AN ANALYSIS OF IMPLANT INTEGRITY USING TWO DIFFERENT METHODS OF FUSIONLESS SCOLIOSIS TREATMENT

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Introduction

Two different concepts for fusionless scoliosis correction were compared in this study: a rigid SMA (shape memory alloy) staple versus a flexible ligament loop attached to a bone anchor.

The purpose of this study was to analyze the integrity of the rigid and flexible anterior thoracic tethers used to treat an experimental scoliosis with plain radiographs, gross histology, back-scattered electron (BSE) imaging and implant pullout testing. It was hypothesized that the bone anchors would sustain a greater amount of integrity with the host bone than the SMA staple.

Methods

Scoliosis was created in 20 Spanish Cross X female goats (age 6-8 weeks, weight 8-12 kg) using a flexible left posterior asymmetric tether from the T5 to L1 laminae, in combination with convex rib resection and concave rib tethering from T8-13, as previously described [1]. After 8 weeks of posterior tethering, 14 goats were randomized into two treatment groups; the remaining six goats received no treatment and served as scoliosis controls. Group I (n=7) underwent anterior stapling of the seven apical vertebrae with the rigid SMA staples; Group II (n=7) underwent anterior tethering of the seven apical vertebra with flexible ligament loops attached to bone anchors. Goats were observed for an additional 12-16 weeks after treatment. An additional 5 goats served as growth controls with no induced scoliosis.

Serial plain radiographs were used to determine the gross integrity of the implants throughout the study. All staples and anchors that demonstrated loosening, radiolucency, drift, or back-out were noted. Following euthanization, the apical segments (T9-11) were embedded in methylmethacrylate and coronally sectioned for additional analysis. The sections of vertebrae were qualitatively analyzed using gross histologic techniques. Using a scanning electron microscope and BSE imaging techniques, three different quantitative indices were obtained. An osseointegration index (OI) was calculated by dividing the length of bone osseointegrated with the implant by the total length of the implant. The bone proximity index (BPI) represented the average distance the host bone was situated from the implant. The bone ingrowth (BI) was determined as the percentage of bone within the confines of the bone anchor. OI, BPI and BI were all determined for the staples and anchors.

Implant pullout testing was performed using a servohydraulic materials testing machine (Instron 8500, Canton, MA) at two time points: Time 0 and 12-16 weeks post-implantation. Time zero data was collected from the 6 untreated scoliotic spines as well as the 5 growth control goats. Staples were implanted across the T7-8 and T12-13 segments in these 11 goats. After staple testing, bone anchor pullout testing was accomplished in the remaining four goats. The vertebral body from the 14 treated goats were used to determine the 12-16 week post-implantation pullout strengths. Pullout fixtures were applied to staples and anchors in these 14 goats with minimal soft tissue dissection.

The data was analyzed using independent t-tests with the level of significance set to p < 0.05.

Results

During the treatment period, the scoliosis progressed in the stapled goats from 77.3° to 94.3°, demonstrating little effect when compared to the untreated goats which progressed from 79.5° to 96.8°. In contrast, the scoliosis in the goats with ligament tethers attached to bone anchors corrected from 73.4° to 69.9°. Serial radiographs demonstrated 18 of 42 staples (43%) were loose (2 staples were completely dislodged), while only 2 of 49 anchors (4%) demonstrated a slight drift or radiolucency. Gross inspection of histological sections revealed a consistent halo of fibrous soft tissue around staple tines, but well fixed bone anchors at all sites. This finding was consistent with the measurements collected from the BSE images (Figure 1). OI values of 40.1 ± 17.5%, for the staples, and 76.4 ± 6.8%, for the anchors, were collected (p < 0.001). The BPI for the staples was 702 ± 138 µm, while the anchors were significantly lower at 215 ± 69 µm (p < 0.001). Additional fixation of the anchor was achieved through 11.0 ± 3.8% bone ingrowth within the chamber compared to 21.7 ± 4.9% bone in the host region.

The average time zero staple pullout strength was 101.40 ± 23.03 N, while this slightly decreased to 86.03 ± 48.56 N at 12-16 weeks post-implantation. The bone anchors measured 495.41 ± 171.30 N at time zero, while this significantly increased to 639.76 ± 213.36 N following 12-16 weeks post-implantation (p = 0.004). Additionally, in 21 out of the 28 anchors pulled at the 12-16 week time point, the bone of the vertebral body failed as opposed to the anchor cleanly pulling out. At both time points, the anchor strength was significantly greater than the staple (p < 0.001) (Figure 2).

Figure 1. Backscattered electron images representing a section of the bone anchor being strongly osseointegrated with the host bone (right), while a portion of a staple tine demonstrates a greater distance to the host bone (left). Both images are taken at 20x magnification.

Figure 2. Implant pullout strengths at time 0 and 12-16 weeks post-implantation. The chart demonstrates the greater integrity of the anchor at both time points (p < 0.001), as well as a significant increase in pullout strength of the anchor following 12-16 weeks post-implantation (p=0.004).

Discussion

The data from this study demonstrate greater integrity of a bone anchor attached to a ligamentous tether versus an SMA staple in the fusionless treatment of an experimental scoliosis. In vivo, plain radiographs demonstrated less loosening of the anchor versus staple over the treatment period. In vitro, after harvest of the goat spines, gross histology, BSE imaging, and implant pullout testing confirmed the superior fixation of the anchor versus staple.

Differences in implant integrity are likely due to multiple factors. Implant design favors the hollow anchor (with screw threads and fenestrations for improved bony purchase) versus the smooth staple tine. Additionally, the flexible ligament loops spanning the disc spaces, likely protected the anchors from the high peak forces of spinal motion. The rigid staple, however, was not afforded this protection and loosened at a high rate.

While other investigators [2] have demonstrated the short term clinical efficacy of anterior thoracic stapling in the fusionless treatment of scoliosis, multiple staples were implanted at each level in these patients. Our study utilized only one staple per level and therefore we are unable to comment on the effectiveness of multiple staples. Additional studies are underway to determine the biomechanics of multiple staples per segment.

References


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