Biphasic Interpositional Allograft for Rotator Cuff Repair Augmentation Is Safe in an Ovine Model

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MIDWEST ORTHOPAEDICS AT RUSH

BACKGROUND

- Rotator cuff tears (RCTs) affect nearly 40% of the population over 60 with nearly 500,000 rotator cuff repairs (RCRs) performed annually
- Retear rate after RCR is influenced by tear size, amount of retraction, tendon quality, and degree of fatty infiltration
- Patch augmentation of RCR is an increasingly popular method for improving the likelihood of successful repair in patients at high risk for retear

- A variety of graft choices and sources including xenografts, allografts, synthetic grafts, scaffolds, on-lay patches, interpositional patches, and biologic injections (e.g. BMAC, PRP) have been attempted to with variable success

- Recently, an acellular biphasic interpositional cancellous allograft (BioEnthesis, Sparta BioPharma Inc, Madison, NJ) was developed to provide a porous scaffold for endogenous biological factor migration and potentially address the lack of enthesis recapitulation
- The graft's calcified layer is meant to promote osseointegration by retaining important bone growth factors in its manufacture while the demineralized layer supports soft tissue ingrowth

PURPOSE

This study is a preclinical histological assessment of a biphasic acellular interpositional cancellous allograft in an ovine model of RCR designed to better understand its safety profile and effects on tendon healing after rotator cuff repair.

METHODS

Study Design

- 30 skeletally mature sheep with clinically normal shoulders underwent a previously published fenestration procedure to model a degenerative infraspinatus tendon (IST) tear
- 6 weeks after degenerative model creation, sheep were randomized to a standard double row repair or if part of the treatment group, the same procedure augmented with a biphasic interpositional allograft implanted between the IST and humeral footprints (**Figure 1**)
- Animals were euthanized according to AVMA guidelines at 3-weeks, 6-weeks, and 12-weeks and *Ex Vivo* histological analysis was performed
- Sheep were appropriately monitored for orthopedic or medical complications throughout the study period

Ex Vivo Histological Analysis

- After gross dissection, rotator cuff specimens were fixed with formalin and polymerized for sectioning and staining
- *Ex vivo* analysis included blinded histological scores evaluating inflammatory cell infiltrates, signs of degradation, particulate debris, collagen arrangement, neo-vascularization, and enthesis qualitative measures

RESULTS

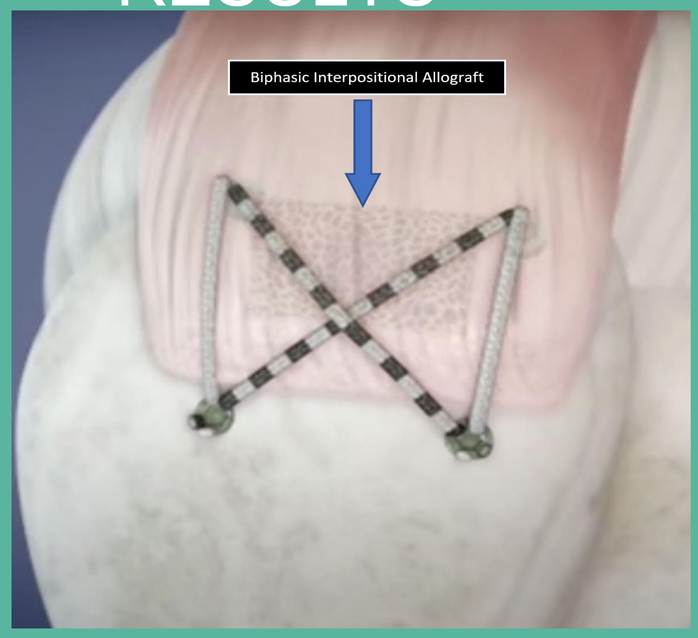

Figure 1. A standard double row technique with suture tape was used to secure the infraspinatus tendon and the acellular biphasic interpositional cancellous allograft (blue arrow) interpositionally at the humeral footprint.

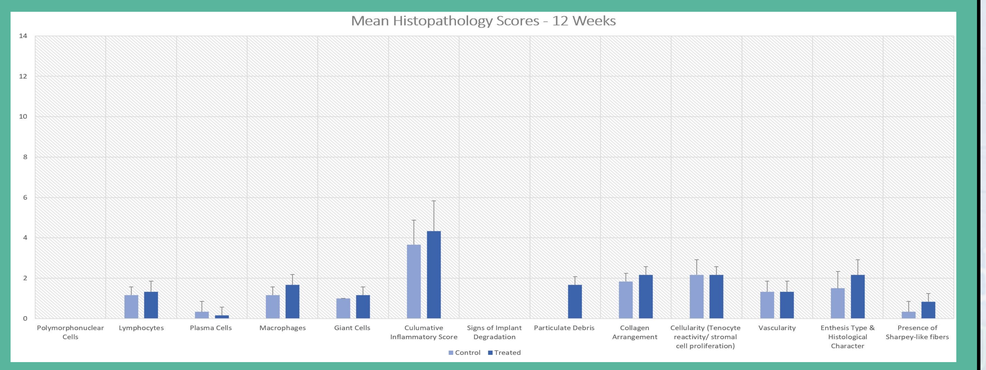

Figure 2. The mean histopathology scores with error bars representing standard deviations are shown for 12-weeks post-intervention for polymorphonuclear cells (p = 1.00), lymphocytes (p = 0.51), plasma cells (p = 0.51), macrophages (p = 0.08), giant cells (p = 0.21), cumulative cells (p = 0.38), signs of implant degradation (p = 1.00), particulate debris (p = 0.45), collagen arrangement (p = 0.42), cellularity (p = 0.22), neovascularity (p = 1.00), enthesis type (p = 0.20), and Sharpey like fibers (p = 0.09).

