Biomechanical Analysis of Rotator Cuff Repairs With Extracellular Matrix Graft Augmentation

Erin E. Ely, MD; Nathania M. Figueroa, MD; Gregory J. Gilot, MD

The goals of rotator cuff (RTC) repair are to achieve high initial fixation strength, minimize gap formation during the repair and gap formation prior to healing. This study evaluated the gap formation and ultimate tensile failure loads of a RTC repair with a decellularized human dermal allograft. Augmentation of a RTC repair with an extracellular matrix graft decreased gap formation and increased load to failure in a human RTC repair model. [Orthopedics. 2014; 37(9):608-614.]

Abstract: Despite advances in surgical techniques, 20% to 90% of rotator cuff (RTC) repairs fail. They tend to fail at the suture-tendon junction due to tension at the repair and gap formation prior to healing. This study evaluated the gap formation and ultimate tensile failure loads of a RTC repair with a decellularized human dermal allograft. Augmentation of a RTC repair with an extracellular matrix graft decreased gap formation and increased load to failure in a human RTC repair model. [Orthopedics. 2014; 37(9):608-614.]

The authors are from the Department of Orthopaedic Surgery, Cleveland Clinic, Weston, Florida.

The authors have no relevant financial relationships to disclose.

Correspondence should be addressed to: Erin E. Ely, MD, Department of Orthopaedic Surgery, Cleveland Clinic, 2950 Cleveland Clinic Blvd, Weston, FL 33331 (eely@slu.edu).

Received: February 26, 2014; Accepted: May 13, 2014; Posted: September 9, 2014.

doi: 10.3928/01477447-20140825-05

Few studies exist evaluating the outcomes and the biomechanical properties of RTC repair augmented with ECM graft. Derwin et al15 compared the biomechanical, biochemical, and cellular properties of 5 commercially available ECM scaffolds. They found that the elastic moduli of the grafts were lower than that of a tendon and thus play a limited mechanical role in RTC augmentation. Barber et al16 concluded that RTC repair augmented with GraftJacket (Wright Medical Technologies, Arlington, Tennessee), a human dermal graft, improved load to failure by a statistically significant amount. However, load sharing, including cyclic loading, and gap formation were not studied. Shea et al14 showed that the application of a xenograft ECM (Conexa; Tornier, Edina, Minnesota) decreased gap formation and increased load to failure by a statistically significant amount in a cadaveric model. Barber
et al.\(^{17}\) have performed several biomechanical studies evaluating ECM scaffold grafts. They found that ECM-augmented RTC repairs increased the load to failure by a statistically significant amount. In addition, dermis was significantly stronger than porcine small intestinal submucosa, and human dermis was significantly stronger than xenograft. They also found that human dermal grafts were significantly stronger than polyurethane urea fabric and pericardium xenografts after cyclic loading.\(^{18}\)

The purpose of this study was to compare the biomechanical results of RTC repair with and without human dermal allograft augmentation. The hypotheses of this study were as follows:

1. The gap formation at the free edge of the repaired RTC following 200 cycles would be significantly smaller in the shoulders reinforced with an ECM graft compared with the control.
2. The yield load would be significantly increased in the ECM-augmented repair compared with the control.
3. The stiffness of the ECM-augmented repair would be significantly increased compared with the control.
4. The ultimate load to failure would be significantly increased in the ECM-augmented repair compared with the control.

