Analysis of the risk factors for early tether breakage following vertebral body tethering in adolescent idiopathic scoliosis

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Abstract
Introduction  Tether breakage is a common mechanical complication after VBT. When this occurs shortly after surgery, patients may be at higher risk for loss of correction. Aim of this study was to analyze demographic and radiographic parameters that may potentially be risk factors for early tether breakage, as no data are yet available on this topic.

Materials and methods  All skeletally immature patients who underwent VBT and for whom a 1-year follow-up was available were included in the study. Demographic, intraoperative and coronal and sagittal parameters from the preoperative and 1st standing X-rays were collected. Patients were divided in two groups according to the presence or absence of a breakage and the outcomes of interest were compared.

Results  Data from 105 patients were available (age 14.2 ± 1.5, 153 curves). Lumbar curves showed a higher risk of breakage than thoracic ones (71% vs. 29%, P < 0.0001). Overall, preoperative risk factors were a high curve magnitude (MD, mean difference −4.1°, P = 0.03) and a limited flexibility (MD 8.9%, P = 0.006); postoperative risk factors were a large residual curve (MD −6.4°, P = 0.0005) and a limited correction (MD 8.4%, P = 0.0005). The same risk factors were identified in thoracic curves, while in lumbar instrumentation only a higher preoperative Cobb angle represented a risk factor for breakage. Age and skeletal maturity did not represent risk factors.

Conclusion  The main preoperative risk factors for early tether breakage after VBT are a high curve magnitude and a limited flexibility. A limited curve correction also represents a risk factor for this complication.

Keywords  Scoliosis · Adolescent idiopathic scoliosis · Vertebral body tethering · Fusionless anterior scoliosis correction · Risk factor · Tether breakage · Tether rupture

Introduction
Vertebral body tethering (VBT) is gaining popularity as a fusion-less surgical therapy for selected patients with adolescent idiopathic scoliosis. One of the most common mechanical complications of VBT is represented by tether breakage [1–3]. While breakages are asymptomatic most of the times and often do not lead to a worsening of the curve, thus not requiring any further management [2], it is important for the surgical planning and for the informed consent to identify what patient characteristics represent a risk factor for tether breakage. In particular, breakages occurring within a year from surgery may have a higher clinical relevance. In case of an early breakage, musculofascial and bony structures may have not been subjected long enough to the forces applied by the Hueter-Volkmann principle or by Wolff’s law to maintain the correction despite a breakage [4]. Thus, patients presenting an early tether breakage may be at higher risk for experiencing an increase of the treated curve over time.

The present study investigated the risk factors for early tether breakage after VBT. In particular, we analyzed the influence of patient demographic, pre- and postoperative radiographic parameters and intraoperative correction technique on the risk of early tether breakage in patients who underwent VBT.
Materials and methods

Patients’ recruitment

This study was conducted according to the STROBE statement [5]. All consecutive, skeletally immature patients (Risser ≤ 4, Sanders ≤ 7) who underwent VBT at our institution between June 2017 and October 2020 and for whom a one-year follow-up was available, were included in the study. All surgeries were performed by one author (PT) as previously described [6].

Data extraction

Demographic data and information regarding the use of intraoperative correction techniques (use of a double tether, use of lateral disk releases) were obtained. Radiographic data from the preoperative and first-standing X-rays (coronal and sagittal parameters) were collected. Coronal balance (CB) was defined as the linear distance between the C7 plumb line and the central sacral vertical line. Curve flexibility was measured as 100 – (curve magnitude in bending × 100/curve magnitude in standing) (e.g. curve magnitude standing = 60°, curve magnitude bending = 20°, flexibility = 67%). The percentage of curve correction and the difference between the coronal balance before and after surgery (ΔCB) was also measured. Risser and Sanders score were treated as continuous parameters to allow statistical analysis.

Outcomes of interest

Early tether breakage was defined as a breakage occurring within one year from surgery. A breakage was suspected when the angulation between two adjacent screws changed by > 5° among two successive X-rays [7].

Patients were divided into two groups according to whether or not a tether breakage had been observed (Breakage vs. No-Breakage). The outcomes of interest were analyzed first for the entire cohort, and then separately for thoracic and lumbar curves.

Statistical analysis

The statistical analyses were performed using the software IBM SPSS 25. Data were analyzed per instrumented curve, the curves without suspect tether breakage were compared with those with a suspect breakage. For continuous data, mean difference (MD) effect measure was evaluated with t-test to assess statistical significance. For binary data, odds ratio (OR) effect measure was performed with the \( \chi^2 \) test to assess statistical significance. The confidence interval (CI) was set at 95% in all comparisons. Values of \( P < 0.05 \) were considered statistically significant.

Results

Patient recruitment

In the observation period, 125 consecutive patients who met the inclusion criteria underwent VBT at our institution. For 20 of them, the 12-months follow-up was not available or was not of sufficient quality. One of these 20 patients underwent revision-VBT in her home country. Thus, data from 105 patients and 153 curves were available (84 thoracic and 69 lumbar curves).

