Introduction

Currently scoliotic deformities are surgically corrected by means of spinal fusions. These fusions have a number of disadvantages including: loss of flexibility, adjacent segment disorders, and termination of spinal growth. Two new concepts of fusionless scoliosis correction were to be compared in this study: a flexible ligament loop attached to a bone anchor versus a rigid SMA (shape memory alloy) staple. These new methods could potentially eliminate the problems associated with spinal fusions. The hypothesis of this study was that the ligament tether with bone anchor would better correct an experimental, idiopathic-type scoliosis in an immature goat model, than the SMA staple without loss of implant fixation.

Methods

Scoliosis was created in 24 Spanish Cross X female goats (age 6-8 weeks, weight 8-12 kg) using a left posterior asymmetric tether from the T4-6 to L1-2 laminae using a method similar to that previously described. The braided synthetic ligament (3.5 mm polyethylene core/polyester sleeve, Medtronic Sofamor Danek, Memphis, TN) used for the flexible posterior asymmetric tethering in this study was placed through a standard posterior approach. Minimal dissection at the left T4-6 and L1-2 laminae allowed for sublaminar placement of the ligament. Submuscular tunneling between T4-6 and L1-2 prevented any disruption of the spinal elements along the curve. Convex rib resection and concave rib tethering from T8-13 were performed, without disruption of the spinal elements, prior to tensioning of the posterior tether. The tensioned ligament was sutured to itself over three to four centimeters in a side-to-side fashion using #2 Ethibond (Ethicon, New Brunswick, NJ).

After 8 weeks of posterior tethering, all goats were randomized into three treatment groups: Group I, no treatment of the experimental scoliosis; Group II, anterior SMA staple (Medtronic Sofamor Danek, Memphis, TN); Group III, anterior ligament tether with bone anchor (Medtronic Sofamor Danek, Memphis, TN). The six levels of maximal curvature were instrumented in Groups II and III via a standard right thoracotomy to approach the convexity of the curve. All goats were followed for an additional 12 to 16 weeks of observation with serial radiographs at four week intervals. All goats maintained the posterior asymmetric tether throughout the study. The data was analyzed using student t-tests to check for statistical significance, with the level of significance set to P < 0.05.

Essential Results

Of the 24 goats, 2 goats died in the early post-operative period due to pulmonary complications. Of the remaining 22 goats, 20 (91%) achieved progressive, structural, idiopathic-type, lordoscoliotic curves convex to the right in the thoracic spine over the eight week tethering period. Two goats developed non-progressive curves and were eliminated from the study. The 6 goats in Group I (no treatment) demonstrated continuous progression of scoliosis over the treatment period, with initial curves of 79.5° and 96.8° at 12 to 16 weeks (P < 0.001). The 7 goats in Group II (SMA staple) demonstrated little correction in curve magnitude at the time of operation following the stapling procedure (77.3° to 76.1°). The data demonstrated that this group had a continuous progression over the subsequent 12 to 16 week treatment period to 94.3°, similar to the untreated group. In contrast, the 7 goats randomized to Group III (anterior ligament tether) demonstrated an initial reduction in scoliosis following the anterior ligament tether with bone anchor procedure. An initial reduction in scoliosis at the time of operation from 73.4° to 62.0° (P = 0.01) was measured and showed little variation over the subsequent 12 to 16 week treatment period. The average final scoliosis in Group III was 69.9°. There were no complications related to either of the two correctional procedures. The data shows that the anterior ligament tether demonstrated a surgical advantage over the rigid SMA staple.

Discussion

The data in this study demonstrates the ability of an anterior ligament tether attached to a bone anchor to prevent progression of an experimental scoliosis without fusion in an animal model. The results supported the hypothesis that the anterior ligament tether would be correct the experimental scoliosis than the rigid SMA staple without loss of fixation. It is believed that the anterior ligament tether provided a much more stable implant which led to more effective results. The radiographs showed some staple dislodgement as well as an increased amount of radiolucency surrounding the SMA staples over the bone anchors, suggesting that the rigid staple implants likely drifted following implantation. Also, due to the flexibility of the ligament tether and stability of the bone anchors the Group III goats demonstrated the most favorable results. Further analysis is required, which is currently being conducted, to verify reasons that the anterior ligament tether showed better correction.

Though the initial correction with this ligament procedure was substantial, further correction was not demonstrated over the course of the study. The inability to demonstrate any substantial control of the scoliosis progression in this study is likely due to the substantial increased severity and the malignant progression of these deformities, as seen in the untreated curves in this study.

Scoliosis correction using an anterior ligament tether with bone anchor or shape memory alloy staple represents an initial step in the investigation of convex tethers to treat progressive scoliotic deformities without fusion. By inhibiting the exuberant growth on the convexity of a curve, and perhaps, encouraging the lagging growth on the concavity of a curve, correction of deformity can occur (Huebner-Volkmann principle). Correction by growth modulation, rather than by instrumented fusion, may offer substantial advantages to patients both in the short and long term. Future studies which continue to examine the feasibility of this new correctional technique of anterior ligament tethering may lead to a better quality of life for scoliotic patients.

Reference