

Allograft Fascia Lata as an Augmentation Device for Musculoskeletal Repairs

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ABSTRACT

Musculoskeletal soft tissue injuries during combat are a source of debilitating pain, the treatment and evaluation of which pose a significant challenge to the orthopedic community. Extracellular matrix (ECM) scaffolds derived from various sources and species are being explored for the repair of musculoskeletal tendon injuries. In this paper we demonstrate that amongst these ECM scaffolds, only tensor fascia lata has structural and tensile material properties comparable to tendon, but fascia has poor suture retention properties. We have devised a novel means to increase the suture retention properties of fascia lata by developing a composite of the ECM tissue and biodegradable polymers. This technique may facilitate the efficacious use of fascia lata in the area of regenerative medicine, particularly for musculoskeletal repairs.

1. INTRODUCTION

In recent years natural extracellular matrices (ECMs) have been procured, processed and marketed for clinical use as patches to reinforce soft tissue repair. It is believed that ECMs may provide temporary mechanical support with inherent biological properties that can influence host cell attachment, proliferation and differentiation and ultimately improve tissue healing.

Several commercial products exist with specific indication for the problematic musculoskeletal condition of rotator cuff tendon repair (Aurora et al., 2007). These products include collagen-rich ECMs such as dermis (GraftJacket[®], TissueMend[™], Zimmer[®] Collagen Repair Patch), small intestine submucosa (Restore[®], CuffPatch[®]) and fascia lata (AlloPatch[™]). To date, several retrospective clinical studies (Metcalf et al., 2002; Sclamberg et al., 2004; Malcarney et al., 2005; Labbe, 2006; Dopirak et al., 2007; Burkhead et al., 2007) but only one prospective study with a control group (Iannotti et al., 2006) have been published using either Restore[®] or GraftJacket[®] for rotator cuff tendon repair. Although ECM patches are widely considered to enhance soft tissue healing, the indications and functional requirements for the efficacious use of ECM patches for rotator cuff tendon repair remain to be demonstrated.

We have focused our research on ECM derived from human tensor fascia lata. The tensor fascia lata is the deep fascia of the thigh, originating from the tensor fascia lata muscle and inserting into Gerdy's tubercle at the knee. Auto- and allograft fascia lata has been used for many years in the surgical treatment of soft tissue repairs or reconstructions by orthopaedists (Bright and Green, 1981; Iannotti et al., 2002; Haas et al., 2003; Heikel, 1968) as well as ophthalmologists (Bedrossian, Jr., 1993) and urogynecologists (Handa et al., 1996; Wright et al., 1998; FitzGerald et al., 1999). Basic studies of the biomechanical properties of fresh and processed fascia lata have been published previously (Butler et al., 1984; Hinton et al., 1992; Lemer et al., 1999). Here we characterize the variation and biophysical properties of human fascia lata as well as protocols to substantially decrease the DNA content. Further, we compare the biomechanical properties of fascia lata to other ECM materials derived from dermis and small intestine. Finally, we demonstrate a novel means to increase the suture retention properties of fascia lata.

2. HUMAN FASCIA LATA ECM

We assessed the regional variability, processing methods, mechanical, biochemical and cellular properties of human fascia lata as a scaffold for soft tissue repair and tissue engineering applications (Derwin et al., 2008). Ten pairs of fascia lata (donor age 18 – 55) were used. One fascia patch from each pair was used to assess the geometric and biomechanical variability of fresh fascia. The other from each pair was subjected to one of two allograft processing methods: antibiotic soak alone or acellularization plus antibiotic soak. Stiffness, modulus, hydroxyproline, chondroitin/dermatan sulfate glycosaminoglycan (CSDS GAG) and DNA content were quantified in fascia from fresh and treated groups.

