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Basic Science

The Development of a Representative Porcine Early-Onset Scoliosis Model With a Standalone Posterior Spinal Tether

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Abstract

Study Design: In vivo analysis in a porcine model.

Objectives: To develop a porcine experimental scoliosis model representative of early-onset scoliosis (EOS) with the use of a radiopaque ultra-high molecular weight polyethylene (UHMWPE) posterior spinal tether.

Summary of Background Data: Large animal experimental scoliosis models with substantial growth potential are needed to test new fusionless scoliosis correction techniques. Previously described scoliosis models involve rib procedures, which violate the thoracic cage and affect subsequent corrective procedures. Models omitting these rib procedures have experienced difficulties in producing persistent three-dimensional structural deformities representative of EOS.

Methods: Scoliosis was induced in 14 immature pigs using an asymmetric posterior radiopaque UHMWPE spinal tether fixated to an offset device at lumbar and thoracic levels. Radiographs were taken at 2-week intervals, and frontal and sagittal Cobb angles were measured. A tether release was performed at the 10-week follow-up, and the animals were observed for another 10 weeks.

Results: Four animals had complications (infections and/or screw breakout) and were excluded from the study. Eight animals developed progressive curves with a mean frontal Cobb angle of 62°. A thoracic lordosis (34°) and a thoracolumbar kyphosis (22°) formed. CT analysis, acquired prior to tether release, showed a mean vertebral rotation of 37° at the apex with a mean vertebral wedge angle of 10°. After tether release, the frontal Cobb angles decreased to 46° at the 20-week follow-up. Sagittal curvature was not substantially affected after tether release.

Conclusions: We describe a large animal scoliosis model, which exhibits a substantial deformity in three planes without the use of rib procedures additional to a posterior spinal tether. The created deformities showed persistence after tether release. With the management of infection and enhancement of instrumentation stability, the creation of a valid model for testing new devices in fusionless scoliosis surgery seems feasible.

Level of Evidence: Level V.

Keywords: Early-onset scoliosis; Radiopaque UHMWPE tether; Scoliosis model; Wedging; Rotation

Introduction

Within the last decades, it has become clear that fusionless surgical scoliosis correction techniques are essential for the treatment of early-onset scoliosis (EOS), but their merits and potential are also increasingly explored for the treatment of adolescent idiopathic scoliosis (AIS). For EOS patients, it is imperative to retain longitudinal spine growth, thereby maintaining volumetric thoracic cage growth and lung development [1]. Fusionless scoliosis correction devices for EOS patients may be classified into growth-guidance (Shilla and Luque trolley) or

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distraction-based techniques (growing rods, vertical expandable prosthetic titanium rib) [2]. For AIS patients, compression-based anterior devices are used to modulate vertebral growth by utilizing the Hueter-Volkmann principle [3] to slow or halt growth on the convex side of the deformity, thereby attaining gradual curve correction. Examples of such compression-based modulation are the use of vertebral body staples and an anterior spinal tether [2].

The most generic method for the preclinical evaluation of fusionless scoliosis correction devices is using a two-step approach: A structural, idiopathic-like scoliosis is created in a first procedure and later corrected using the proposed scoliosis correction device in a second procedure. Posterior spinal tethering is the preferred index procedure [4], as it produces significant, progressing deformities that most closely approximate the three-dimensional (3D) nature of the deformity as seen in idiopathic scoliosis (progressive coronal curvature, loss of thoracic kyphosis, and axial vertebral rotation) [5-7].

We have previously reviewed large animal models in fusionless scoliosis correction research [8]. The similarity between human and porcine spinal anatomy in addition to the fast, large growth rate makes pigs commonly used animals for experimental scoliosis models. The main differences between models described by different authors are age at index procedure, length of follow-up period, pretensioning of the tether, and whether rib procedures (rib tethering with or without rib resection) additional to the spinal tether were performed. Rib procedures may lead to high postoperative morbidity and may cause spontaneous rib fusion with a very stiff curve as a result [9]. These irreversible thoracic changes will affect subsequent testing procedures. Odent et al. [10, 11] have demonstrated that rib tethering may be omitted when sufficient spinal tether offset is used. However, their described model exhibited substantial loss of deformity, loss of approximately 45% of the curve magnitude in the frontal plane, after tether release.

The purpose of this study was to create an early-onset scoliosis model, without additional rib procedures, in which all 3D scoliosis-like structural changes occur and persist after tether release. A posterior technique with a radiopaque flexible ultra-high molecular weight polyethylene (UHMWPE) spinal tether with an offset device was used to create a progressive lordoscoliotic curve. This model should ultimately allow for preclinical testing of fusionless scoliosis correction techniques in a growing animal.