Demographic data

The mean age of the patients was 14.2 ± 1.5 years, 14 were male (13%) and 91 female (87%). Twenty-seven patients were Risser 0 (26%), 11 were Risser 1 (11%), 8 were Risser 2 (8%), 18 were Risser 3 (17%) and 41 Risser 4 (40%). A Sanders score was available for 82 patients: 2 were Sanders 2 (2%), 18 were Sanders 3 (22%), 6 were Sanders 4 (7%), 12 were Sanders 5 (14%), 5 were Sanders 6 (7%) and 39 were Sanders 7 (48%).

According to a previously published classification [6], 13 patients were type 1 (lumbar curve), 60 were type 2 (double curve), 11 were type 3 (long thoracic curve), 18 were type 4 (short thoracic curve) and 3 were type 5 (rigid high thoracic curve).

Radiographic data

The mean thoracic Cobb angle was 57.5 ± 17° prior to surgery, 28.5 ± 12.2° at the 1st standing X-ray and 31.6 ± 13.6° at the 1-year follow-up. The mean lumbar Cobb angle was 49.2 ± 13.9° before VBT, 18.6 ± 11.7° at the 1st standing X-ray and 24.8 ± 11.5° at the 1-year follow-up. Details of the radiographic parameters at different follow-ups are shown in Table 1.

At the last, 12-months follow-up, a tether breakage was observed in 41 of 69 lumbar curves (59%) and 17 of 84 thoracic curves (20%). Eight of the 105 included patients required revision surgery, six of them for loss of correction due to tether breakage and two due to add-on scoliosis. Clinical examples of two patients who presented a tether breakage are shown in Figs. 1 and 2.
Outcomes of interest

The outcomes of interest observed for the entire cohort are reported in Table 2. Lumbar curves presented a higher risk of tether breakage than thoracic ones (71% vs. 29%). Observing preoperative data, larger curves showed a higher risk of breakage. Also, a limited flexibility (and thus higher values of Cobb magnitude in bending X-rays) was also associated with a higher risk of tether breakage. All other preoperative comparisons did not yield significant results. Considering the 1st standing X-rays, patients with a bigger residual curve and with a smaller amount follow-up, a tether breakage was observed between T9 and T10, as the angle between these screws increased from 6° to 13°. Despite the rupture, at the 1-year follow-up the thoracic curve measured 29° and the lumbar curve 8°.
of correction were at higher risk for presenting a tether breakage within one year from VBT.

Observing the cohort of thoracic instrumentations only, higher Cobb values in the anteroposterior and bending films again represented a risk factor for tether breakage. Also in this case, patients with a larger residual curve were at higher risk for tether breakage. For lumbar curves, only a higher preoperative curve magnitude represented a risk factor for tether breakage. Separate data for the groups of thoracic and lumbar curves are presented in Table 3.

Discussion

The main finding of this analysis is that, overall, large, rigid curves present a higher risk of an early tether rupture. Also, lumbar instrumentations present a higher risk of breakage than thoracic ones: out of 58 curves with a breakage, 17 were thoracic (29%) and 41 were lumbar (71%). Similarly, out of 95 curves without breakage, 67 were thoracic (71%) and 28 were lumbar (30%). Age and skeletal maturity, on the other hand, did not represent a risk factor for this mechanical complication.

It may be intuitive that larger and less flexible curves place the tether under a higher mechanical load, which in turn leads to material wearing and breakage. Similarly, a bigger residual curve would cause a higher lateral momentum and thus a higher rate of material wearing. This finding, however, contrasts with the observation that lumbar curves, which in our cohort showed a higher flexibility, also showed a higher rupture rate. Possible explanations may be found in the different orientation and tropism of the thoracic and lumbar facet joints, which may cause a different load sharing in different segments of the spine [8–10]. Another possible hypothesis is represented by the higher range of motion of the lumbar spine in respect to the thoracic spine [11], which may lead to a quicker wearing of the material. However, targeted biomechanical studies will be required to test these hypothesis.

It is of interest that age or skeletal maturity did not represent a risk factor for tether breakage. Thus, performing surgery in patients approaching skeletal maturity does not put these subjects at a higher risk for early tether breakage. This statement is also supported by the fact that no strong correlations exist between age and curve magnitude or flexibility [12].
It is surprising that techniques such as the use of a double tether, which are employed to reduce or delay the rate of tether breakage [2], did not show a protective effect in the patients of this cohort. However, the use of a double tether was introduced at our institution in January 2019. As many patients of the presented cohort underwent VBT prior to this date, data regarding the effect of the use of a double tether on the breakage rate may be understated and a new analysis on a bigger cohort will be required to clarify this point.

Similarly, we only rarely perform lateral disk releases in the lumbar spine and, if so, only at T12/L1 or L1/L2 level. Furthermore, we usually perform thoracic lateral disk releases only in curves of large magnitude, which may represent a confounding factor in the evaluation on the effects of this technique on the risk of tether breakage. Thus, data are not yet sufficient to reliably evaluate the effects of these techniques and further studies will be required.

