INTRODUCTION

Rotator cuff tears affect 40% of people upwards of the age of 60, which raises the importance of the orthopedic treatment. However, even with surgical apposition the poor innate healing properties of these tissues result with high re-tear rates [1]. 20%-70% of rotator cuff repairs fail within 6-12 weeks after the operation, where the failure commonly occurs at the suture-tendon interface [2]. Early mechanical overload post-surgical repair and incomplete regeneration of the native tissue are contributing causes for this failure. Electrospinning has become a promising field of study in tissue engineering because electrospinning synthetic polymer scaffolds has advanced the feasibility of replicating material and mechanical properties of the native tendon. Therefore, presenting a promising means to reduce the high failure rate in surgical rotator cuff repair. However, current commercially available scaffolds provide poor load bearings when compared to that of native tendon.

Poly (L-Lactic) Acid (PLLA), a polymer known to possess high mechanical properties, can obtain high mechanical strength when electrospun. Furthermore, co-electrospinning PLLA with Gelatin, a processed type I collagen, mixed with tendon extracellular matrix (tECM) components can be used to match that of the extracellular matrix of native tendon, which is predominantly type I collagen. A PLLA-Gelatin/tECM scaffold would provide early mechanical and biological support for healing tendon by inducing native cues of regeneration that tendon alone poorly produces. Along with the scaffolds assistive regeneration property, the scaffold is also biodegradable at a rate that it can promote tendon healing and then degrade before being rejected by the body.

Furthermore, collagen in tendon run parallel and when the sutures experience tension they shear between the collagen experiencing little resistance, thus explaining why the suture-tendon interface is the common location of failure. Utilizing textile techniques, such as braiding, distributes applied forces on the scaffold in various directions and in doing so increasing the scaffolds uniaxial tensile strength. With these scaffolds possessing the necessary biocompatibilities and mechanical properties they can accompany surgically repaired tendon to decrease the current issue of a high failure rate.

OBJECTIVE

The objective of this study is to electrospin synthetic PLLA-Gelatin/tECM braided scaffolds that replicate native tendon and can be clinically used to decrease the high failure rate of surgically repaired rotator cuff tendon. Approaching this study we established that the initial focus was the fabrication of the scaffold that can match the mechanical properties of healthy native tendon.

HYPOTHESIS

Current commercially available synthetic polymer scaffolds lack either the mechanical or biological properties needed for support during the early healing period. However, a scaffold containing PLLA and Gelatin/tECM should be able to support a damaged tendons mechanical and biological needs during the early period of healing Therefore, we propose that the failure rates of surgically repaired rotator cuff tendon can improved by suturing a PLLA-Gelatin/tECM electrospun scaffold to the suture-tendon interface.

METHOD

In regard to commercially available polymers, Poly-(L-lactic) acid (PLLA) possesses high mechanical properties and is the main contributor to the strength of the scaffold. PLLA was most efficient during electrospinning when dissolved in a solution containing 10% (mass/volume or m/v) PLLA and a 4:1 (v/v) mix of Dichloromethane (DCM) to Dimethylflouride (DMF). Additionally, Gelatin/tECM contributes to the biocompatibility of the scaffold as tECM excretes growth factors to promote cellular proliferation within the damaged tendon. Gelatin/tECM appeared to be most efficient dissolved in a solution consisting of 20% (m/v) Gelatin/tECM, 60% (v/v) acidic acid, and 0.9% (m/v) NaCl.

The PLLA and Gelatin/tECM solutions were each loaded into syringes to undergo electrospinning. Electrospinning utilizes an electrical charge that guides the nanofibers, drawn from a syringe, onto a grounded collector, which continuously collects the fibers, consequently forming a fibrous sheet. Figure 1 portrays the apparatus used during the electrospinning process.