Material and Methods

Surgical procedure

All animal procedures were approved by the Animal Ethical Committee of the Maastricht University Medical Center (approval no.: DEC 2011-005). A total of 16 immature landrace pigs (female, 8 weeks old, weight range 10−13 kg) were included in this study. Each operation was performed under strict, sterile conditions. Antibiotics (amoxicillin/clavulanic acid 1.2 g) were administered intravenously 1 hour before incision and 6 hours postoperatively. After 7 days of acclimatization at the institutional animal facility, the animals were sedated by intravenous administration of thiopental (10−15 mg/kg), followed by endotracheal intubation and general anesthesia using 1% to 2% isoflurane. Pain medication was administered and adjusted if needed during surgery (sufentanil 10−30 μg/kg per hour intravenously). Electrocardiogram registration, ventilation curves, temperature, oxygen saturation level, and heart rate were continuously monitored. With the animal in prone position, two small midline incisions were made at thoracic and lumbar levels under fluoroscopic control. The transverse processes and the facet joints were minimally exposed unilaterally on the left side by partially detaching the erector spinae using electrocautery.

Instrumentation technique and material specification

In a pilot study involving two animals, polyaxial pedicle screws (4.5 mm diameter, 22−26 mm length; Vertex, Medtronic) were placed unilaterally at T6−T7 and L1−L2 under fluoroscopic guidance. Two custom-made offset devices (28 mm offset from pedicle screws) were fixed using a 3.2-mm titanium rod in between each set of adjacent pedicle screws (Fig. 1). A 4-mm-wide flat wire woven from ultra-high molecular weight polyethylene (UHMWPE) Dyneema Purity® Radiopaque fibers (DSM

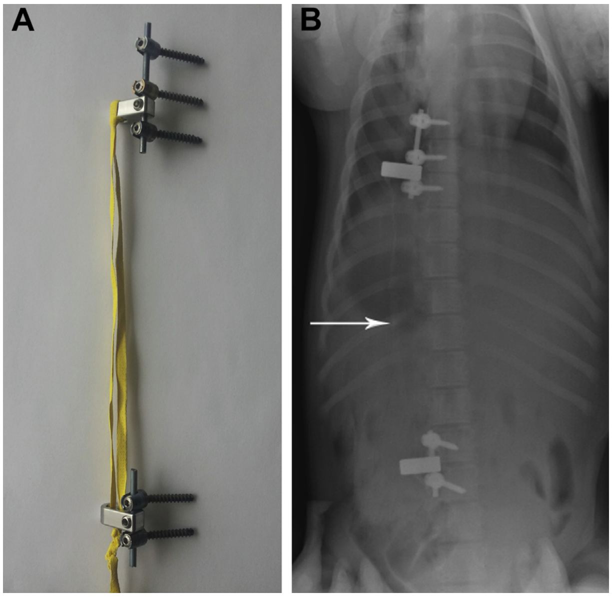

Fig. 1. (A) Offset devices with rods, pedicle screws and the radiopaque ultra-high molecular weight polyethylene (UHMWPE) double loop tether. (B) Offset device implanted in the porcine spine. The radiopaque tether (arrow) is attached to the offset devices without any tension.

Biomedical B.V., Geleen, the Netherlands) was used as a posterior tether. Bismuth oxide (Bi_2O_3) particles are blended into each individual fiber for radiopacity [12]. The wire was folded in half and the two ends were passed through the cranial offset device and through the loop created in the wire, thereby securing the cranial end of the tether. The caudal end was secured using multiple square knots. In these initial two animals, the UHMWPE tether was placed under tension before fixation. This created a Cobb angle of approximately 20°. After 4 weeks, screw breakout was observed at both caudal and cranial levels with loss of deformity. The large offset in combination with pretensioning of the tether was assumed to be the reason for this early failure. For this reason, in the definitive series of animals (n = 14) the construct was altered slightly. First the thoracic offset device was secured using three instead of two thoracic pedicle screws (T5–T7), and the lumbar instrumentation was reinforced with a UHMWPE sublaminar wire [13]. Furthermore, no pretension was applied to the tether and the offset was reduced to 20 mm. In the first four animals, proximal fixation was located at levels T5–T7 with caudal fixation on L1–L2. After experiencing problems reaching the deep cranial thoracic vertebra because of thick musculature in these first four procedures, the proximal fixation site was moved to levels T7–T9 and distal fixation site to L2–L3.

Observation, radiology, and tether release

The wound was ultimately closed in layers. Postoperative pain management (buprenorphine 0.05 mg/kg, carprofen 2–4 mg/kg intramuscularly) was provided until the animals had returned to activities ad libitum. Antibiotic treatment was administered intramuscularly 6 hours after surgery. Initially, no postoperative wound dressing was applied. However, as three of the first four animals developed postoperative wound infections, the wound was dressed using an iodide film, which was kept in place for 3 days postoperatively. No more wound infections occurred in the subsequent animals.

