Assessment of a Novel Bone-Tendon Allograft Technique for Repair of the Rotator Cuff in a Canine Model

Jayabalan P; *Waters NP, *Cook CR; *Kuroki K; *Carson W; *Cook JL
+*Comparative Orthopaedic Laboratory, University of Missouri, Columbia, MO
CookJL@missouri.edu

Introduction:
Repair of chronic tears of the rotator cuff fail in 30-90% of cases. Current repair techniques do not re-establish normal bone-tendon (B-T) or tendon-muscle (T-M) junctions. Optimizing the strength and function at these junctions may result in lower failure rates with greater clinical success. We developed a bone-tendon allograft technique (as opposed to a soft tissue scaffold only) which has the potential to provide immediate bone-tendon integrity and function. The purpose of this study was to test the B-T allograft repair technique using a canine model to assess clinical, imaging, histologic, and biomechanical outcomes compared to allograft tendon alone treatment and two different control groups. We hypothesized that the B-T allograft would be superior to tendon-alone allograft for rotator cuff repair in a canine model.

Methods:
All procedures were approved by the institutional ACUC. The study used four adult purpose-bred mongrel dogs (8 shoulders). Dogs underwent bilateral infraspinatus tendon (IST) partial tenectomy. The defect was then repaired by one of two techniques:
(1) Bone-Tendon (B-T) allograft (n=3) – Cannulated screw fixation of allograft bone block to host bone. (Fig 1)
(2) Tendon alone allograft (TA) (n=3) – Suture Bridge Technique

Figure 1 - A) The Bone-Tendon allograft, B) Suture of tendinous part of B-T allograft to native IST C) B-T attached to native bone by cannulated screws D) Post-op radiograph following B-T allograft implantation

Two control groups were used – i) In situ B-T autograft (n=2) in which the IST with a bone block at its insertion was elevated and replaced using cannulated screw fixation (Autograft Control) and ii) age, weight, and breed matched normal canine cadaveric shoulders (n=4) (Normal). Post-surgery the dogs were housed in individual cages and allowed unrestricted mobilization for 12 weeks prior to euthanasia.

Limb function scoring: A previously validated lameness assessment system was used to score (0-5) each forelimb of each dog at 12 weeks post-surgery. Zero represented normal functional use of the limb and 5 represented no functional use.

Imaging: Cranial-caudal and medial-lateral radiographs of the shoulders were obtained at sacrifice to assess implants, graft union, and radiographic pathology. Ultrasonography on the day of sacrifice was used to assess IST architecture and integrity from origin to insertion.

Biomechanical testing: Non-destructive biomechanical testing was performed after sacrifice. The IST bone-tendon-muscle complex was excised en bloc. The humerus was secured in a jig with muscle attached to test machine ram to pull the IST lateral to the bone. Three optical markers were mounted with consistent initial distance between them: 1) on muscle above T-M junction, 2) on tendon between T-M and B-T repair sites, and 3) on bone below B-T repair site. Elongation of the repair sites was measured as the change in distance between adjacent markers by a 0.01mm resolution optical tracking system (NDI Optotak, ON, Canada) synchronized with measurement of the applied tensile force. IST were pulled at 0.10 mm/sec to a maximum load of 50N (walking load for a dog) or an elongation of 2mm of either the B-T or T-M junction, whichever occurred first.

Histologic assessment: Following decalcification, haematoxylin and eosin stained sections of each IST complex were assessed for cell and tissue morphology by a pathologist blinded to treatment.

Statistical analysis: Data from each group were pooled and means and standard error determined. Statistical analyses (one-way ANOVA) were performed using a computer software program (Sigma Stat). Significance was set at p<0.05.

Results:
Functionally, all dogs recovered fully post-operatively and had normal limb function with respect to the surgical treatments performed. Radiographs showed evidence of good bone healing and integration of bone blocks in both B-T allograft and Autograft Control groups. No evidence of implant failure, migration, infection or shoulder arthritis was noted in any shoulder. Sonographic assessment revealed normal appearing bone-tendon attachment for B-T allograft and Autograft Control groups in contrast to the TA group where attachment of tendon to bone was via tissue with a disorganized and heterogenous echogenic appearance. Histologically, bone-bone integration was very similar for allograft versus autograft groups. Bone blocks showed good incorporation into host bone with no untoward inflammatory response and no to minimal gap formation at 12 weeks. The B-T junction was nearly identical histologically compared to Autograft Control groups with maintenance of the normal tendon attachment. In the TA group, the attachment to host bone at the insertion site ranged from loose connective tissue to robust fibrous tissue. Areas of graft degeneration and chondroid metaplasia were also noted in this group. The tendinous portions of both allograft groups showed maintenance of tissue integrity and good integration with host tendon and muscle.

Discussion:
Non-strenuous shoulder and limb function were not compromised by any surgical technique. Based on radiographs and histologic findings, bone integration and healing were excellent for both B-T allograft and autografts with no evidence of untoward immunological reaction. Sonography and histology showed that the B-T attachment had normal tissue architecture and integrity with evidence of cellular repopulation for the B-T allograft repairs. This finding suggests potential advantages over the tendon only group which showed B-T attachment via disorganized fibrous repair tissue only. Correspondingly, the degree of elongation was lower and the stiffness was higher for the B-T allografts compared to the tendon only allografts but was not of statistical significance. Irrespective of these observations, both allograft repair techniques allowed for adequate healing in terms of non-strenuous functional strength and elongation (i.e.capable of resisting the 50N walking load for a dog with less than 2 mm elongation). Biomechanical tests to repair site catastrophic failure to determine their ultimate strength were not conducted in this study to be able to perform histologic assessment. Ultimate strength data would be an indicator of in vivo repair site resistance to failure during strenuous activity, and thus should be generated in future studies. We also plan to test the novel bone-tendon allograft repair technique in a chronic massive tear model with associated tissue retraction and muscle degeneration in the process of optimizing this technique for clinical use.

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