**Materials and Methods**

Eleven matched pairs of fresh-frozen cadaveric shoulders were thawed to room temperature and dissected free of soft tissue to isolate an intact supraspinatus muscle tendon. Four female and 7 male cadavers were used, with a mean age of 54.7 years (range, 44-64 years) (Tables 1-2). Specimens were kept moist at room temperature with saline during the entire experiment. One randomly selected shoulder from each matched pair served as the control. In the control shoulder, the supraspinatus tendon was detached from the humerus at its insertion site on the greater tuberosity and then reattached in the same location using a modified, double-row, transosseous equivalent (DR TOE) repair using 2 Bio-Corkscrew Anchors (Arthrex, Naples, Florida) medially at the lateral margin of the anatomic footprint to create a medial row. The anchors were inserted according to the manufacturer’s instruction. One anchor was double loaded with high-strength sutures and the other was triple loaded. A combination of simple and mattress sutures were passed through the tendon 2 to 3 mm lateral to the muscle-tendon junction with the use of the Scorpion (Arthrex) suture passing device. The most anterior and posterior sutures from opposite anchors were tied in a simple fashion with a sliding-locking arthroscopic knot followed by 2 alternating half hitches and cut with 2- to 3-mm tails. The 3 innermost sutures were passed similarly in a mattress fashion with a sliding-locking arthroscopic knot followed by 2 alternating half hitches and cut with 2- to 3-mm tails. The 3 innermost sutures were passed similarly in a mattress fashion and tied. Alternating limbs of the 3 mattress sutures were crisscrossed and loaded into 1 of 2 Bio-SwiveLock Anchors (Arthrex) and then inserted into cortical bone along the great-

<table>
<thead>
<tr>
<th>Donor Number</th>
<th>Age (y)/Sex</th>
<th>Side</th>
<th>Ultimate Load (N)</th>
<th>Yield Load (N)</th>
<th>Stiffness (N/mm)</th>
<th>Video Tracking Displacement (mm)</th>
<th>Mode of Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>45/M</td>
<td>R</td>
<td>605</td>
<td>317</td>
<td>60</td>
<td>0.9</td>
<td>Medial row anchor pullout and tendon tearing</td>
</tr>
<tr>
<td>2</td>
<td>51/F</td>
<td>L</td>
<td>562</td>
<td>562</td>
<td>32</td>
<td>2.7</td>
<td>Medial row anchor pullout and tendon tearing</td>
</tr>
<tr>
<td>3</td>
<td>55/F</td>
<td>R</td>
<td>449</td>
<td>449</td>
<td>40</td>
<td>1.5</td>
<td>Tendon torn by sutures</td>
</tr>
<tr>
<td>4</td>
<td>56/M</td>
<td>R</td>
<td>653</td>
<td>591</td>
<td>69</td>
<td>3.7</td>
<td>Medial row anchor pullout and tendon tearing</td>
</tr>
<tr>
<td>5</td>
<td>62/M</td>
<td>L</td>
<td>458</td>
<td>434</td>
<td>52</td>
<td>2.7</td>
<td>Tendon torn by sutures</td>
</tr>
<tr>
<td>6</td>
<td>57/F</td>
<td>R</td>
<td>580</td>
<td>436</td>
<td>50</td>
<td>4.0</td>
<td>Medial row anchor pullout</td>
</tr>
<tr>
<td>7</td>
<td>64/M</td>
<td>L</td>
<td>397</td>
<td>227</td>
<td>40</td>
<td>4.0</td>
<td>Medial row anchor pullout and tendon tearing</td>
</tr>
<tr>
<td>8</td>
<td>54/F</td>
<td>L</td>
<td>754</td>
<td>754</td>
<td>86</td>
<td>2.1</td>
<td>Medial row eyelet break and tendon tearing</td>
</tr>
<tr>
<td>9</td>
<td>53/M</td>
<td>L</td>
<td>431</td>
<td>412</td>
<td>50</td>
<td>4.8</td>
<td>Medial row anchor pullout and tendon tearing</td>
</tr>
<tr>
<td>10</td>
<td>61/M</td>
<td>R</td>
<td>511</td>
<td>511</td>
<td>48</td>
<td>1.3</td>
<td>Medial row anchor pullout and tendon tearing</td>
</tr>
<tr>
<td>11</td>
<td>44/M</td>
<td>R</td>
<td>662</td>
<td>662</td>
<td>57</td>
<td>3.4</td>
<td>Medial row anchor pullout and eyelet break</td>
</tr>
<tr>
<td>Average</td>
<td></td>
<td></td>
<td>551</td>
<td>487</td>
<td>53</td>
<td>2.8</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td></td>
<td></td>
<td>113</td>
<td>151</td>
<td>15</td>
<td>1.3</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: F, female; L, left; M, male; R, right; SD, standard deviation.
er tuberosity approximately 2 cm lateral to the first row, according to the manufacturer’s instruction. Adequate tension was applied to all 6 suture limbs completing the lateral row TOE repair. The anterior and posterior sutures used to secure the anterior and posterior margins of the repair were not incorporated into the lateral row (Figure 1). The humeral head was covered and the RTC footprint was reestablished. The modified DR TOE was used because it is the preferred method of the lead author (G.J.G.) for arthroscopic RTC repairs.