One animal with a profound infection was euthanized because of instrumentation failure and observed animal discomfort. In the other animals with wound infections, the infection was controlled with the administration of antibiotics (amoxicillin/clavulanic acid 1.2 g) for several days and wound lavage without loss of the curvature.

Plain full spine radiographs were taken directly postoperatively and subsequently at 2-week intervals under light tiletamine-zolazepam (8 mg/kg) sedation. Routine supine dorsoventral and lateral radiographs were acquired to assess curve progression. Frontal and sagittal Cobb angles were measured at each radiologic assessment. Radiographs were also analyzed for positioning and possible pullout or breakage of the instrumentation.

Tether release and computed tomographic analysis

At 10-week follow-up and upon reaching a frontal Cobb angle of minimally 40°, a tether release was performed in eight animals. The radiopaque tether was localized under fluoroscopy and cut through a minimal stab incision at the caudal end. Animals were followed for another 10 weeks with radiographs every 2 weeks, and euthanization was performed using pentobarbital overdose (200 mg/kg). After sacrifice, the spines were harvested.

Computed tomographic (CT) scans were acquired before tether release at the 10-week follow-up under general anesthesia (Somatom Definition Flash; Siemens, Erlangen, Germany). Three-dimensional reconstructions of each spine were obtained to assess vertebral rotation, rib hump, and apical vertebra wedging. Rib hump elevation located at the convex side was considered a positive result for the model. Vertebral rotation was measured relative to the anterior midline of the body [14,15]. Rotation and rib hump were assessed by analyzing a transversal CT slice at the level of the apex vertebra using the Synedra View program (Synedra, Innsbruck, Austria). The position of the apical vertebra was determined in three planes. Apical vertebral wedging was measured from the reconstructed coronal CT images. Convex and concave heights for each apical vertebra were also determined.

Results

Of the 14 animals included within the definitive surgical protocol, one animal died as a result of respiratory distress after extubation. Autopsy did not reveal any other cause of death. No neurologic complications occurred during any of the surgeries. Mean weight gain was approximately 5 kg/week. Eight animals developed a structural complex 3D scoliotic curvature with a chest wall deformity and a positive rib hump elevation. In this group, the mean Cobb angle at the 10-week follow-up was 62° (range 43°–72°) in the frontal plane (Fig. 2). In the sagittal plane, a thoracolumbar kyphosis developed between the anchor sites (22°, range 7°–44°), and a thoracic lordosis formed at the anchor levels (35°, range 21°–53°), presumably as a result of continued anterior growth (crankshafting) (Fig. 3). In five animals, a long-segment curvature (11–12 vertebrae in the curvature) with large Cobb angles (mean 68.3°) developed. In three animals, a shorter (5–6 vertebrae in the curvature) thoracic curve (mean 51.9°) developed probably because of an epiphysiolysis or fracture of one vertebra, which was observed in both anchor location groups (T5–T4–T3/L1–L2 and T7–T6–T5/L2–L3). In three animals, screw breakout or slippage of the knot securing the tether was observed, resulting in loss of the curvature, and therefore these animals were sacrificed. In two animals, the cause of this failure was not determined. The other case had developed a postoperative infection