The effect of location was not significant for thickness or stiffness within a 6 x 12 cm region of the iliotibial tract of fresh human fascia lata. Acellularization processing did not significantly change the stiffness, modulus, or CSDS GAG content of fascia ECM. However, hydroxyproline (collagen) content was significantly reduced in acellularized fascia, probably reflecting a removal of soluble collagen during the

treatment ($p < 0.02$). Processing reduced the DNA content of fresh fascia approximately 10-fold ($p < 0.001$). We conclude that the mechanical, chemical and ultrastructural similarities between fascia lata and tendon may make fresh or processed fascia an attractive ECM scaffold for soft tissue, particularly tendon, repair.

3. BIOMECHANICAL PROPERTIES OF ECMS

The mechanical properties of GraftJacket[®] (human dermis), TissueMend[®] (fetal bovine dermis), Restore[®] (porcine small intestine submucosa), CuffPatch[™] (crosslinked porcine small intestine submucosa) and AlloPatch[™] (fascia lata) were quantified and compared (Derwin et al., 2006; Aurora et al., 2007). The elastic moduli were also compared to normal canine

infraspinus tendon. Representative stress-strain (material property) curves from tensile tests of 4 mm wide by 30 mm long samples are plotted in Figure 1. SIS ECM devices (Restore[®] and CuffPatch[™]) reached their linear regions (maximum material properties) after ~20% stretch whereas dermis ECM devices (TissueMend[®] and GraftJacket[®]) reached their linear regions after 50-80% stretch. SIS and dermis ECM devices stretch considerably more than canine infraspinus tendon before reaching their maximum material properties and have linear moduli that are an order of magnitude lower than tendon. In contrast, the linear region strain and modulus of elasticity for fascia lata ECM (AlloPatch[™]) are similar to canine infraspinus tendon (Figure 1) and also to the human supraspinatus tendon (Itoi et al., 1995).