Figure 1. An electrospinning apparatus. Gelatin/tECM and PLLA solutions are loaded into syringes (present on opposite sides of the collector) with a voltage applied to the needle of each syringe. The charge applied continuously draws the fibers from the needle and onto the grounded collector (represented as the mandrel in the middle).
PLLA and Gelatin/tECM have their own set of corresponding electrospinning parameters that were, referred to as the optimal electrospinning parameters. Table 1 displays these parameters.

### Optimal Electrospinning Parameters

<table>
<thead>
<tr>
<th></th>
<th>Flow Rate (ml/hr)</th>
<th>Applied Voltage (KV)</th>
<th>Needle Gauge</th>
<th>Collector Distance (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PLLA</td>
<td>2.0</td>
<td>17</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>Gelatin/tECM</td>
<td>1.2</td>
<td>24</td>
<td>22</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 1. Displays optimized parameters of the electrospinning process of PLLA and Gelatin/tECM.

Prior to constructing the various scaffolds it was essential to determine the fiber distribution across the produced fibrous sheet. A scanning electron microscope (SEM) was used to determine if there would be a homogenous distribution of PLLA and Gelatin/tECM throughout the scaffold.

Proving a homogenous distribution, the fibrous sheet was cut to construct three types of scaffolds: braided, rolled, and layered scaffolds, where the layered scaffolds acted as a control. Consistence was kept by contributing an equal volume of fibers across each scaffold. Once prepared the constructed scaffolds were exposed to uniaxial tensile loading to characterize their mechanical properties. Each scaffold was clamped into a mechanical testing device that pulled the scaffolds at a rate a 1 mm/sec until failure, where the force (N) and displacement (mm) of the scaffold are recorded.

### RESULTS

SEM images, Figure 2, were taken of the fibrous sheet to determine a homogeneous distribution of fibers. Figure 2.a & b show that the fiber diameter of PLLA is greater than that of Gelatin; as expected knowing that PLLA possesses greater mechanical strength. In Figure 2.c it is apparent that both thick and thin fibers are uniformly distributed, thus concluding that the fibrous sheet created from electrospinning has in fact a homogeneous distribution of PLLA and Gelatin fibers.

![Figure 2. SEM images (1000x) of electrospun nanofibers of (A) PLLA (B) Gelatin/ECM and (C) PLLA+Gelatin/ECM co-spun with Gelatin/ECM.](image)

The collected data from the mechanical is represented by the three curves in Figure 3. These curves characterize their respective scaffolds mechanical properties such as yield load, ultimate load, and stiffness.

![Figure 3. Load-Displacement curves for the braided scaffold (blue), rolled scaffold (red), and the plied scaffold (green).](image)

The representation of mechanical properties in Figure 3, shows that the plied scaffolds expressed a greater stiffness than both the rolled and braided scaffolds. However, the yield and ultimate loads of the braided scaffold are greater than that of the plied scaffold and approximately equivalent to that of the rolled scaffold. As a result of this conclusion it can be said that braiding does in fact increase a scaffolds mechanical strength.

### DISCUSSION

Current commercially available scaffolds are unable to support surgically repaired rotator cuff tendon because they do not possess both the mechanical and biological properties needed for successfully functionality during implantation. SEM imaging confirmed a homogeneous distribution of PLLA and Gelatin nanofibers throughout our electrospun scaffolds. Additionally, our results showed that both braided and rolled scaffolds have a higher mechanical strength than the plied scaffold. The results of these tests support our initial hypothesis that braiding PLLA-Gelatin/tECM can be used to better support rotator cuff tendon repair than currently commercially available scaffolds.

Meeting mechanical testing objectives we plan to determine biocompatibility and bioactivity of the scaffolds. Progressing in this direction would be to conduct in vivo experiments in small animal models and, ultimately, clinical application, once receiving FDA approval.

### ACKNOWLEDGMENTS

- Department Of Orthopedic Surgery
- University of Pittsburgh

SUPPORT: CATER 5T32-EB001026, DEPT. OF DEFENSE GRANT #W81XWH-11-2-0143, PA COMMONWEALTH DEPT. OF HEALTH #SAP4100050913

### REFERENCES