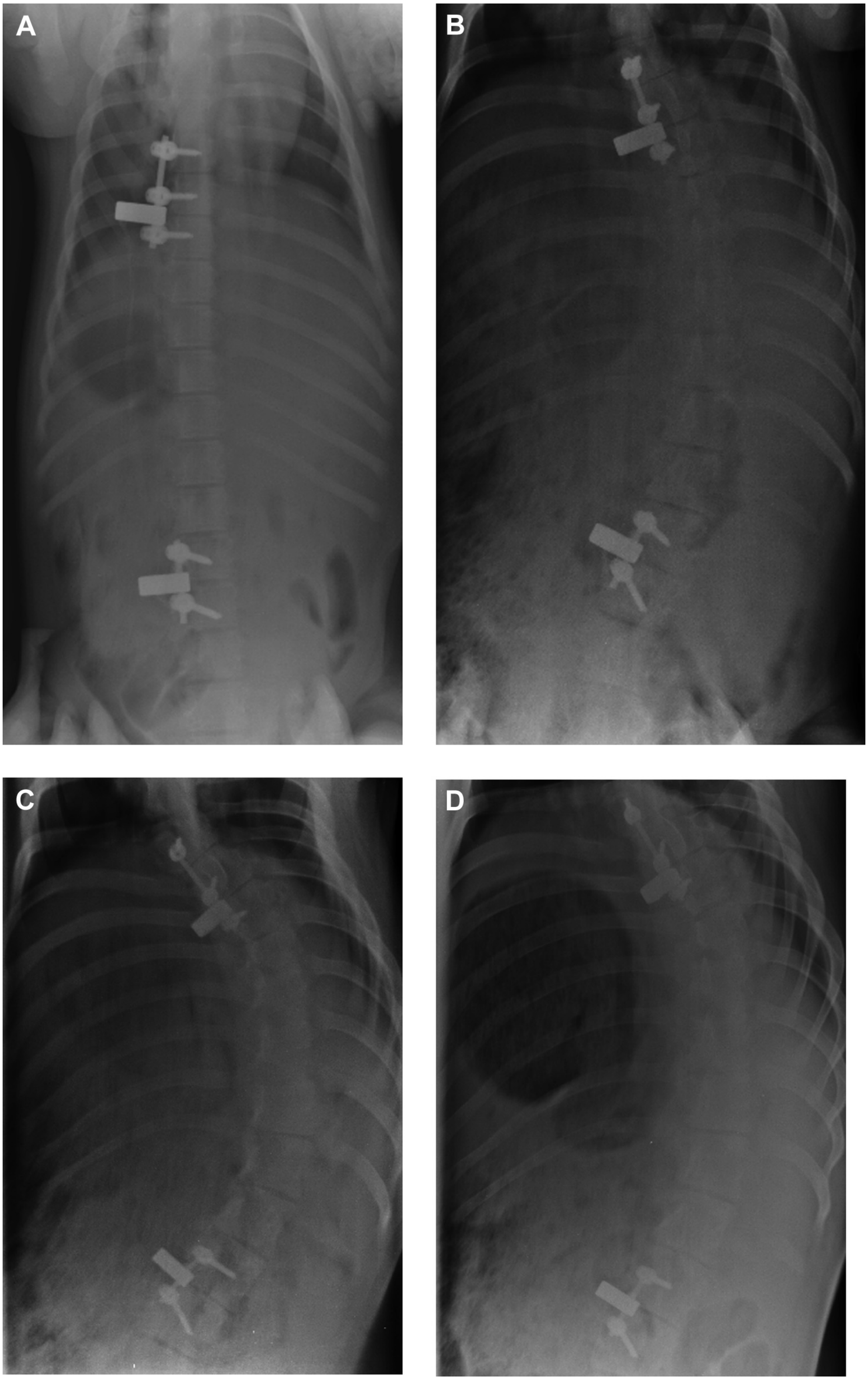

Fig. 2. (A) Instrumentation with straight spine direct postoperatively. (B) Four-week follow-up with the development of a C-type curvature with thoracic asymmetry. (C) Ten-week follow-up before tether release. (D) Twenty-week follow-up with slight loss of curvature 10 weeks after tether release.