The other randomly selected shoulder of the matched pair was repaired with the addition of augmentation with ArthroFlex (LifeNet Health, Virginia Beach, Virginia), a decellularized human dermal allograft matrix. The graft measured approximately 5×5 cm with a uniform thickness of 1.5 to 2 mm. The graft was trimmed into a semi-circular shape (Figure 2). The modified DR TOE repair described above was used with incorporation of the graft into the repair. The innermost mattress sutures were left untied and passed through the medial free edge of the graft with the use of a free needle according to the spacing of the mattress sutures. Holding the suture limbs on tension, the graft was placed onto the supraspinatus tendon using a “parachute” technique. The mattress sutures were all tied using a sliding-locking knot as described above. The graft was reduced onto the repair site and enough tension was applied to remove slack. Alternating limbs of the 3 mattress sutures were criss-crossed and loaded into 1 of 2 Bio-SwiveLock Anchors and then inserted into cortical

<table>
<thead>
<tr>
<th>Donor Number</th>
<th>Age (y)/Sex</th>
<th>Side</th>
<th>Ultimate Load (N)</th>
<th>Yield Load (N)</th>
<th>Stiffness (N/mm)</th>
<th>Video Tracking Displacement (mm)</th>
<th>Mode of Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>45/M</td>
<td>L</td>
<td>793</td>
<td>793</td>
<td>72</td>
<td>1.2</td>
<td>Medial row anchor pullout and eyelet break</td>
</tr>
<tr>
<td>2</td>
<td>51/F</td>
<td>R</td>
<td>390</td>
<td>261</td>
<td>47</td>
<td>1.8</td>
<td>Medial row and lateral row anchor pullout</td>
</tr>
<tr>
<td>3</td>
<td>55/F</td>
<td>L</td>
<td>899</td>
<td>899</td>
<td>65</td>
<td>1.0</td>
<td>Medial row eyelet break</td>
</tr>
<tr>
<td>4</td>
<td>56/M</td>
<td>L</td>
<td>666</td>
<td>666</td>
<td>93</td>
<td>1.9</td>
<td>Medial row anchor pullout and tendon tearing</td>
</tr>
<tr>
<td>5</td>
<td>62/M</td>
<td>R</td>
<td>597</td>
<td>597</td>
<td>55</td>
<td>1.7</td>
<td>Medial row anchor pullout and tendon tearing</td>
</tr>
<tr>
<td>6</td>
<td>57/F</td>
<td>L</td>
<td>485</td>
<td>485</td>
<td>47</td>
<td>3.6</td>
<td>Tendon tore at sutures</td>
</tr>
<tr>
<td>7</td>
<td>64/M</td>
<td>R</td>
<td>609</td>
<td>609</td>
<td>47</td>
<td>2.2</td>
<td>Tendon tore at sutures</td>
</tr>
<tr>
<td>8</td>
<td>54/F</td>
<td>R</td>
<td>786</td>
<td>766</td>
<td>58</td>
<td>2.6</td>
<td>Tendon tore at sutures and at freeze clamp</td>
</tr>
<tr>
<td>9</td>
<td>53/M</td>
<td>R</td>
<td>711</td>
<td>711</td>
<td>67</td>
<td>0.9</td>
<td>Medial row eyelet break and tendon tearing</td>
</tr>
<tr>
<td>10</td>
<td>61/M</td>
<td>L</td>
<td>603</td>
<td>501</td>
<td>56</td>
<td>4.7</td>
<td>Medial row anchor pullout and tendon tearing</td>
</tr>
<tr>
<td>11</td>
<td>44/M</td>
<td>L</td>
<td>533</td>
<td>533</td>
<td>83</td>
<td>2.9</td>
<td>Medial row eyelet break and tendon tearing</td>
</tr>
<tr>
<td>Average</td>
<td></td>
<td></td>
<td>643</td>
<td>620</td>
<td>63</td>
<td>2.2</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td></td>
<td></td>
<td>148</td>
<td>176</td>
<td>15</td>
<td>1.2</td>
<td></td>
</tr>
<tr>
<td>Significance (P)</td>
<td></td>
<td></td>
<td>.136</td>
<td>.104</td>
<td>.073</td>
<td>.293</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations: F, female; L, left; M, male; R, right; SD, standard deviation.
bone along the greater tuberosity approximately 2 cm lateral to the first row. Adequate tension was applied to all 6 suture limbs completing the lateral row TOE repair. The anterior and posterior sutures used to secure the anterior and posterior margins of the repair were not incorporated into the lateral row (Figure 3).

