INTRODUCTION

Rotator cuff injuries requiring treatment are a common clinical problem. Treatments for large to massive chronic rotator cuff tears have not yielded consistently good results. Tendon to bone healing and long-term functional success rates for retracted tendons are relatively low. Current biomaterials used to augment surgical rotator cuff repair are not intended to be used as “span” or “structural” grafts because they are heterotopic allografts or xenografts which have inferior biomechanical properties, poor incorporation characteristics, and/or engender immune or inflammatory responses. Recapitulation of normal tendon-bone attachment is not attained using current techniques and is likely a major component of the high failure rates reported in the literature. In a previous study, we reported promising results for rotator cuff repair in a canine infraspinatus tendon (IST) model using a novel bone-tendon allograft implant and technique (Jayabalan, et al, ORS 2009, patent pending). The bone-tendon allograft technique was associated with highly functional healing of the infraspinatus muscle-tendon-bone unit in an acute resection model based on clinical, imaging, biomechanical, and histologic outcome measures. However, in the clinical setting the quality of the remaining tendons and musculature are often poor because of degeneration, fatty infiltration, and retraction. Therefore, the objective of the present study was to test our novel bone-tendon allograft technique for chronic, large rotator cuff defect repair using a canine model and compare the results to treatment using a commercially available human dermis patch (GraftJacket®) and debridement alone.

METHODS

All procedures were approved by the animal care and use committee. Mature-purpose-bred dogs (n=15 dogs) were used. Through a 2 cm incision over the proximal humerus, the right IST of each dog was identified and isolated. A radiopaque marker wire was placed 5 mm caudal to its insertion and then the tendon was completely transected at its insertion and allowed to retract. Radiographs were obtained post-retraction to document the degree of tendon retraction. Three weeks after tendon transection, radiographs were again obtained and each dog underwent surgical treatment of the right IST. The IST was treated by debridement (n=5) (D) of proliferative fibrous tissue, direct repair of the tendon to bone using a suture bridge technique and a human dermis patch (GraftJacket®) (n=5) (GJ) augmentation, or with the novel bone-tendon allograft (n=5) (BT) technique. Postoperative radiographs were obtained. The dogs were allowed full weightbearing, but were restricted to kennel rest for 6 weeks and then allowed enrichement activities. Temporal outcome measures included last lameness evaluation at 0, 4, 8, 12, and 24 weeks, radiographs at 0, 4, 12, and 24 weeks, and ultrasonographic assessment at 0, 12, and 24 weeks. Dogs were sacrificed 6 months after surgery and operated and non-operated shoulders assessed biomechanically for stiffness and displacement during cyclic mechanical testing and for histologic appearance. Treatment groups were compared to one another and to contralateral (normal) controls for statistically significant (p<0.05) differences.

RESULTS

Retraction of the IST was noted on all post-release radiographs. All dogs were sound at the start of the study and all dogs showed mild, visible lameness (grade 1-2 of 5) 3 weeks after IST release. Six months after treatment, degree of lameness was 1.6 ± 0.6 for D, 1.4 ± 0.6 for GJ, and 0.4 ± 0.5 for BT with BT significantly (p=0.01) less lame than the other groups. Subjective radiographic (Fig. 1), ultrasonographic, and gross assessments (Fig. 2) of IST integrity and healing at 6 months post-repair all indicated that BT repairs all had good bone-bone healing and had superior bone-tendon, tendon, and tendon-muscle integrity when compared to D and GJ repairs. Biomechanical testing of the IST bone-tendon-muscle complex with optical tracking to determine elongation and tensile loading at 0.10 mm/sec to a maximum load of 50N (walking load for a dog) or an elongation of 2mm showed that all repairs had significantly lower stiffness (p<0.04) than normal controls (Fig. 3), while group D had significantly (p=0.05) more elongation than all other groups (Fig. 4). Of the three treatment groups, BT repairs had stiffness and elongation characteristics that most closely matched normal controls.

DISCUSSION

The results of this study support those from our previously reported work in showing that our novel bone-tendon allograft repair method establishes a very functional IST bone-tendon-muscle unit based on clinical, imaging, biomechanical, and histologic outcome measures. In this study, the use of a chronic IST release model with tendon retraction and comparison to debridement and suture repair with a human dermis derived patch provide further evidence for the translational potential of this rotator cuff repair technique. We showed clearly that integrity of the original repair (based on radiopaque marker location) was maintained only in the BT group. Ultrasonographic, radiographic, biomechanical and histologic data provided further evidence showing incorporation of allograft bone, tendon-muscle healing, maintenance of tissue architecture and material properties, biocompatibility, and safety. The superior functional outcomes for the novel bone-tendon allograft compared to tendon allografts in our previous study and debridement and dermal patch-augmented repair in the present study are likely related to bone-bone fixation and healing, maintenance of a normal bone-tendon junction in the allograft, use of isotopic tissue, and the material properties of the graft and the repair. Clinical trials using this novel bone-tendon allograft technique appear to be warranted.

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