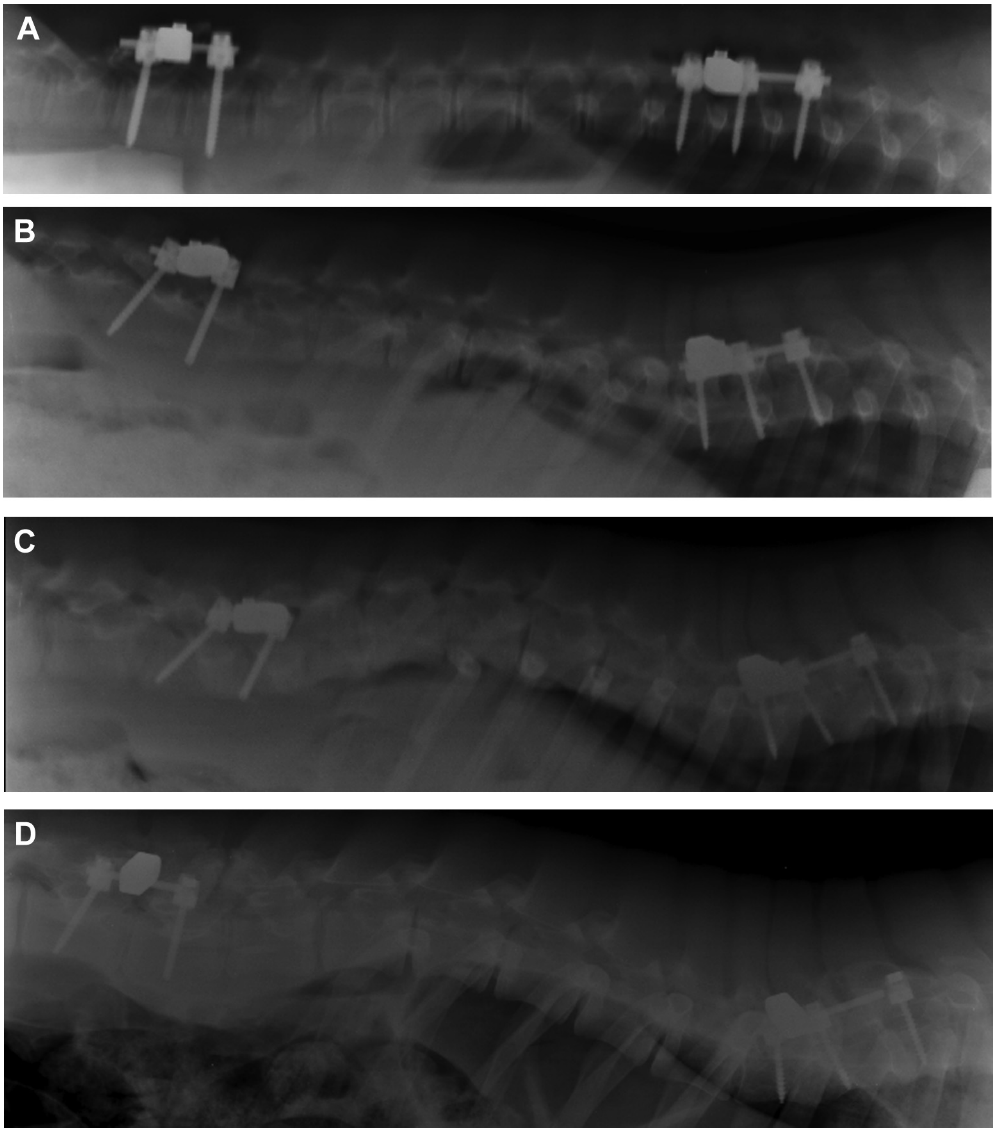

Fig. 3. Lateral radiographs. (A) Instrumentation with nearly straight spine postoperatively. (B) Four-week follow-up with the development of a small thoracic lordosis. (C) Ten-week follow-up before tether release with presence of a thoracolumbar kyphosis and thoracic lordosis. (D) Twenty-week follow-up with unchanged curvature 10 weeks after tether release.

with the observation of radiolucency around the screws. Loosening of the screws eventually resulted in failure of instrumentation. The final two animals developed curves with Cobb angles of 31° and 34°, which did not progress any further because of unknown reasons. These animals were also subsequently sacrificed. CT scanning and subsequent tether release was performed in the eight animals that developed progressive structural scoliosis. These animals were followed for an additional 10-week time period after tether release (Fig. 4). CT imaging revealed structural characteristics of the deformity, with most wedging and axial rotation occurring at the apex of the curvature (Fig. 5). The mean apical vertebral rotation was 37.3° (range 25°–54°), while substantial apical wedging also occurred: convex height minus concave height measured a mean of 4.2 mm, which resulted in a mean vertebral wedge angle of 10.4° (range 5.7°–17.2°) (Fig. 6).

After tether release, the frontal Cobb angles immediately decreased from 62° to 56° and showed a further decrease at 10 weeks' additional follow-up to 46.7° (Fig. 7, Table 1). In two animals, there was loss of curvature within the midsegments at 20 weeks' follow-up. Lateral tilting of the cranial and caudal segments, however, still resulted in a curvature with persistent thoracic asymmetry. Sagittal profiles did not show substantial changes after tether release (Table 2).

