



## Biomechanical effect of rotator cuff augmentation with an acellular dermal matrix graft: A cadaver study

Hiromichi Omae<sup>a</sup>, Scott P. Steinmann<sup>b</sup>, Chunfeng Zhao<sup>a</sup>, Mark E. Zobitz<sup>a</sup>, Prasit Wongtriratanachai<sup>a</sup>, John W. Sperling<sup>b</sup>, Kai-Nan An<sup>a,\*</sup>

<sup>a</sup> Biomechanics Laboratory, Division of Orthopedic Research, Mayo Clinic, Rochester, MN 55905 USA

<sup>b</sup> Department of Orthopedic Surgery, Mayo Clinic, Rochester, MN 55905 USA

### ARTICLE INFO

#### Article history:

Received 23 December 2011

Accepted 1 May 2012

#### Keywords:

Dermal graft  
Augmentation  
Rotator cuff  
Biomechanics  
Cadaver study

### ABSTRACT

**Background:** Acellular human dermal matrix grafts (Graftjacket; Wright Medical Technology, Arlington, TN, USA) are used clinically for rotator cuff augmentation without a detailed understanding of their biomechanical effects. The purpose of this study was to evaluate the effect of augmentation with dermal grafts on the biomechanical effects of rotator cuff repairs.

**Methods:** Nine matched pairs of human cadaveric shoulders were used. A single-row rotator cuff repair combined with an augmentation graft was performed on one shoulder, and a single-row repair was performed on the contralateral shoulder as a control. An acellular dermal matrix graft was sutured to the tendon medially and fixed to the humerus laterally. The constructs were preloaded at 10 N and then cyclically loaded between 10 and 180 N for 1000 cycles, followed by tensile testing to failure at 1.0 mm/s.

**Findings:** The maximum load of the augmentation group (560.2 N, SD 95.5) was greater than that of the control group (345.7 N, SD 60.8), while the linear stiffness of the augmentation group (65.2 N/mm, SD 15.6) was less than that of the control group (77.2 N/mm, SD 15.7). Reliable gap distance data were not obtained during cyclic loading in 5 of 9 augmented repairs due to the elasticity of the dermal matrix graft.

**Interpretation:** The dermal matrix graft augmentation increased the maximum load but did not increase the linear stiffness. The elasticity of the dermal matrix graft affected the biomechanical effects of the augmented rotator cuff repairs.

© 2012 Elsevier Ltd. All rights reserved.

### 1. Introduction

Various new techniques for repairing rotator cuff tears have been developed to achieve better postoperative results. These techniques have been reported to decrease gap formation and increase both the area of the footprint and the initial failure load. The use of an augmentation graft is a new procedure for rotator cuff repair. In this procedure, the graft is sutured to the intact tendon (medial to the reattachment site) and to the greater tuberosity (lateral to the reattachment site). Theoretically, muscle contraction forces may be partially transferred to the greater tuberosity through the augmentation graft. This load shielding by the graft may directly protect the underlying repair from gap formation and prevent potential re-rupture of the repair site. The augmentation graft may promote the biological healing of the reattachment site during early rehabilitation programs.

Acellular human dermal matrix grafts have been used for rotator cuff repair both experimentally and clinically (Fini et al., 2007, Wong et al., 2010). Banked human cadaver skin is the source of the

graft tissue intended for transplantation. The epidermis, or the outer layer of skin, and dermal cells are removed to reduce the immune response of the recipient to the material. The intact collagen matrix of the dermis, which includes the native elastin, proteoglycans, basement membrane, and vascular channels, is the only human tissue that remains (Barber et al., 2006).

The purpose of this study was to evaluate the effects of augmentation with a dermal graft on the gap formation and failure properties of a rotator cuff repair using a human cadaveric model. We hypothesized that the dermal augmentation graft would decrease gap formation and increase the maximum load.

### 2. Methods

#### 2.1. Specimen preparation

Following the approval of our institutional review board, nine matched pairs of fresh-frozen human cadaveric shoulders were selected for this study. Specimens with rotator cuff tears that were identifiable through gross observation were not included in this study. There were five male and four female cadavers, with a mean age of 84.4 years (SD 9.1). The shoulder specimens were stored at  $-20^{\circ}\text{C}$  and thawed

\* Corresponding author at: Mayo Clinic, 200 First Street Southwest, Rochester, MN 55905, USA.