We work under the hypothesis that, next to the Hueter-Volkmann principle, tissue remodelling mediated by Wolff’s law also takes place. Thus, the longer a tether would hold, the higher the chance that bony and soft tissues would have already adapted to the new shape of the spine and, eventually, the tether would have little mechanical relevance. Following this hypothesis, an early rupture would be of greater clinical importance, as the remodelling process would still be progressing. Conversely, a later rupture would be less relevant, as the remodelling process would for the most part have already taken place. This theory may explain why most curves showing signs of breakage do not require surgical revision [2]. Further studies will be required to investigate this hypothesis.

The main limitation of the present study, beside its retrospective nature, is represented by the lack of a subanalysis for the different curve types (lumbar, bilateral, long and short thoracic and rigid high thoracic curves). This could not be performed due to the limited number of included subjects. As almost all patients were female, an analysis of the possible effect of gender on tether breakage could not be performed.

**Conclusion**

The main preoperative risk factors for tether breakage are represented by large curve magnitude and limited flexibility. Lumbar curves present a higher risk of breakage than

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**Table 2** Main results of the comparisons

| Endpoint                        | Breakage | No-breakage | MD/OR  | 95% CI       | P    |
|---------------------------------|----------|-------------|--------|--------------|------|
| **Preoperative data**           |          |             |        |              |      |
| Age (years)                     | 14.2 ± 1.4 | 14.1 ± 1.4 | 0.1    | −0.49 to 0.29| 0.6  |
| Risser                          | 2.4 ± 1.7 | 2.3 ± 1.7   | 0.1    | −0.57 to 0.37| 0.7  |
| Sanders                         | 5.5 ± 1.7 | 5.5 ± 1.7   | −0.0   | −0.47 to 0.47| 1.0  |
| Thoracic curve (n)              | 29% (17/58) | 71% (67/95) | 5.77   | 2.81 to 11.82| <0.0001 |
| Lumbar curve (n)                | 71% (41/58) | 30% (28/95) | 0.17   | 0.08 to 0.35  | <0.0001 |
| Cobb angle (°)                  | 60.6 ± 14.2 | 56.6 ± 11.2 | −4.1   | −7.56 to −0.43| 0.03 |
| Bending (°)                     | 38.0 ± 18.9 | 29.3 ± 15.1 | −8.7   | −13.47 to −3.92| 0.0004 |
| Curve flexibility (%)           | 40.0 ± 22.1 | 48.9 ± 23.0 | 8.9    | 2.60 to 15.19 | 0.006 |
| Thoracic kyphosis (°)           | 33.9 ± 14.8 | 33.2 ± 12.9 | −0.8   | −4.57 to 3.17  | 0.7  |
| Lumbar lordosis (°)             | 54.0 ± 11.1 | 53.2 ± 12.0 | −0.8   | −4.02 to 2.42  | 0.6  |
| Pelvic incidence (°)            | 48.1 ± 11.3 | 50.5 ± 13.3 | 2.4    | −1.04 to 5.84  | 0.2  |
| Pelvic tilt (°)                 | 7.3 ± 6.4   | 9.3 ± 8.0   | −2.0   | −0.02 to 4.02  | 0.06 |
| Sagittal vertical axis (mm)     | 2.8 ± 32.1  | 4.1 ± 29.0  | 1.3    | −7.23 to 9.83  | 0.8  |
| Coronal balance (mm)            | 9.4 ± 18.2  | 12.0 ± 19.4 | 2.6    | −2.64 to 7.84  | 0.3  |
| **Intraoperative data**         |          |             |        |              |      |
| Double tether (n)               | 29% (17/58) | 18% (17/95) | 0.53   | 0.24 to 1.13   | 0.1  |
| Lateral disk release (n)        | 38% (22/58) | 52% (49/95) | 1.74   | 0.89 to 3.39   | 0.1  |
| **First standing X-ray**        |          |             |        |              |      |
| Cobb (°)                        | 27.2 ± 14.5 | 20.8 ± 11.0 | −6.4   | −9.98 to −2.81 | 0.0005 |
| Curve correction (%)            | 56.9 ± 17.9 | 65.3 ± 15.3 | 8.4    | 3.75 to 13.04  | 0.0005 |
| Thoracic kyphosis (°)           | 35.0 ± 12.4 | 34.9 ± 12.2 | −0.1   | 3.756 to 13.04 | 0.9  |
| Lumbar lordosis (°)             | 47.0 ± 9.8  | 44.7 ± 10.8 | −2.3   | −5.17 to 0.57  | 0.1  |
| Sagittal vertical axis (mm)     | 29.0 ± 25.6 | 31.8 ± 24.1 | 2.8    | −4.13 to 9.73  | 0.4  |
| Coronal balance (mm)            | 19.1 ± 21.2 | 21.3 ± 21.1 | 2.2    | −3.69 to 8.09  | 0.5  |
| Δ Coronal balance (mm)          | 8.8 ± 17.1  | 8.3 ± 21.1  | −0.5   | −4.85 to 5.85  | 0.9  |

**OR** odd ratio; **MD** mean difference; **CI** confidence interval
thoracic ones. Patients with a large residual curve are also more prone to develop a tether breakage. These findings are relevant for the planning of VBT and for the informed consent of the patients.

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

**Declarations**

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

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

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

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