Each construct was mechanically tested using an Instron machine (model 8871; Instron, Norwood, Massachusetts). The shaft of the humerus was potted in fiberglass and clamped to a fixed angle device that allowed for the direction of pull to be 45° to the humeral axis. The tendon was secured to the cross head in a custom freezing clamp with dry ice.

Each specimen had a 10-N preload placed through the supraspinatus tendon. Cyclic loading was performed from 10 to 100 N at a rate of 1 Hz for 200 cycles. A tissue marker was used to mark 4 points along the lateral edge of the repaired tendon (within and outside the repair area). One mark was also made on the bone itself. Digital video tracking software (MaxTRAQ and MaxMATE; Innovation Systems, Inc, Columbus, Michigan) was used to compare the relative movement of the tendon markers with that of the bone marker from the first to the 200th cycle. Ultimate load was defined as the highest load reached, and yield load was the first point at which there was no increase in load over 0.5-mm displacement. Stiffness was defined as the slope of the linear portion of the load-displacement curve immediately after cyclic loading and prior to loads above 300 N.

**STATISTICAL ANALYSIS**

The data for the ECM-reinforced repair and the control were averaged by use of SigmaPlot software (Systat Software, Inc, Chicago, Illinois). The data were compared by use of paired t tests to confirm statistical significance at a level of \( P < .05 \) (Tables 1-2). A post hoc power analysis was also performed to determine an adequate sample size for this study. A sample size of 19 is required to achieve a power of 0.8 with an alpha of 0.05, a mean difference of 90 N, and a standard deviation of 130 N (the average of the standard deviations of the 2 groups).

**RESULTS**

**Load**

Ultimate load, or load to failure, was the highest load reached, whereas yield load was the first point at which there was no increase in load over 0.5-mm displacement. Stiffness was defined as the slope of the linear portion of the load-displacement curve immediately after cyclic loading and prior to loads above 300 N. The mean ultimate load to failure was 551±113 N for the control specimens and 643±148 N for the ECM-reinforced specimens (Figure 4). The difference was not statistically significant (\( P = .136 \)). The mean yield load was 487±151 N for the control specimens and 620±176 N for the ECM-augmented specimens. The difference was not statistically significant (\( P = .104 \)).