E-mail address: [an.kainan@mayo.edu](mailto:an.kainan@mayo.edu) (K.-N. An).

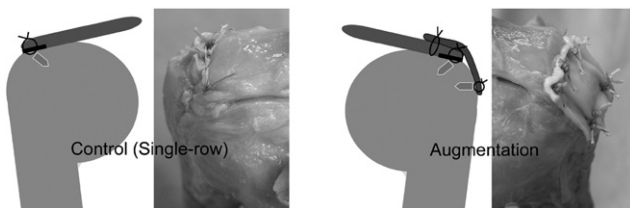
for 24 h at room temperature before dissection. The supraspinatus muscle was sharply dissected to free it from the scapular origin, as was the tendon from its insertion on the greater tuberosity. The posterior supraspinatus and anterior infraspinatus muscles were separated by the scapular spine. However, the posterior supraspinatus and anterior infraspinatus tendons were overlapped and were difficult to isolate at their insertion points. The posterior margin of the supraspinatus tendon was defined as the line that was parallel to the anterior margin of the supraspinatus tendon and connected to the posterior margin of the supraspinatus muscle. All soft tissues except the supraspinatus tendon were dissected from the scapula and proximal humerus. The distal 5-mm section of the supraspinatus tendon was sharply resected to simulate a rotator cuff tear. The distal humerus was cut transversely, approximately 20 cm from the surgical neck. The specimens were kept moist with normal saline solution during the dissection, preparation, and testing.

## 2.2. Repair technique

For each matched pair, one limb was randomly chosen for single-row rotator cuff repair combined with an augmentation graft, and the other limb was used for single-row rotator cuff repair without an augmentation graft as a control. All measurements were collected using calipers to standardize the technique for each specimen. All knots were tied as simple half-hitch knots with a total of five throws.

After each specimen was mounted on the clamp, two holes were punched 5 mm lateral to the articular cartilage edge; the anterior suture anchor was placed 5 mm posterior to the bicipital groove, and the posterior suture anchor was placed 5 mm anterior to the posterior edge of the supraspinatus tendon. The holes were placed at a 45° angle relative to the footprint surface. We used two 5.5-mm Corkscrew FT II anchors (Arthrex, Naples, FL, USA), which were double-loaded with two No. 2 FiberWire sutures. Simple suture configurations were utilized to fix the tendon to the bone. In the anterior–posterior plane, the sutures were passed 7 mm apart and centered over each corresponding suture anchor (Fig. 1).

An acellular dermal graft (Graftjacket regenerative tissue matrix – Maxforce – Extreme, Wright Medical Technology, Arlington, TN, USA) was used in this study. The average thickness of this graft was listed as 2.0 mm in the information provided by the manufacturer. The graft was cut into a rectangular shape with a width of 3.5 cm and a length of 4.0 cm. The graft was sutured to the supraspinatus tendon 5 mm medial to the sutures of the primary repair and 3 mm lateral to the edge of the graft with four horizontal mattress suture configurations using No. 2 FiberWire sutures (Arthrex). Two holes were punched 10 mm lateral to the lateral edge of the footprint. These two holes were parallel to the anchors of the primary repair, and they were placed at a 90° angle relative to the humeral surface. Each 5.5-mm Corkscrew FT II anchor was fixed in a hole. After being sutured to the tendon, the graft was pulled laterally, covering the primary repair, and subsequently pulled inferiorly on the lateral aspect of the humerus with



**Fig. 1.** Schematics of the repair procedures and the respective photographs. In the control group, the rotator cuff was repaired with the single-row suture anchor technique (black bar represents the footprint of the greater tuberosity). In the augmentation group, the dermal graft, covering the primary repair, was sutured to the tendon medially and fixed to the humerus laterally.

a 20-N load applied to the graft for 3 min. This pre-load was chosen to decrease the elasticity of the dermal matrix graft without damaging the supraspinatus muscle of the specimen in the pilot study.

