INTRODUCTION

The objective of the current study was to assess the extent to which augmentation of a primary human rotator cuff repair with a novel reinforced fascia patch can reduce gap formation during in vitro cyclic loading. Our hypothesis was that tendon repairs augmented with a reinforced fascia patch would have significantly less gap formation and increased cycles to failure compared to non-augmented tendon repairs.

MATERIALS AND METHODS

I. Surgical Method: Nine pairs of human cadaveric shoulders had their supraspinatus tendon sharply dissected at its insertion and repaired with two mattress sutures (Fig 1). The intervals between the supraspinatus and its adjacent tendons were closed using two simple sutures. Shoulder pairs were randomized for augmentation with a reinforced fascia lata patch. The patch was fixed to the specimen under 10N of anterior-posterior and medial-lateral tension with simple sutures two bone anchors.

II. Markers for Measuring Tendon Gapping: Using a custom arthroscopic device, two 1.6mm tantalum beads were embedded within the tendon just medial to the primary repair suture line, 1 cm apart in the anterior-posterior direction. One tantalum bead was embedded into the humeral head at the lateral margin of the repair footprint, flush with the bone surface. During cyclic biomechanical testing, the position of the tendon beads was measured with respect to the bone bead to provide a measure of tendon gapping.

III. Biomechanical Testing: Humeri were fixed in aluminum pots with Cerrobend. The supraspinatus muscle belly was gripped with a custom cryo-clamp and aligned with the actuator direction of pull of an MTS system. The infraspinatus and subscapularis muscle bellies were clamped and held with 70N of static force along their anatomic directions of pull. The supraspinatus underwent a loading protocol of 5-180N at 0.25Hz for 1000 cycles in air, at room temperature, and kept moist with intermittent saline spray. Live, magnified fluoroscopy, sampling at 8 frames per second (fps) was used to determine the position of each tendon bead and the bone bead on fluoroscopic images from the peaks and valleys of select cycles. The one-dimensional, in-axis distances between each tendon bead and the bone bead were calculated and averaged for each specimen/cycle. To validate the fluoroscopic method, comparison to a standard optical method was made in six of the primary repairs using additional tantalum beads affixed to the surface of the tendon just medial to the embedded beads. These surface beads were visible using both fluoroscopy and standard optical methods. The RMS error between the two methods was 0.18 ± 0.07 mm over 1000 cycles, demonstrating that they provide essentially identical results.

IV. Measuring Tendon Gapping: Custom texture correlation software was used to determine the position of each tendon bead and the bone bead on fluoroscopic images from the peaks and valleys of select cycles. The one-dimensional, in-axis distances between each tendon bead and the bone bead was computed and averaged for each specimen/cycle. To validate the fluoroscopic method, comparison to a standard optical method was made in six of the primary repairs using additional tantalum beads affixed to the surface of the tendon just medial to the embedded beads. These surface beads were visible using both fluoroscopy and standard optical methods. The RMS error between the two methods was 0.18 ± 0.07 mm over 1000 cycles, demonstrating that they provide essentially identical results.

RESULTS

Table 1 summarizes the tendon gap formation at cycles 1, 10, 100 and 1000 for both the non-augmented and augmented repair groups. Augmentation significantly decreased the amount of gap formation at all cycle points (p<0.01) (Fig 2). In addition, three non-augmented specimens failed to remain intact for the duration of testing—and one failed during the first loading cycle. No augmented specimens failed prior to completion of testing.

Table 1: Tendon gapping for augmented and non-augmented tendon rotator cuff tendon repairs subjected to cyclic loading.

<table>
<thead>
<tr>
<th>Cycle #</th>
<th>Augmented (Mean ± SD)</th>
<th>Non-Augmented (Mean ± SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3.6 ± 1.0 [n=9]</td>
<td>1.8 ± 0.6 [n=9]</td>
<td>0.004</td>
</tr>
<tr>
<td>10</td>
<td>4.3 ± 1.1 [n=8]</td>
<td>2.3 ± 0.7 [n=9]</td>
<td>0.005</td>
</tr>
<tr>
<td>100</td>
<td>5.8 ± 1.1 [n=7]</td>
<td>3.4 ± 1.0 [n=9]</td>
<td>0.007</td>
</tr>
<tr>
<td>1000</td>
<td>7.3 ± 1.3 [n=6]</td>
<td>4.7 ± 1.4 [n=9]</td>
<td>0.004</td>
</tr>
</tbody>
</table>

DISCUSSION

This work presents a clinically relevant cadaver model to assess the extent to which augmentation of a rotator cuff repair with a reinforced fascia patch can reduce gap formation during in vitro cyclic loading. The average gap formation of the augmented repairs was 1.8 mm after the first cycle of pull (versus 3.6 mm for non-augmented repairs) and remained less than 5 mm after 1000 cycles of loading. During the testing protocol, augmented repairs gapped 40% less than non-augmented repairs. Such a reduction in gap formation becomes increasingly clinically relevant for primary repairs that would otherwise gap 5 – 10 mm or more in the absence of augmentation.

In addition to a reduction in cyclic gap formation, all augmented repairs were able to complete the cyclic loading protocol while three of nine non-augmented repairs underwent catastrophic failure prior to completion. The ability to eliminate this 33% repair construct failure rate by applying a reinforced fascia patch to the primary repair construct is of significant potential clinical value.

SIGNIFICANCE

This study supports the potential use of reinforced fascia patches to provide mechanical augmentation, minimize tendon retraction and possibly reduce the occurrence of rotator cuff repair failure.

REFERENCES


ACKNOWLEDGEMENTS

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