Evidence-based rational for the use of a novel biological scaffold in tendon and ligament repairs

Brunelle J, Ritter G, Ray A, Sander T, and Nataraj C.
Pegasus Biologics Inc., Irvine, CA

Introduction The use of soft tissue augmentation grafts for tendon a ligament repair has gained interest in recent years due to advances in tissue processing technologies and the need to restore weakened native tissue (Ref 1). Literature review indicates several factors to play a critical role in the clinical success of such repairs. These include similar inherent viscoelastic property to native tissue (Ref 2), ability to be optimally tensioned (Ref 3), retention of this tensioned state through remodeling (Ref 4), structural and biomechanical survival in the scaffold in a matrix degrading/remodeling environment (Ref 5,6), and biocompatibility (Ref 7). The OrthADAPT™ Bioimplant (Pegasus Biologics, Irvine, CA) is a type I collagen scaffold derived from equine pericardium, that is stabilized and sterilized using novel EDC chemistries. Additionally, we hypothesized on a unique surgical technique (circumferential tensioning) that incorporates critical biomechanical features to optimize clinical success. We then translationally evaluated the outcome of combining the novel matrix and the surgical technique in a rotator cuff model.

Methods Biomechanical properties were assessed by standard tensile strength tests and cyclic creep at loads relevant to rotator cuff function. Given the anisotropy of the scaffold (pericardium), strength tests were also conducted to evaluate the role of collagen fiber orientation. Structural stability of the scaffold to survive the remodeling environment was assessed by mass and strength (suture pullout) loss studies after exposure to collagenase. The technique to apply the graft was achieved by placing a suture 45^{o} off the tangential edge of the scaffold which ensured biaxial tension throughout the scaffold. Using this technique, the force required for optimal tensioning at each fixation point was measured with a force gage. Test samples were evaluated for suture pullout resistance in both transverse and longitudinal orientations after surgical placement in cadaver shoulders. Finally, clinical outcome of the product and technique was evaluated by initiating follow-up on a patient series (n=26), which included standard suture repair (control group) and use of OrthADAPT™ to augment surgical repair (test group) of their torn rotator cuffs.

Results Tensile failure loads were 218N vs 221N depending on the orientation (transverse vs. longitudinal) of OrthADAPT™, and cyclic loading (10-120N) showed no creep after 30 cycles ($p<0.05$). Exposure to collagenase did not affect mass (>90% retained) or strength (>85% retained) of OrthADAPT™ over a 48h exposure. A variety of commercially available products failed ($p<0.05$) when subjected to a similar test protocol. Cadaver studies showed a force of 7N to be necessary to achieve optimal tension circumferentially, and suture pullout for the transverse and longitudinal was 18.6N and 17.7N respectively for OrthADAPT™, fulfilling the requirement for surgically applying the bioimplant. Clinically, preliminary results indicate augmented patients healed uneventfully, and were able to return to full range of motion earlier than controls. Specific outcome metrics with time are underway to quantify the clinical outcome.

Conclusion The unique processing and inherent properties of the OrthADAPT™ bioimplant was able to specifically address the demands of tendon and ligament repair environment. When complemented with the novel surgical technique (circumferential tensioning) to apply the scaffold, these properties appear to translate to a successful biological outcome, as evidenced by the preliminary clinical feedback.

References:

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