with a late breakage will maintain stable results, and to investigate the effects of an early breakage on the long term.

## Conclusion

In conclusion, tether breakage is a common complication after VBT. According to the results of our study, early breakages occurring within 12 months from surgery will have a more impactful effect on curve correction. On the other hand, patients with a late breakage occurring after 12 months from VBT showed similar results to those of the patients who did not experience a tether breakage.

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**Data availability** Data can be made available in anonymized form and upon reasonable request.

## Declarations

**Conflict of interest** PDT: Globus Medical (personal fees), Zimmer Biomet (personal fees). AB, FM, JE, FH: none.

**Ethical approval** RWTH Aachen, Faculty of Medicine, approval EK 130/19.

**Consent to participate and publication** Due to the retrospective nature of the study, consent to participate or for publication was not required.

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