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Enhanced tendon-to-bone repair through adhesive films

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ABSTRACT

Tendon-to-bone surgical repairs have unacceptably high failure rates, possibly due to their inability to recreate the load transfer mechanisms of the native enthesis. Instead of distributing load across a wide attachment footprint area, surgical repairs concentrate shear stress on a small number of suture anchor points. This motivates development of technologies that distribute shear stresses away from suture anchors and across the enthesis footprint. Here, we present predictions and proof-of-concept experiments showing that mechanically-optimized adhesive films can mimic the natural load transfer mechanisms of the healthy attachment and increase the load tolerance of a repair. Mechanical optimization, based upon a shear lag model corroborated by a finite element analysis, revealed that adhesives with relatively high strength and low stiffness can, theoretically, strengthen tendon-to-bone repairs by over 10-fold. Lap shear testing using tendon and bone planks validated the mechanical models for a range of adhesive stiffnesses and strengths. *Ex vivo* human supraspinatus repairs of cadaveric tissues using multipartite adhesives showed substantial increase in strength. Results suggest that adhesive-enhanced repair can improve repair strength, and motivate a search for optimal adhesives.

Statement of Significance

Current surgical techniques for tendon-to-bone repair have unacceptably high failure rates, indicating that the initial repair strength is insufficient to prevent gapping or rupture. In the rotator cuff, repair techniques apply compression over the repair interface to achieve contact healing between tendon and bone, but transfer almost all force in shear across only a few points where sutures puncture the tendon. Therefore, we evaluated the ability of an adhesive film, implanted between tendon and bone, to enhance repair strength and minimize the likelihood of rupture. Mechanical models demonstrated that optimally designed adhesives would improve repair strength by over 10-fold. Experiments using idealized and clinically-relevant repairs validated these models. This work demonstrates an opportunity to dramatically improve tendon-to-bone repair strength using adhesive films with appropriate material properties.

Abbreviations: PBS, phosphate buffered saline; x, position along adhesive lap; $\tau(x)$, shear stress in the adhesive layer; τ_{fail}, failure shear stress of adhesive; E_b, bone elastic modulus; E_t, tendon elastic modulus; G_a, adhesive shear modulus; t_t, tendon thickness; t_a, adhesive thickness; t_b, bone thickness; P_{max}, force P causing joint failure; χ, variable related to geometry and material properties; THPC, tetrakis (hydroxymethyl) phosphonium chloride; L, adhesive lap length; τ_{ave}, average shear stress, i.e., P/wL; $\bar{\sigma}_t(x)$, normal stress in tendon normalized by normal stress at $x = 0$; x/L, position along adhesive lap normalized by lap length; E_t^*, tendon elastic modulus normalized by bone elastic modulus; G_a^*, adhesive shear modulus normalized by bone elastic modulus; t_t^*, tendon thickness normalized by bone thickness; t_a^*, adhesive thickness normalized by bone thickness; P, normal force across joint far from insertion, i.e., $x = 0$ and $x = L$; $L_{intersect}$, lap length where asymptotic limits for load transfer intersect; β, characteristic (inverse) length scale related to geometry and material properties.

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1. Introduction

Tendon-to-bone repair presents a challenging mechanical problem: repairs require strength and resilience to accommodate forces from activities of daily living and to avoid repair site elongation or rupture; however, the strong anchor sutures used for repairs cause stress concentrations that limit attachment strength. This is compounded by stress concentrations associated with the mismatch between compliant tendon and stiff bone [1]. The healthy tendon enthesis facilitates load transfer from tendon to bone in several ways, including by (*i*) distributing force over a relatively large footprint area to reduce local stresses, (*ii*) using a compliant transitional fibrocartilaginous tissue to minimize stress concentrations and toughen the attachment [2–5], and (*iii*) using randomness of composition and structure to distribute stress during failure [6].

Surgical repairs have high failure rates, possibly because they not only fail to recreate these resilience mechanisms, but also introduce stress concentrations at sutures. For example, rotator cuff healing after repair is notoriously challenging, with post-repair rupture rates ranging from 20% for young, healthy patients with small tears to as high as 94% for massive tears in elderly patients [7,8]. These failure rates are not surprising from a mechanical perspective. While current double-row suture bridge repair techniques apply compression to the tendon over a large portion (78%) of the bony footprint [9], almost all of the force from muscle to bone is transferred in shear across only two anchor points, where the suture from a bone anchor punctures through the tendon near the musculotendinous junction (Fig. 1A). These stress concentrations, coupled with possible vascular compromise in the same region due to strangulation from inappropriately tensioned repairs [10], lead to the vast majority (86%) of rotator cuff repair ruptures by the tendon pulling through the sutures at those anchor points [11]. Approaches that distribute shear stresses and increase strength without causing tissue strangulation would theoretically decrease failure rates. Approximately half of the US population over 60 years old has a rotator cuff tear, leading to over 500,000 repairs annually [12]. With a growing aging and elderly population, improving on these failure rates is critical to reinstate shoulder function in these patients.