**Displacement (Gap Formation)**

Displacement was determined with the use of digital video tracking to compare the relative movement of the tendon markers with that of the bone marker from the first to the 200th cycle. Mean displacement after cyclic loading was 2.8±1.3 mm for the control group compared with 2.2±1.2 mm for the ECM-augmented group (Figure 5).
The difference was not statistically significant ($P=0.293$).

**Discussion**

Although surgical repair of large to massive RTC tears has resulted in consistent pain relief and improved function, re- tear rates have remained high despite advances in surgical technique. Failure of the repair is less likely to occur due to weak tendon-to-bone fixation. There have been advances in fixation techniques from the single-row (SR) to the double-row (DR) to the DR TOE. To date, studies show that the DR technique offers twice the footprint coverage compared with the SR technique. Additionally, the DR technique increases initial strength and stiffness while decreasing gap formation and strain when compared with the SR technique. Studies also have shown that the TOE technique restores the footprint dimensions and provides a stronger repair with increased ultimate load to failure when compared with the DR technique.

More likely causes of repair failure include tendon degeneration, fatty atrophy, fatty infiltration of muscle, and lack of tendon vascularity. Therefore, several methods to augment RTC repairs and decrease failure rates have emerged, including autografts of fascia lata, triceps, and biceps, freeze-dried RTC allografts, carbon fibers, and polytetrafluoroethylene felt. In addition, several biologic augmentations have also been studied, including bone morphogenic proteins, fibroblastic growth factors, matrix metalloproteinases, platelet-rich plasma, platelet-rich fibrin matrix, and bisphosphonates. Varying results have been achieved with these methods.

Currently, one of the most common and promising augmentation techniques is the use of ECM scaffold grafts. Extracellular matrix scaffold grafts are 3-dimensional and include the structural and functional proteins, including collagen, elastin, growth factors, and proteoglycans. They act as a biological stimulus to recruit host cells to deposit a tendon-like matrix to improve native tendon healing. In addition, the ECM graft is used to decrease gap formation and increase load sharing, thereby increasing the probability of healing. Few biomechanical studies exist evaluating the biomechanics of an ECM-augmented RTC repair vs control under cyclic loading. Cadaveric analyses of dermal allografts have shown a statistically significant increase in failure loads and a decrease in gap formation. Barber et al used a human dermis allograft and a load-sharing SR technique to show a significant 19% increase in ultimate load in GraftJacket vs controls (325 vs 273 N). They did not evaluate gap formation or stiffness. Shea et al used a DR technique with load sharing through the lateral row and showed a significant 28% increase in ultimate load with the porcine dermal graft Conexa compared with control specimens (429 vs 335 N). In addition, they also showed a significant 38% decrease in gap formation with the use of Conexa compared with control specimens (1.3 vs 2.1 mm). They did not evaluate stiffness of the graft. Furthermore, they recommend pre-tensioning for bioactivity (not biomechanical enhancement), which is difficult to do arthroscopically. The aforementioned studies also secured the draped-over ECM graft to the tendon with simple suture and did not incorporate the graft into the repair.

Beitzel et al used the human dermal allograft ArthroFlex in a TOE repair. They evaluated both an intersection of the graft into the repair and an overlay. The intersection TOE significantly increased failure loads by 35% (470 vs 349 N) and significantly decreased gap formation by 25% (1.8 vs 2.4 mm). The overlay TOE significantly increased failure loads by 65% (576 vs 349 N) and significantly decreased gap formation by

