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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

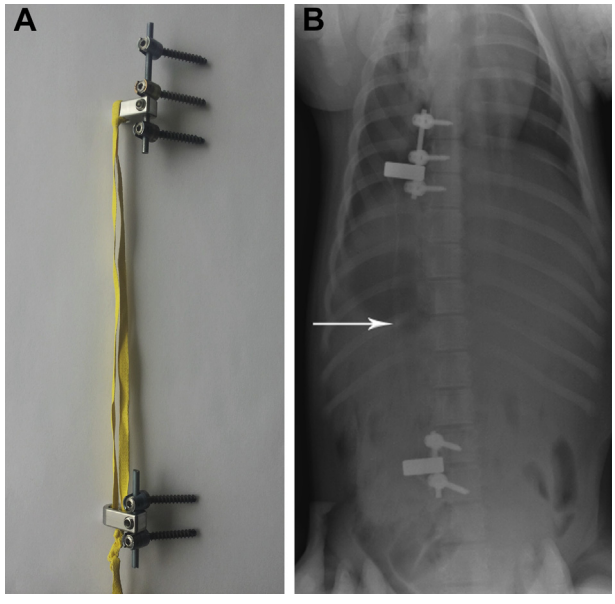

Fig. 1. (A) Offset devices with rods, pedicle screws and the radiopaque ultra-high molecular weight polyethylene (UHMWPE) double loop tether. (B) Offset device implanted in the porcine spine. The radiopaque tether (arrow) is attached to the offset devices without any tension.