In vivo comparison of ACL reconstruction in the ovine model between a sterile allograft and autograft tendon

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Statement of Purpose: The "gold standard" for intervention of ACL rupture is reconstruction with autograft tendon. However, contraindications of this procedure consist of donor site pain and second site morbidity. Allograft is an acceptable alternative that addresses the limitations of autografts, but concerns persist regarding disease transmission and its *in vivo* performance. BioCleanse® (Regeneration Technologies Inc. Alachua, FL), a unique low temperature sterilization process developed for bone and soft tissue allografts, removes and inactivates infectious agents. Tissue is submerged in a chamber while applying oscillating pressure/vacuum cycles to facilitate introduction of germicides while removing endogenous material. This essentially renders an intact sterile collagen-based tissue matrix. The sterilization potential and preservation of mechanical performance of this process on tissue has been previously established.[1,2] The purpose of our investigation was to compare *in vivo* performance between autograft tendons to allograft tendons treated through the BioCleanse tissue sterilization process.

Methods: The right ACL was reconstructed in 24 skeletally mature female sheep. The allograft patellar tendon was aseptically harvested from an additional set of donor animals, sectioned in half and treated through the BioCleanse tissue sterilization process. The autograft bone tendon bone (BTB) was removed from the lateral half of the patellar tendon encompassing the area between the patella and tibial insertion. In both groups, the grafts were shaped to similar size for placement in 8-9mm tunnels and secured with 5-6mm titanium interference screws. At 12 and 24 weeks after surgery, animals were sacrificed and gross appearance and function, destructive biomechanical properties, and histological properties were evaluated. Furthermore, *in situ* laxity of the operated knee was measured (via a modified KT-1000 arthrometer) at the following intervals: preoperatively, after transecting the native ACL, postoperatively, after reconstruction and at 12, 18, and 24 week time points. Gait analysis was performed weekly on a scale from 0 (normal) to 3 (not weight bearing). Immediately following necropsy, all soft tissue except the ACL was removed and joints were mechanically evaluated using custom fixturing attached to an Instron 4302 material testing machine. Three unoperated knees served as controls. The tendon was tensioned to approximately 12N along the long axis of the tunnels, followed by loading at the rate of 24.5 mm/min until failure.

Results / Discussion: Kruskal-Wallis ANOVA non parametric analysis revealed the gait scores between treatment groups at 1, 6, and 12 weeks were not significantly different (p=0.07, p=0.085, and p=0.33 respectively). However, trends exist that hold over time through 12 weeks post surgery. In all cases the allograft BTB treatment group exhibited the lowest median and mean gait scores.

One-way ANOVA was used to evaluate any differences in percent change in KT laxity from pre- to post-surgery between treatment groups. No significant differences between autograft and processed allograft BTB were detected ($p = 0.573$), with mean values of 97% and 78%, respectively. Comparison of percent change in laxity from pre-surgical and 12 weeks post-surgery indicated that the processed allograft group was significantly less lax with one-way ANOVA ($p = 0.004$). The laxity increase between presurgery and 12 weeks for the allograft and autograft group was identified to be 32% and 48%, respectively.

The failure load of the grafts at the 12-week time point revealed significant differences between the two treatment groups (p=0.012). The average load of the autograft group and allograft group was identified to be 140N (10% of control) and 417N (30% of control) respectively.

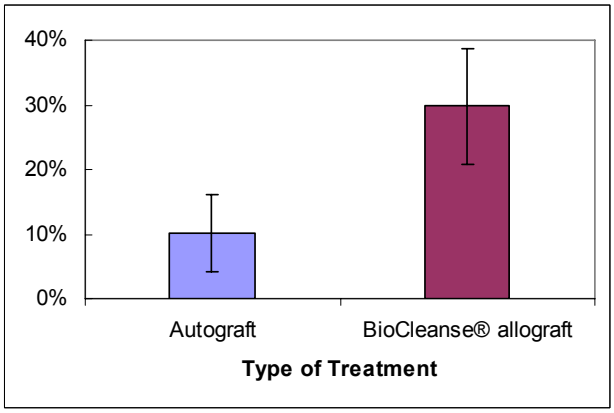

Figure 1. Percent of native ACL failure load at 12 weeks.

Conclusions: The data at these early time points support the hypothesis that allografts treated through the BioCleanse tissue sterilization process result in better *in vivo* performance when compared to autograft tendons. Long term follow-up as well as histological data at the additional time points will more fully characterize similarities and differences between these two treatments.

References:

1. *BioCleanse Tissue Processing System: Biological Safety.* Mills, C. Randal et al. Regeneration Technologies, Inc – Technical Monograph. 2000.
2. Mechanical evaluation of soft tissue treated through a new tissue sterilization process. Vangsness T et al. 70th Annual Meeting of the American Association of Orthopaedic Surgeons. New Orleans, La 2003.