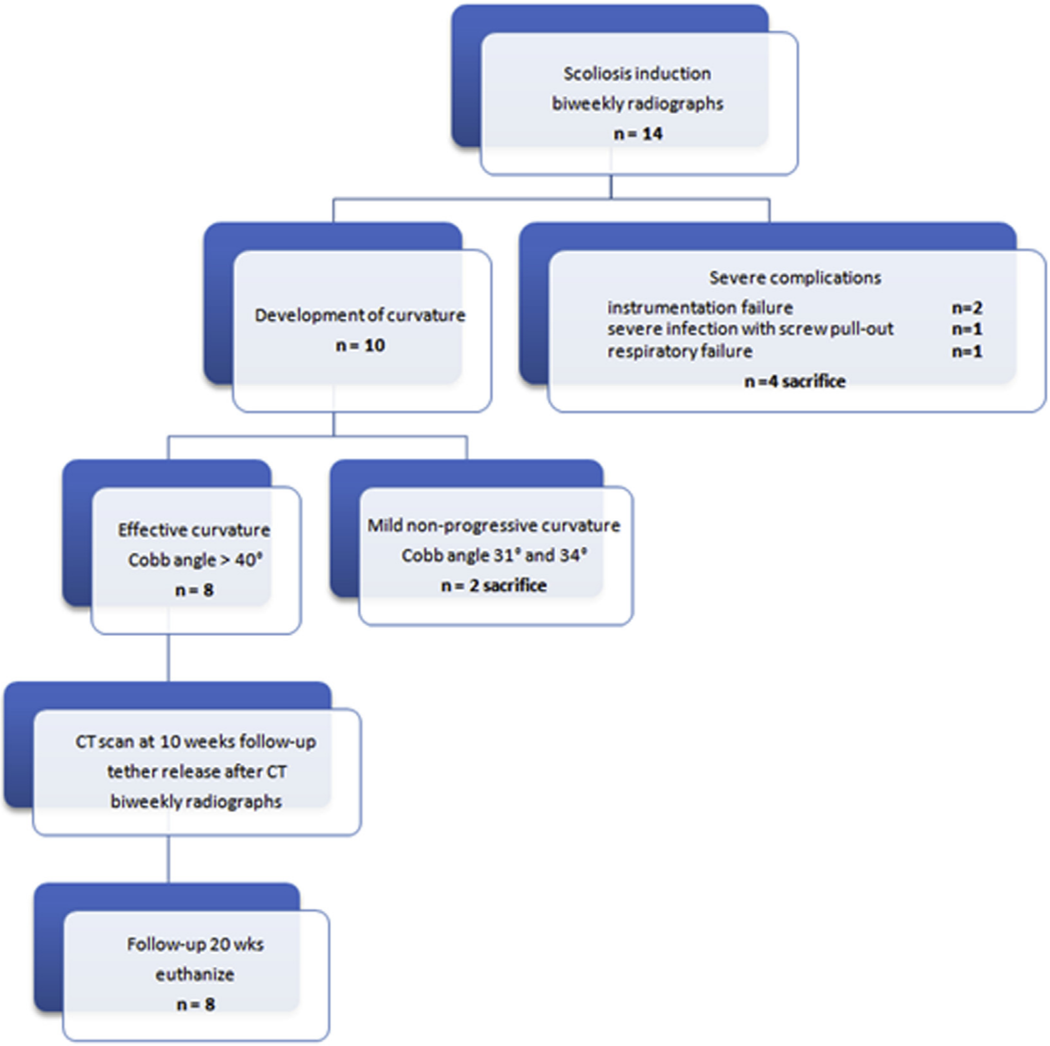

Fig. 4. Flowchart of experimental group.

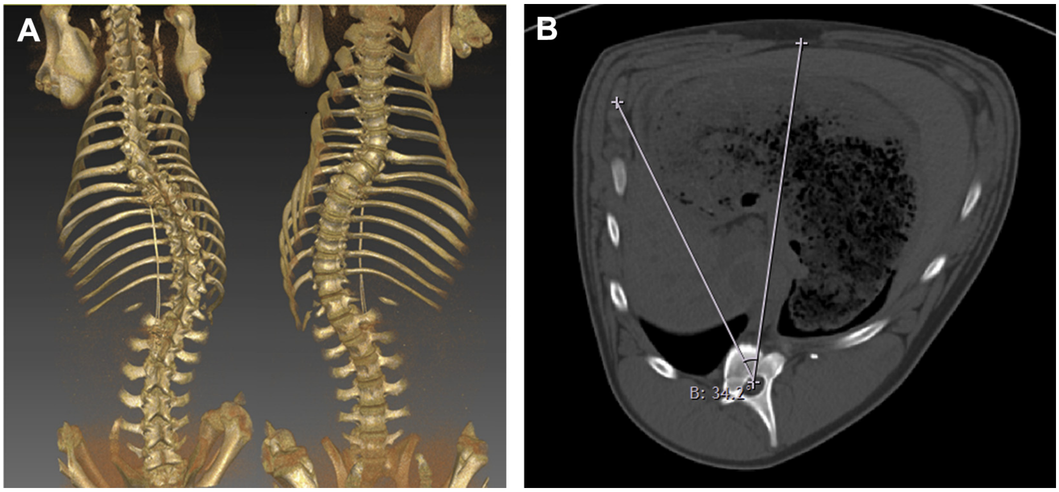

Fig. 5. (A) Frontal (right) and posterior (left) view of a three-dimensional computed tomographic (CT) reconstruction of the lordoscoliotic deformity at the 10-week follow-up before release of the tether. Sagittal reconstruction clearly showing the thoracic asymmetry. (B) Axial CT slice showing how rotation was measured at the level of the apical vertebra by measuring the angle between the anterior midline and the line perpendicular to the transverse processes.

Fig. 6. Coronal reconstructed image showing the wedging of the apical vertebrae.

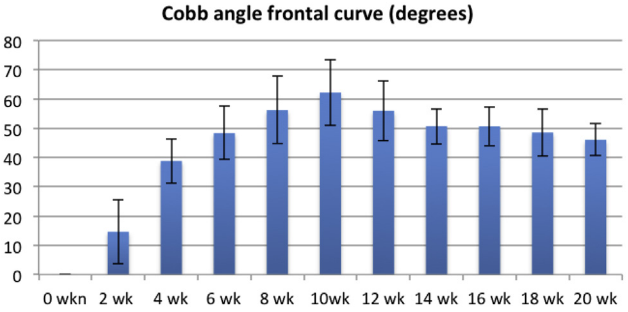

Fig. 7. Evolution of scoliosis after placement of the tether. At 10-week follow-up, the tether release is performed.