**Table 3**

**Comparison of Cadaver Studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>Graft</th>
<th>Method</th>
<th>Failure Loads (Control vs Augmented)</th>
<th>Gap Formation (Control vs Augmented)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barber et al $^{16}$</td>
<td>GraftJacket</td>
<td>SR load sharing</td>
<td>273 vs 325 N (19%)</td>
<td>NR</td>
</tr>
<tr>
<td>Shea et al $^{14}$</td>
<td>Conexa</td>
<td>DR load sharing (Lateral row)</td>
<td>335 vs 429 N (28%)</td>
<td>2.1 vs 1.3 mm (38%)</td>
</tr>
<tr>
<td>Beitzel et al $^{19}$</td>
<td>ArthroFlex</td>
<td>DR TOE</td>
<td>$^d$349 vs 470 N (35%)</td>
<td>$^d$2.4 vs 1.8 mm (25%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$^e$349 vs 576 N (65%)</td>
<td>$^e$2.4 vs 1.5 mm (37.5%)</td>
</tr>
<tr>
<td>Current</td>
<td>ArthroFlex</td>
<td>Modified DR TOE load sharing (Medial row)</td>
<td>551 vs 643 N (17%)</td>
<td>2.8 vs 2.2 mm (21%)</td>
</tr>
</tbody>
</table>

**Abbreviations:** DR, double row; DR TOE, double-row, transosseous equivalent; NR, not read; SR, single row.

$^a$Wright Medical Technologies, Arlington, Tennessee.

$^b$Tornier, Edina, Minnesota.

$^c$LifeNet Health, Virginia Beach, Virginia.

$^d$DR TOE interposition.

$^e$Overlay.
The current authors used a modified DR TOE with load sharing through the medial row to show an increase of 29% in ultimate load with the human dermal allograft ArthroFlex compared with control specimens (643 vs 551 N). In addition, their gap formation decreased by 21% in the ArthroFlex-augmented group (2.8 mm) compared with the control group (2.2 mm). Although neither result was statistically significant, the graft augmentation did show improvement in both ultimate load and gap formation and did not negatively affect the repair. Pre-tensioning is not recommended with the use of ArthroFlex; the authors’ lateral row is placed in bone, outside of the repair, thereby negating the need for pre-tensioning. Repetitive loading of the RTC repair is thought to be the mechanism that creates gap formation; ECM scaffold grafts help to decrease gap formation by allowing load sharing (Table 3).11,12,14 In addition, the authors’ ultimate load with graft augmentation (643 N) is the first study to most closely approximate the ultimate load of an intact supraspinatus tendon. In 1943, Wilson and Duff determined the failure load of an intact supraspinatus tendon to be 784 N.40 More recently, Itoi et al determined the failure load of the supraspinatus tendon to be 652 N.

The cadaveric model used in the current study is recognized to exhibit biomechanical aspects similar to in vivo RTC repair. The goal of the study was to evaluate whether a human dermal ECM graft has the ability to increase load, decrease gap formation, and increase stiffness of the repair. Although none of the data points were statistically significant, the ultimate load increased, the stiffness increased, and the gap formation decreased. Derwin et al concluded that ECM grafts were not stiff enough to share load with the RTC; however, the current authors have shown that the ECM grafts increase the stiffness of the repair. In addition, this is the first study to examine a modified DR TOE technique with incorporation of the graft into the repair. Furthermore, this experiment is strengthened because the technique is easy to apply to both open and arthroscopic RTC repairs.

This study had a few limitations. First, because cadavers were used, the authors were unable to account for variability in tissue quality. Second, the data may be relevant only to the specific graft tested. Different grafts, even those made with similar material, have different mechanical properties. Third, only time zero behavior of the ECM augmentation in an ex vivo cadaveric model was examined. Tissue changes and biologic reactions over time may affect the biomechanics of the graft.

**CONCLUSION**

This study showed that RTC repair with human dermal allograft ECM scaffold increased the ultimate load to failure by 29% and decreased gap formation by 21% compared with non-augmented controls. In addition, the ultimate load to failure is the first ECM biomechanical study to most closely approximate the ultimate load to failure of a native supraspinatus tendon. The results suggest that the human dermal allograft is able to provide load sharing to protect the repair site during the early healing period. This is a clinically relevant model with a modified DR TOE technique that warrants further in vivo testing.

**REFERENCES**


