Spinal Hemiepiphysiodesis by Modified Implant Design Induces Curvatures

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Introduction: Staple hemiepiphysiodesis is an established method of treating limb deformities. Similar, prototypical, procedures have also been shown to alter spine alignment in animal models, including in a previously reported porcine model1. Gradients in physeal structure have been reported from this model1. Toward clinical trial, selected changes were made in materials and surgical methods. Changes in material, implant structure, and implantation procedures might be expected to affect the extent and timing of growth modification. The purpose of this study was to determine if this modified system remained effective in altering spine growth asymmetrically.

Methods: An in vivo animal model of progressive scoliosis as an inverse analog of a potential method of early surgical treatment was conducted in an independent contract facility (approved by IACUC), in accordance with the provisions of the FDA GLP Regulations (21 CFR, Part 58). In 12 live skeletally immature domestic pigs, custom titanium staple-like clips were implanted across 5 to 6 mid-thoracic intervertebral levels using thoracoscopic surgical techniques. Each staple, which spanned a disc and two growth plates, was placed without piercing the disc, in contrast to preliminary study1,2. The clips were fixed to vertebrae using custom bone screws. Coronal plane traction, sagittal, and right oblique planar radiographs were taken immediately after surgery and at 2, 4, 6 and 8 weeks after surgery. Cobb angles were measured. Paired t-tests (α=0.05, 2-tail) were used to determine differences between early and final post-operative curvatures. The distance between blade tips were measured by 3 observers before implantation and after removal.

Results: Coronal plane curvature increased by 9.8° (± 4.4), statistically significantly, from 4.7° to 14.4°. Sagittal plane curvature changes (kyphosis/lordosis) were not statistically significant. Animal weight increased by 196 N (± 50) over the study period. Nine animals completed the full protocol, 6 with complete results. Complications in 3 animals were attributed to factors other than device placement. Distance between blades was 12.007 mm (±0.013) before implantation, and 12.007 mm (±0.013) after explant, no significant deformation (p=0.28).

Discussion: Spinal hemiepiphysiodesis using a staple-like implant and thoracoscopic procedures which were modified for possible clinical trial induced spine curvatures in a porcine model. Curves increased significantly, consistent with a previous study, despite changes to protocol that included elimination of a guide-wire, titanium rather than stainless steel staples, simplified base and blade design, and shorter bone screws. Results indicate that this modified implant system, like the earlier prototype, guided spine growth by asymmetrical inhibition of vertebral growth. No plastic deformation of the implant under dynamic growth force loading was detectable in this porcine model. Staple hemiepiphysiodesis is an established method of treating lower limb deformities. Surgical correction, instrumentation and fusion techniques for spine deformity in children and adolescents are invasive and may lead to adjacent segment degeneration. Hemiepiphysiodesis has altered spine alignment in preclinical models and so remains intriguing as a potential method of treating adolescent idiopathic scoliosis.

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Fig. 1. Intra-operative images of clip implantation. Left: Thoracoscopic photograph shows 2 implanted clips, the insertion tool, center, securing one clip during insertion of caudal screw, foreground. Right: Fluoroscopic image of a clip during implantation, showing blades centered over intervertebral disc, and 2 previously implanted clips.

Fig. 2. Radiographs of thoracic spine after implantation of 6 clips. Left: Immediate post-operative; Right: 8 weeks post-op (same subject)

Fig. 3. Mean coronal plane curvatures increased with time

Fig. 4. Mean curvatures in sagittal plane did not change with time

Fig. 5. Weight gain was lower than previous study