Table 1
Evolution of the Cobb angles before and after tether release and at 10 weeks post tether release.

Animal	Instrumentation level	Cobb angle								
		Precut tether 10 wks			Post tether release			End follow-up 20 wks		
		Frontal	Sagittal		Frontal	Sagittal		Frontal	Sagittal	
			Lordosis	Kyphosis		Lordosis	Kyphosis		Lordosis	Kyphosis
1	Ll–L2/T5–T4–T3	72.4	44.1	19.8	58.2	39.1	16.6	44.5	32	12
2	Ll–L2/T5–T4–T3	61.7	44	20	51	38.6	19.6	39,4	32.7	13.6
3	Ll–L2/T5–T4–T3	43.3	21.4	6.8	38.6	28.5	6.8	40.7	30	4.4
4	Ll–L2/T5–T4–T3	62.8	32	21	62	—[b]	20.3	50.3	—[b]	20
5	L2–L3/T6–T5–T4–T3[a]	75.6	29.1	15.4	65.6	51.1	15	50.7	49.4	12
6	L2–L3/T7–T6–T5	70.7	30.2	17	65.2	28.1	14.6	52.6	40.7	4.5
7	L2–L3/T7–T6–T5	60.9	20.1	30	58.8	20.4	23.2	43.2	29.8	20
8	L2–L3/T7–T6–T5	49.7	53.3	44	48.2	35.8	31.2	51.8	36.6	33.5
Mean		62.1	34.3	21.8	56.0	34.5	18.4	46.7	35.9	15

[a] Extra pedicle screw insertion because of minimal screw support.

[b] Quality of radiographs not suitable for adequate sagittal measurements.

Table 2
Spinal parameters with Cobb angle, apical vertebrae rotation and wedging of the different specimen at 10-week follow-up before tether release.

Animal	Cobb frontal (°)	Apical vertebral rotation (°)	No. of vertebrae in curve	Vertebral wedging (°)	Height convex (mm)	Height concave (mm)
1	72.4	44.4	11	5.7	25.9	24.4
2	61.7	36.2	11	6.8	25.1	22.1
3	43.3	25.2	6	8.1	26	24.2
4	62.8	54.4	6	9.7	28.2	23.4
5	75.6	36.9	12	16.1	26.6	19.5
6	70.7	43.1	11	8.5	28.8	24.7
7	60.9	34.6	11	10.4	29	25.1
8	49.7	23.8	5	17.2	25.7	21
Mean	62.1	37.3	9.1	10.4	27	22.8

Discussion

Numerous attempts have been made to create reproducible large animal scoliosis models for preclinical evaluation of fusionless scoliosis correction techniques [4,8,10,14,16-19]. A representative experimental early-onset scoliosis model should exhibit the following features: structural, persistent frontal and sagittal curvatures with sufficient rotation and wedging at the apex of the curvature, and adequate growth potential remaining to perform subsequent correction procedures [8].

Despite experiencing several technical problems in our study, we were able to create a scoliosis-like deformity, progressive while the tether was in situ in 8 of 14 animals without the use of rib tethering procedures. Magnitudes and 3D characteristics of the attained curves showed idiopathic-like features, with a mean Cobb angle of 62° and a mean vertebral rotation of 37° at the apex vertebra. The sagittal profile was not predominantly lordotic, and curves were therefore not idiopathic-like in that sense. The three shorter thoracic curves with rigid segments, formed as a result of vertebra fracture or epiphysiolysis, are less idiopathic-like and perhaps more similar to a congenital scoliosis. Such curves would be of limited usefulness for the assessment of fusionless scoliosis correction techniques. The low yield and the low consistency of our model remains a concerning issue. Four animals were sacrificed as a result of instrument failure or infection. Infections were prevented after changing the surgical preparation protocol. Despite not applying tether pretension, screw pullout still occurred in three animals. In one case, osteolysis surrounding the screws caused by infection probably resulted in this loss of fixation at the bone-screw interface.