Here, an adhesive-film based approach is proposed to augment standard tendon-to-bone repairs, with a particular focus on supraspinatus tendon rotator cuff repairs for proof-of-concept. This adhesive-based surgical augmentation mimics the natural stress distribution across the repair site to improve repair strength and limit ruptures. We hypothesized that, unlike conventional suture repairs with only a few anchor points (Fig. 1A), this adhesive repair scheme would reinstate load transfer over the entire tendon-to-bone insertion footprint (Fig. 1B). This increase in load transfer is expected to result in an improvement in overall repair construct mechanical properties, similar to an adhesive-coated suture case we examined previously [13]. Achieving the full strength of a healthy tendon enthesis may not be necessary, since the enthesis can accommodate higher loads than are applied physiologically during non-traumatic activities. We therefore aim to generate functional repairs that are capable of sustaining activities of daily living and enhanced rehabilitation protocols.

Following a similar approach to [13], we employed a shear lag analysis to predict the ability of adhesive interlayers to improve load transfer across a repaired tendon-to-bone enthesis. We then analyzed a finite element model with the same geometric and material properties to establish the limits of the scaling law from shear lag analysis for adhesive thickness and adhesive shear modulus. Using these models, we identified desirable adhesive mechanical properties for use in adhesive films for tendon-to-bone repair. We then biomechanically tested adhesives between tendon and bone planks and in human cadaver rotator cuff repairs to validate the models and assess adhesives' potential for clinical usefulness.

2. Theory

2.1. Shear lag model

A shear lag model was studied to (*i*) identify adhesives with desirable properties for tendon-to-bone repair, and (*ii*) anticipate load transfer in idealized experiments to assess adhesive properties. The model predicted load sharing across an idealized tendon-to-bone insertion site using an interposed adhesive layer at the interface. The idealized repaired tendon and bone were both modeled as isotropic, homogenous tissue planks for this one-dimensional model.

The model, following Volkersen [15] and Cox [16], is based upon the free body diagram in Fig. 2A,B and the following assumptions: (*i*) the tendon, adhesive, and bone are linear elastic materials, (*ii*) viscous effects are negligible, and (*iii*) thickness-axis displacements, strains, and stresses are small. The latter assumption is appropriate for thin adhesive layers. These results are also corroborated by 2-dimensional finite element modeling with

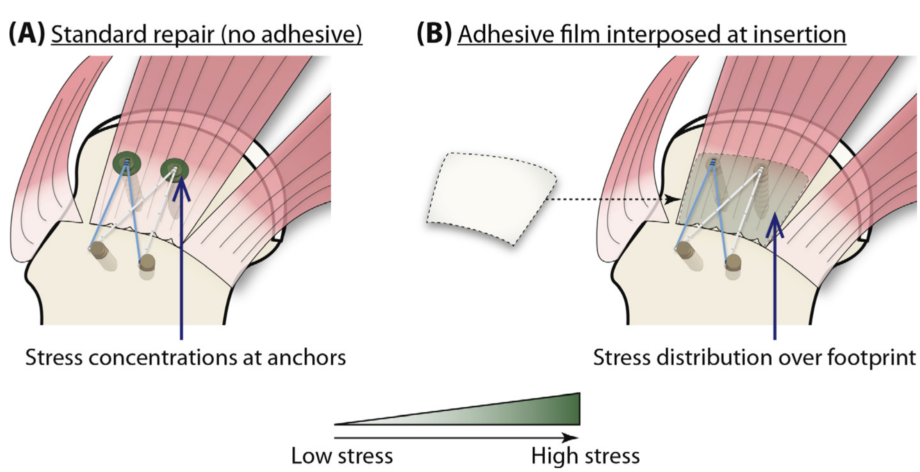

Fig. 1. A double-row suture bridge technique is shown for repairing human supraspinatus tendon tears [14]. Green shading indicates location and magnitude of load transfer. (A) Current repair techniques generate stress concentrations at anchor points where the sutures from bone anchors puncture through the tendon, correlating with tissue failure at those points [11]. (B) Adhesive films interposed between the tendon and bone could distribute load transfer over the entire insertion footprint, similar to native tissue, thereby reducing peak stresses and improving overall repair construct mechanics.

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