Rotator Cuff Repair Augmentation in a Canine Model Using a Woven PLLA Device

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Introduction
Scaffolds derived from extracellular matrix (ECM) are commercially available for augmentation of rotator cuff repair. Despite the current clinical use of ECMS for rotator cuff repair, the clinical data show mixed results with regard to surgical outcomes and complication rates. Further, the ability of any ECM device to improve healing rates of rotator cuff repair in a prospective, controlled clinical study has yet to be demonstrated. Hence, there remains a need to establish an effective strategy for rotator cuff augmentation. Herein we investigate the use of a newly designed PLLA repair device for rotator cuff repair augmentation (X-Repair, Synthasome Inc., San Diego, CA). The purpose of this study was to evaluate the extent to which augmentation of acute rotator cuff tendon repairs with X-Repair would improve biomechanical outcomes in a canine model. Our primary hypotheses were two-fold: (1) repairs augmented with X-Repair would have increased biomechanical properties at time zero than repairs without augmentation, and (2) repairs augmented with X-Repair would have less tendon retraction and increased biomechanical properties after 12 weeks of healing than repairs without augmentation.

Materials and Methods
Eight adult, male mongrel dogs (~30kg) underwent bilateral shoulder surgery as approved by the IACUC at our institution. Both shoulders received the same tendon injury: partial release of the superior 8-9 mm of the infraspinatus tendon, which constitutes ~ 2/3 of the full tendon width. One shoulder underwent tendon release and repair only, and the other was subjected to release and repair followed by augmentation with a woven PLLA scaffold (X-Repair). The scaffold was affixed under tension (to the tendon medially with suture and to bone laterally with a screw-in anchor) so as to “off-load” the repair. At 12 weeks after surgery, the dogs were euthanized. Tendon retraction, stiffness and ultimate load were evaluated. In addition, eight pairs of canine cadaver shoulders underwent infraspinatus injury and repair with and without X-Repair augmentation using identical surgical procedures and served as a time-zero controls. Eight unpaired canine cadaver shoulders were used as normal controls.

Results
X-Repair Device
The X-Repair device used in this study was nominally a 12 mm wide by 34 mm long by 0.8 mm thick woven PLLA graft. The stiffness and ultimate load of the X-Repair device when clamped and tested in air at 30 mm/min were 195 ± 2 N/mm and 796 ± 34 N respectively (n=3). Further, the ultimate load for retention of three, simple, 2-Fiberwire sutures in X-Repair was 397±18N (n=5).

Time zero
At time zero, there was no difference in stiffness between unaugmented and augmented repairs (Fig 1, p=0.76). However, the ultimate load of augmented repairs averaged 133 ± 143 N (23%) more than unaugmented repairs at time zero (Fig 2, p=0.034).

12 weeks of healing
At 12 weeks, all of the repairs were considered to show tendon repair retraction to some extent (Table 1). Tendon retraction was significantly less in augmented shoulders than unaugmented (p=0.008). Five of eight unaugmented repairs gapped by at least 2 cm, whereas, five of eight augmented repairs gapped 1 cm or less and none of the augmented repairs gapped more than 2 cm.

After 12 weeks, the stiffness of augmented repairs averaged 44 ± 26 N/mm (26%) more than paired, unaugmented repairs (Fig 1, p=0.002). Further, at 12 weeks the ultimate load of augmented repairs averaged 246 ± 143 N (35%) more than paired, unaugmented repairs (Fig 2, p=0.009). The stiffness and ultimate load of all 12 week repairs remained significantly less than normal at 12 weeks (Figs 1, 2; p=0.034).

Discussion and Conclusions
At time zero graft augmentation significantly increases the ultimate load of the repair construct, which is likely due to having five points of repair fixation rather than three. However, graft augmentation does not increase the stiffness of the repair construct, despite using a device with similar structural properties as the tendon and deliberately pre-tensioning the device so as to off-load the repair. This result suggests that the ability of any graft to increase repair stiffness when applied in this manner is limited by the “soft” suture connections between the graft and the tendon, at least in the canine model.

During 12 weeks of healing, repair augmentation with the X-Repair device prevented massive (> 2 cm) tendon retraction and maintained a connected tendon-bone bridge. The relevance of this outcome is made manifest by the significant relationship found in this study as well as others between “repair gap distance” and both stiffness and ultimate load: repairs that retract less have higher stiffness and ultimate load. Hence, achieving less retraction by way of device augmentation translates into a stiffer and stronger tendon repair. Further, at 12 weeks repairs augmented with X-Repair demonstrated significantly greater stiffness (26% more on average) and ultimate load (35% more on average) than repairs that had not been augmented. The increase in repair biomechanics may arise at least in part from the device becoming integrated with the underlying tendon via in-growth of host tissue.

<table>
<thead>
<tr>
<th>Repair Retraction</th>
<th>Unaugmented</th>
<th>Augmented</th>
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<tbody>
<tr>
<td>≤ 1 cm</td>
<td>1 of 8</td>
<td>5 of 8</td>
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<tr>
<td>1-2 cm</td>
<td>2 of 8</td>
<td>3 of 8</td>
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<tr>
<td>≥ 2 cm</td>
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In summary, this study showed that PLLA graft augmentation reduces tendon repair retraction and improves the stiffness and ultimate load of the repair at 12 weeks in the canine model. It should be noted that the 12 week time point did not allow us to investigate the longer-term effects of PLLA graft augmentation on the biomechanics of tendon repair. While limiting but not eliminating tendon repair retraction, the graft also appears to serve as a tendon-bone bridge and scaffold for host tissue deposition and in-growth, resulting in improved repair biomechanical properties. These data suggest that such a graft, applied in a similar manner, might offer a similar functional benefit to human patients undergoing rotator cuff repair surgery.

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