After our pilot study in which pretension was applied to the tether and instrumentation failure occurred within 2 weeks postoperatively, we reasoned that pretensioning of the tether causing an immediate scoliosis should not be performed. Schwab et al., however, demonstrated that the larger the initial curve (up to approximately 25°) as induced by applying tension at surgery, the higher the rate of progression observed [11]. In their study, sublaminar cables were used to reinforce the screws and instrumentation was probably partially protected by an ipsilateral rib tether. Zheng et al. have also described a porcine scoliosis model with the use of a posterior tether in combination with an ipsilateral rib tether [20]. By pretensioning the posterior tether, a curvature of 29° was initiated and progressed to 65° at an 8-week tethering period. Apparently, the rib tether aids in early induction of the deformity, reduces load on the spinal tether anchors, and helps avoid screw pullout. Our objective was to develop a persistent spinal deformity representative of EOS with the use of a radiopaque UHMWPE posterior tether and without additional rib procedures. We believe a rib tether violates the chest wall structures and causes irreversible ribcage deformity with the formation of ectopic bone and stiff curves as a result. Subsequent corrective surgery may therefore be more difficult to perform. By omitting rib procedures, we aimed to create less rigid curves, especially around the apex, which subsequently resulted in nonprogressive curves after tether release. Odent et al. have shown earlier that rib procedures can be omitted [10]. However, release of the tether after 2 months led to a regression of the deformity by 45% in their study. In our study, the mean frontal Cobb angle decreased from 62.1° to 46.7° over a 10-week period after tether release. Despite the decline of 25%, a substantial deformity ultimately remains, which is close to the magnitude that would be considered for surgery. Before tether release, the apical vertebrae showed a mean wedge angle of 10°. The emergence of vertebral wedging is necessary for the persistence of scoliotic deformity after tether release. Similarly, in the human spine, apical vertebral wedging is an essential factor in the progression of idiopathic scoliosis according to the Hueter-Volkmann principle [16]. Regression of the deformity can be seen as evidence of a flexible curve, which is a crucial prerequisite for applying growth modulation techniques. The omission of the rib tether exhibited two downsides in a porcine model: the incapability of applying pretension to the tether, and slight curve regression after tether release.

Selection of animal species with anatomy similar to humans' and timing of the procedures are vital factors for creating a successful scoliosis model with sufficiently large Cobb angles [8]. Braun was the first to produce progressive lordoscoliotic deformities in a goat model. However, large pathologic curves were obtained [16,17]. In addition to the pyramidal shape of the thorax, the relatively small size of the goat's vertebra as compared to the human vertebra makes the goat model less suitable for implant testing [21]. The porcine spine is most similar to the human spine in terms of vertebral body height and has the largest growth potential compared to other large animals, with a maximum growth velocity at 3−4 months of age [8]. We opted for pigs, reasoning that the large growth potential is required when no pretension is applied to the spinal tether. We performed the initial procedure at 8 weeks of age and a mean weight of 12 kg. This is well before the growth velocity peak, leaving enough residual growth to evaluate the deformity after tether release (and perform a corrective procedure in the future). However, we experienced some handling problems with the animals, who reached a weight of approximately 50 kg at the time of tether removal and approximately 100 kg at 6 months of age (sacrifice). Other studies describing experimental scoliosis models report different rates of weight increase in pigs, and different rates of growth of the porcine spine, probably the result of discrepancy between porcine races [10,11,20]. The size of our animals during the possible implant test phase (between 50 and 100 kg) is not representative of children under the age of 10 but allows for conceptual feasibility assessment of fusionless scoliosis correction techniques. The described low yield due to screw pullout and low consistency (epiphysiolysis) are also probably related to the rapid porcine growth phase. The use of mini-pigs or species with a slower growth rate such as sheep or goats may help avoid these problems [10,22]. Mini-pigs show a constant growth velocity but lack a growth spurt and will need longer observational periods [8].

Different types of tether materials have been used, and flexible tethers are preferred over a rigid tether in order to maintain spinal mobility and allow for growth modulation in different planes (lordoscoliosis) [10,14,20]. Nonmetal flexible tethers are also used although visualization of the integrity of the tether during follow-up is not possible. The use of a flexible, radiopaque UHMWPE tether [13] facilitated percutaneous tether release with a minimally invasive stab incision under fluoroscopic control. The tensioning and potential loosening of the radiopaque tether could easily be monitored during the postoperative radiologic evaluation, with minimal animal discomfort as a result of leaving the tether in place.

It is evident that measures should be taken to minimize the occurrence of wound infections, not only to decrease the incidence of instrumentation failure but also to decrease overall morbidity. Further limitations of our study include the lack of CT analysis at the 20-week follow-up. Therefore, we were not able to compare rotational deformity between different time points. Although we encountered several problems, we were able to create the foundation for a large animal scoliosis model, which exhibits a substantial 3D deformity without the use of rib procedures additional to a posterior spinal tether. The resulting deformities were not progressive but showed persistence after tether release. The high complication rate remains a concern and poses questions regarding the feasibility of subsequent corrective operative procedures. We conclude that despite extensive research and incorporating previous recommendations from other models, the development of a reproducible experimental scoliosis large animal model without severe complications remains challenging. We would like to emphasize that the current work requires further work and validation before adoption, preferably in an animal model with a slower growth rate, to improve the yield and consistency.

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