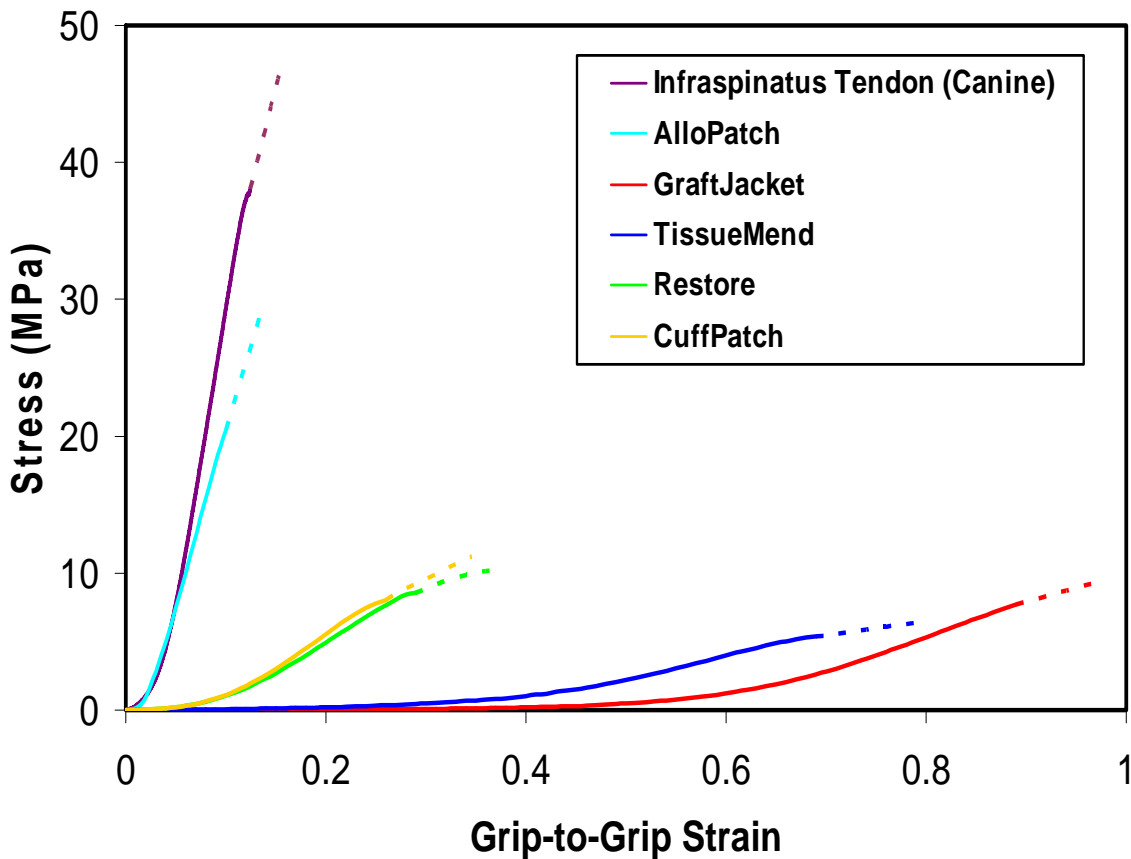


Fig. 1: Representative stress-strain curves for commercially available ECM scaffolds; 4 mm wide by 30 mm long strips were tested (Aurora et al., 2007).

Stiffness is a clinically relevant biomechanical parameter because it accounts for the geometry (size) of the device, not just fundamental material behavior. For instance, GraftJacket[®] is stiffer than Restore[®], CuffPatch[™] and TissueMend[®] because it is a significantly thicker device than these tissues (Derwin et al., 2006). AlloPatch[™] is the stiffest device (Derwin et al., 2008), demonstrating stiffness similar to human infraspinatus tendon (97-171 N/mm)(Halder et al., 2000).

The disparity between the structural and material properties of SIS and dermis ECMs compared to tendon suggests that in their current configuration SIS and dermis devices may not be capable of providing appreciable mechanical reinforcement to primary rotator cuff repairs. In contrast, the similar mechanical properties between fascia lata ECM and tendon, suggest

fascia devices may be able to offer mechanical augmentation.

However, modulus and stiffness alone are insufficient to predict the biomechanical utility of an ECM device. The functional benefit of an ECM graft augmentation procedure also relies on the suture strength of the graft-tendon and/or graft-bone junction. Dermis devices have superior suture retention characteristics compared to SIS or fascia lata (Figure 2). Fascia lata has the lowest suture retention strength of the three ECMs, which may be attributed to the organized nature of its collagen fascicles. Currently, fascia's poor suture retention limits the surgeon's ability to capitalize on its favorable material properties.

