Spine Growth Modulation Using Titanium Clip/Screw Device: Curvature, Vertebral and Disc Height Changes at 1 Year

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Introduction: Preclinical studies have shown that spine growth can be modified asymmetrically, including in the thoracic spine of quadrupeds.1-3 Investigators have reported clinical results of curvature changes with some methods. A prospective, first human use, FDA Investigational Device Exemption (IDE) clinical safety trial was conducted using one method, a titanium clip/screw device, in children with late juvenile and early adolescent idiopathic scoliosis (www.clinicaltrials.gov Identifier: NCT01465295). Early clinical results have been reported.4 The purpose of the present study was to determine radiographic changes to coronal plane symmetry in vertebral and disc heights from immediately preoperatively to 12-months in this cohort. The hypotheses were that disc and vertebral height symmetry in the coronal plane would increase with time at the treated levels.

Methods: Six patients with progressive idiopathic scoliosis underwent endoscopic placement of a titanium clip/screw device (IRB approved). Inclusion criteria were Lenke 1A and 1B single thoracic curves, Cobb angle 25° to 40° between T3-L1, age > 10 years, open triradiate cartilages, Risser stage 0, thoracic kyphosis < 40°. Criteria were chosen to include only patients at very high risk for progression to >50°. Curvatures were averages determined using a data monitoring board. Vertebral and disc heights were measured (Fig. 1) for every patient and at every instrumented level with visible intervertebral boundaries using a clinical PACS system. The two primary outcome variables were side to side height ratios, $H_{concave}/H_{convex}$, for discs and vertebrae at each time point. Ratios were used to account for any magnification factor differences between the two times. Statistical differences were determined using paired t-tests, one-tailed, and Bonferroni ($\alpha=0.05/2=0.025$).

Results: Subjects included 3 females and 3 males, age at surgery 12.1 years (±2). The thoracic curvature was 34° (±3°) preoperatively and 30° (±13°) at 12 months (Fig. 2). Vertebral height ratios at t0- and 12 months were 0.91 (± 0.014) and 0.94 (± 0.031), respectively (p<0.025). Disc height ratios at t0- and 12 months were 0.67 (± 0.049) and 0.82 (± 0.13) (p<0.020) (Fig. 3). Immediately pre-operatively, vertebral heights on concave and convex sides were 17.0 mm (± 1.94) and 18.8 mm (±2.47), respectively. At 1 year post-operative, these values were 18.3 mm (± 1.65) and 19.6 mm (± 1.82), respectively. Disc heights on convex and concave sides, immediately pre-operatively, were 2.63 mm (± 0.35) and 3.95 mm (± 0.62) respectively. At 1 year, these values were 3.42 mm (± 0.49) and 4.31 mm (± 0.91), respectively. Vertebral height increases on convex and concave sides were 4% and 7%, respectively, whereas disc height increases on convex and concave sides were 8% and 23%. In the most recent follow-up to date, the best result to date is a patient who improved from 36° to 12° in 21 months (Fig. 4). However, another patient
increased from 35° preoperatively to 61° at 20 months, and underwent posterior spinal fusion (PSF and segmental spinal instrumentation (SSI)). In the entire cohort, losses in correction occurred primarily due to blade migration in vertebrae.

**Discussion:** At 1 year, mean curvature did not increase significantly from baseline after implantation of a titanium clip/screw implant in a small prospective cohort of very immature patients at extremely high risk of progression. Disc and vertebral height symmetry increased. The largest contributing factor to the symmetry improvement was an increase in the concave side disc height. Limitations include the inability to discern most disc and vertebral heights in patient with greatest axial rotation and largest curve. Results suggest that this method may help decompress the concave side disc and alter side-to-side vertebral heights. Longer-term results, as well as a larger cohort, are essential to clearly determine if spine growth modification occurred at the local level of the vertebrae and discs in any subgroup of subjects that attains, and maintains, curve correction.

**Significance:** In this study of spine growth modification at 1 year, curve changes were highly variable, including one conversion to PSF-SSI to date, yet overall results indicated improvements in spinal symmetry as well as provided proof of concept of growth modification in humans by this method.

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