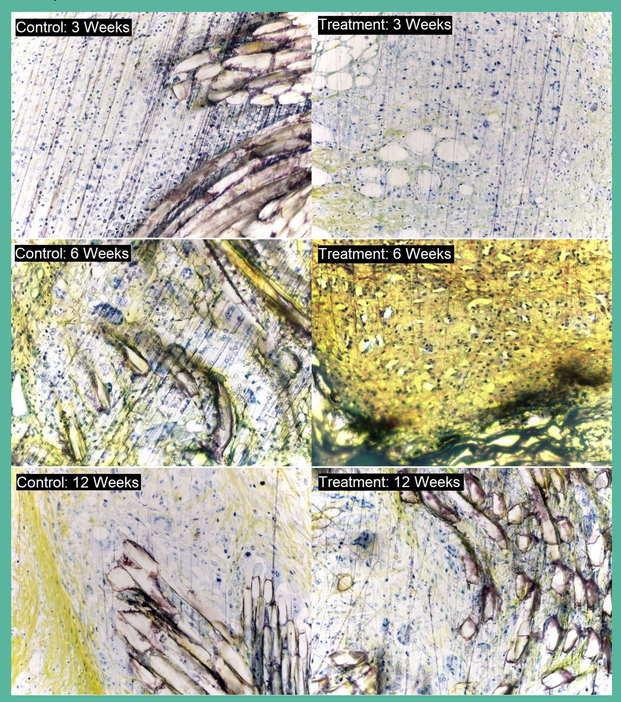

Figure 3. *20x magnification* demonstrating the immune responses and inflammatory infiltrate for all timepoints in the control and treatment arms. Inflammation progressively diminished in both groups from the 3-week timepoint to the 12-week timepoint with decreases in cellularity seen at each time point. No major differences in immune responses were observed between the two groups.

RESULTS

- The scores used to describe various histological measures such as inflammatory cell infiltrates, signs of degradation, particulate debris, collagen arrangement, neo-vascularization, and enthesis qualitative measures proved not to be significantly different at all time points (3-weeks, 6-weeks, and 12-weeks) when comparing the treatment and control RCR groups (**Figure 2**)

- In general, both groups exhibited progressive decreases in inflammation (**Figure 3**), increases in collagen organization, healing of the enthesis, with improvements in mean cumulative inflammatory scores (**Figure 4**)

- The biphasic interpositional allograft produced no significant gap formation, immunogenic or excessive cellular inflammatory infiltrate response, or foreign body reaction engulfing the allograft with giant cells, granuloma tissue, or fibrous capsule

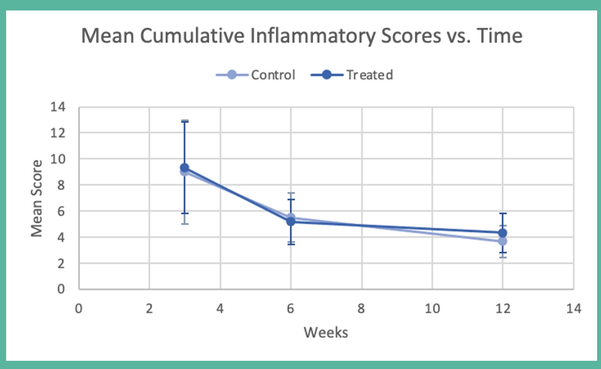

Figure 4. The mean histopathology scores with error bars representing standard deviations are shown (p = 0.20), and Sharpey like fibers (p = 0.09).

CONCLUSION

- This histological study demonstrated the use of a biphasic interpositional allograft in the setting of rotator cuff repair augmentation in an ovine model does not generate an inflammatory response or foreign body reaction
- Use of the biphasic interpositional allograft resulted in a histological profile that was essentially equivalent to that of a standard RCR at 3-, 6- and 12-week post-operative timepoints
- These findings suggest that despite not showing histological benefit, a biphasic interpositional allograft is safe in an ovine model as it exhibited similar mean cumulative inflammatory response scores, demonstrated evidence of excellent biocompatibility, and allows for native enthesis healing

- There is yet to be a scaffold, graft, or growth factors able to regenerate the mechanical properties of a native enthesis, and it remains hopeful that the biphasic interpositional allograft in this study may provide biomechanical and subjective patient reported benefits
- Further clinical investigation should be conducted in humans before broader clinical application