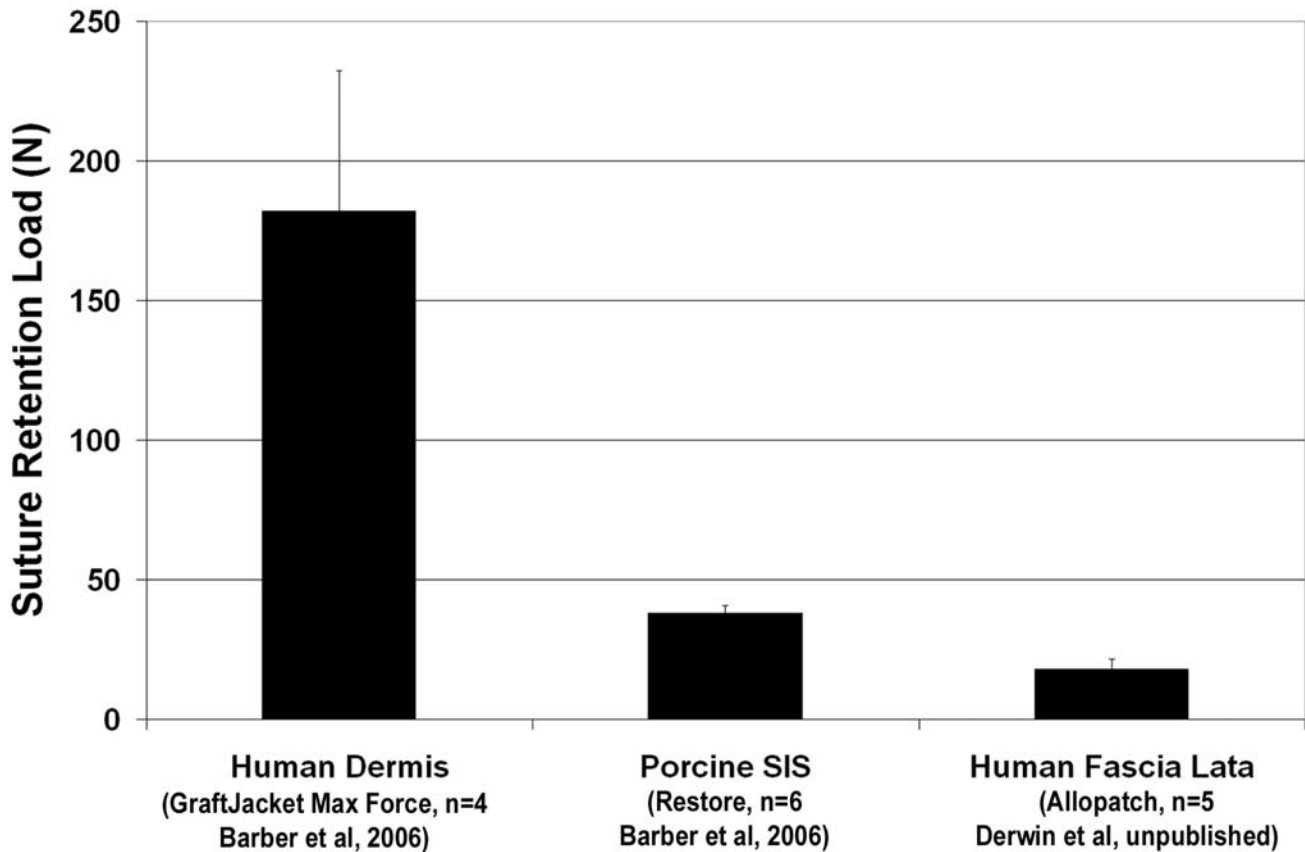


Fig. 2: Suture retention strength of three ECM scaffolds

4. ENGINEERED FASCIA LATA ECM

We have devised a novel means to increase the suture retention properties of fascia lata by developing a composite of fascia lata ECM and biodegradable polymer. We incorporated small amounts of polymer fiber (Concordia Medical, Coventry, RI) into fascia ECM using a proprietary reinforcement technique. Four groups were investigated: native fascia, polylactic acid (PLA) – fascia constructs, polyglycolic acid (PGA) - fascia constructs, polyethylene (PE) – fascia constructs. To quantify suture retention load, a modified ball burst test was used. Circular test samples (4 cm diameter) were prepared with polymer and hydrated for 20 minutes at room temperature in saline. Hydrated constructs were then sutured to a stainless steel ring at 1 cm increments using #2 Fiberwire (Arthrex, Naples, FL) in a simple suture configuration. The fascia-steel ring construct was

cyclically loaded using a 1” diameter stainless steel ball for 10 cycles from 5-15N at 0.25Hz, followed by constant rate distraction to failure at 30mm/min.

The suture retention loads of the polymer-fascia constructs are ~3-fold higher than native fascia (Figure 3). This increase in the suture retention was observed irrespective of the type of polymer used. Further, fascia engineered with polymer had increased stiffness (24.8 ± 2.3 N/mm) compared to native fascia (10.6 ± 1.2 N/mm).

These data demonstrate a novel method to increase the suture retention strength of fascia ECM by ~ 3-fold and stiffness by ~ 2-fold compared to native tissue. We are currently investigating additional polymer techniques as well as the suture retention strength of engineered fascia constructs after simulated *in vitro* degradation and after *in vivo* subcutaneous implantation in rats.

