INTRODUCTION:

Anterior spinal stapling, with a shape memory metal (Nitinol) is a method utilized to limit scoliosis progression in children. This method of “fusionless” surgery is thought to preserve spinal flexibility; a limitation with rigid spinal fusion techniques. Recent clinical literature has shown this method to slow progression in small curves, but larger curves however, required additional surgical procedures to slow curve progression (1). This study was to evaluate the effectiveness of Nitinol staples in the modulation of growth in an animal model. We seek to evaluate the two-dimensional (2D), three-dimensional (3D) and histologic effects of anterolateral vertebral body stapling to modulate spinal growth in a well-established porcine model.

METHODS:

Surgery: Three immature (6 month old) male Yucatan min-pigs underwent vertebral body stapling with a flexible, memory shape alloy staple (Nitinol, Medtronic). The staples were cooled to -20°C; spread apart and were inserted into 3 mid-thoracic intervertebral segments (Fig. 1). The staples then clamp upon warming to body temperature, thus compressing the motion segment. After a 6-month growth period, harvested spines were scanned with computed tomography (CT) and micro CT (36µm resolution), then processed for histology. Radiographic evaluation: Coronal and lateral plane digital radiographs were taken prior to the surgical procedure and every 4 weeks. CT and µCT: 3D reconstructions and analysis with Mimics (Materialise, Leuven, Belgium) and MatLab (Mathworks, Natick, MA) allowed measurement of global coronal Cobb angle of the three levels, global sagittal Cobb angle, true maximal Cobb angle and plane of maximal deformation, coronal and sagittal vertebral wedge and disc wedging, and disc height. Micro-computed tomography (µCT) images were acquired at 35µm resolution to allow visualization of the growth plates. Growth plates were traced using a custom MATLAB script and areas of closure and staple impingement were identified. All measurements were compared between the three stapled motion segments (4 vertebrae with 3 intervening discs, Staple Group) and adjacent motion segments located two levels above and below (Control Group, Control Group). Histology: One motion segment from each spine underwent undecalcified histological processing with sagittal sections were obtained from to gather information about the bone-staple interface. Hypertrophic zones were identified and measured in control and instrumented levels for comparison. Statistics: Mann-Whitney U was utilized to detect differences between growth groups. Values are expressed as averages with standard deviation. Spearman rank correlation coefficient was used to evaluate the relationship between VB wedging and growth plate closure. SPSS (SPSS Inc, Chicago, IL) was utilized for all analyses, alpha set at p<0.05.

RESULTS:

Pig weight increased an average of 98% and body length an average of 22% during the 6-month growth period. After the growth period, the average coronal Cobb determined by computation from 3D CT reconstructions was 13.7±5.5° while kyphosis averaged 11.9±6.9°. The Maximum Cobb Angle was 18.0±8.5° at a plane of 38.9±6.1° from the AP direction. Coronal plane vertebral body wedging in the Staple group was significantly greater than in the Control group (3.6±3.5° vs. -0.8±1.7°; p=0.001, Fig. 2), with no difference between the groups in the Sagittal plane (3.0±5.2° vs. 3.8±1.9°; p=0.63). Disc height was significantly larger in the Stapled than the control discs (1.2±0.46 vs. 2.2±0.38mm, p=0.001), but the stapled group showed no disc height differences between the right (stapled) and left (not stapled) sides (1.35±0.35mm vs. 1.17±0.50mm, p=0.293). Likewise, there was no difference in wedging between staple and control discs in either the coronal (0.24±2.9° vs. -0.58±1.07°, p=0.303) or the sagittal planes (0.43±2.58° vs. -1.59±2.23°, p=0.062). Analysis of hypertrophic zone height showed no significant difference in thee stapled vs control regions (151±28µm vs 150±33µm, p=0.905) or in the right vs left sides of the spine (149±35µm vs 153±27µm, p=0.709). µCT images revealed 2 of the 9 discs (22%) had a staple that breached the vertebral epiphysis and penetrated the disc space (these discs were removed from disc height and wedging analyses). 3D µCT reconstructions of the growth plates showed, on average, 26±23% of the growth plate area was closed in the stapled vertebrae, in comparison to 6±8% in the unstapled controls. There was a significant correlation between growth plate closure and VB coronal wedging, correlation coefficient = 0.999, p<0.001 (Fig 2).

DISCUSSION:

After 6 months of Nitinol intervertebral stapling, vertebral wedging was created and was associated with a mild global coronal deformity. However, this deformity was also associated with a significant loss of disc height, and periodic disc space and growth plate staple encroachment. In comparison, flexible growth tethering maintained disc health while producing a greater deformity in this model.

SIGNIFICANCE:

The results of our study suggest staples may play a role in the modulation of bone growth. However, their application across the spinal motion segments of a growing spine is less clear, thus necessitates further investigation.

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REFERENCE: 1) Lavelle, Samdani et al. 2011