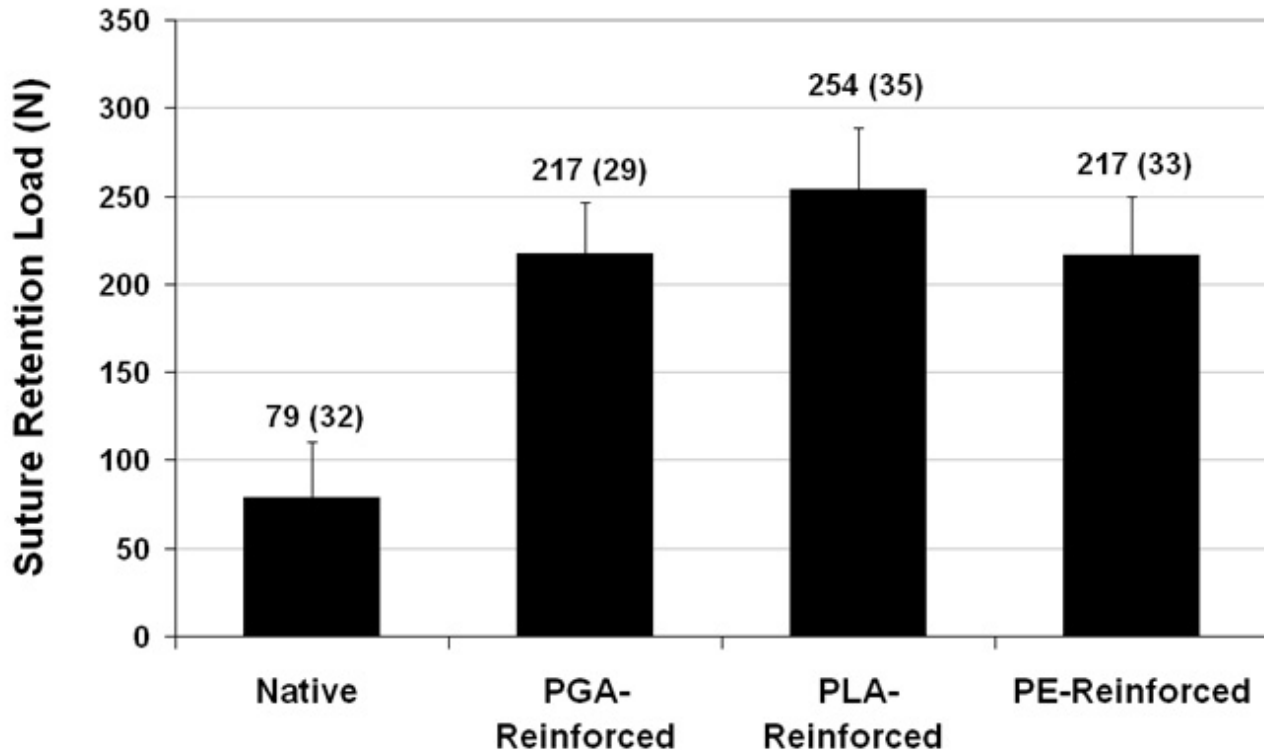


Fig. 3: Suture retention load of various fascia constructs; mean (SD), n=3 per group

CONCLUSIONS

No tissue repair technology currently exists for large tendon and muscle defects that is natural, strong, large, has good suture retention and provides enhanced wound healing. Fascia lata potentially offers all of these advantages based on its mechanical, chemical and ultrastructural similarity to tendon. Engineering fascia to have increased the suture retention strength will support the use of this ECM for musculoskeletal repairs where high mechanical loads are expected. As such, we believe that an engineered fascia device will have indication for augmentation of large tendon defects. An engineered fascia device may also be applicable for ligament repair, extension of rotational muscle transfers, grafting lacerated muscles, periosteal coverage and wound healing. Providing an effective treatment for musculoskeletal conditions such as these promises to have significant impact on both the aging civilian population and as well as the growing numbers of soldiers suffering soft tissue extremity wounds.

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