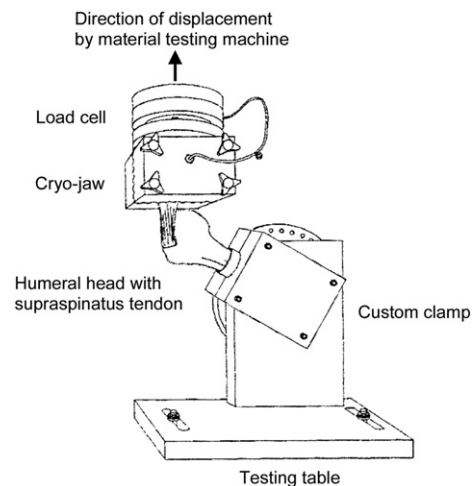
Finally, the graft was sutured to the anchors with four horizontal mattress sutures, while a 10-N load was applied to the graft inferiorly. The suture passes were 7 mm apart and centered over each corresponding suture anchor (Fig. 1).

## 2.3. Biomechanical testing

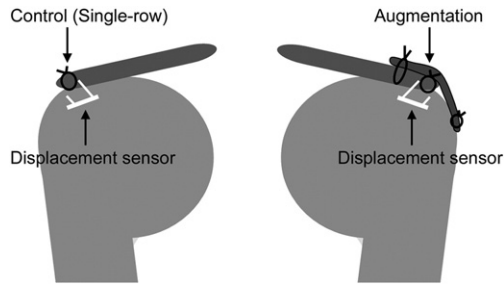
The rotator cuff repair constructs were tested with a multipurpose test machine instrumented with a 5-kN load cell (MTS systems, Model 858 MiniBionix; Eden Prairie, MN, USA). The proximal humerus was potted with bone cement in metal piping and secured with two Kirschner wires. The potted specimen was then secured in 30° of glenohumeral abduction and neutral rotation using a custom clamp (Park et al., 2007). When the humerus was positioned, the free supraspinatus muscle was held in a cryo-jaw at the muscle–tendon junction (Fig. 2). Using liquid carbon dioxide flowing through the cryo-jaw, the clamped muscle belly was frozen to prevent failure at the tendon–grip interface and tissue slippage. The flow of the liquid carbon dioxide was carefully controlled to prevent the tendon from freezing. Every attempt was made to ensure equal and symmetric tension across the tendon before clamping.

## 2.4. Cyclic load testing

Each specimen was pre-loaded with 10 N of tensile force. The tendon was then cyclically loaded under force control from 10 to 180 N at 1 Hz for 1000 cycles. A 180-N load was estimated to correspond to two-thirds of the load resulting from maximum contraction of the supraspinatus muscle (Burkhart et al., 1997). One thousand cycles were applied because the cycle number–gap distance curve became linear near the 100 cycle mark and was nearly flat at 1000 cycles during pilot testing. The gap distance at the reattachment site was measured with two DVRT (Differential variable reluctance transducer) displacement sensors (MicroStrain, Williston, VT, USA) for both groups. The two pins of the sensor, with a span of 6 mm, were inserted into the tendon at the reattachment site and into the bone lateral to the reattachment site (Fig. 3). Initially, the medial pin of the sensor was inserted into the lateral aspect of the tendon, just medial to the suture of the primary repair, without touching the dermal graft on the tendon. Subsequently, the lateral pin was inserted into the bone of the greater tuberosity with the shaft of the sensor parallel to the direction of the



**Fig. 2.** Testing device attached to the material testing machine. The potted specimen was secured in a clamp that was oriented in 30° of glenohumeral abduction. The supraspinatus muscle was held in a cryo-jaw at the muscle–tendon junction.



**Fig. 3.** Schematics of repair procedures and the position of the displacement sensor. The medial pin of the displacement sensor was inserted into the lateral aspect of the tendon just medial to the primary repair suture (without touching the graft on the tendon in the augmentation group). The lateral pin was inserted into the bone of the greater tuberosity. The displacement sensors were attached to the anterior and posterior edges of the tendon because the reattachment site was covered by the graft.

traction. One displacement sensor was attached to the anterior edge of the tendon, and one was attached to the posterior edge of the tendon. The pins were attached at the same positions in both groups. The gap distance at 10 N was recorded over the 1000 loading cycles.

### 2.5. Tensile testing to failure

Following cyclical loading, a 10-N preload was applied, and the specimen was loaded to failure at a rate of 1.0 mm/s (Kim et al., 2006). Displacement was measured by the machine actuator. The maximum load and linear stiffness were calculated from the force–displacement curve. The failure mechanism for each specimen was also recorded.

### 2.6. Statistical analysis

A paired *t*-test was used to analyze the anterior and posterior gap distances resulting from cyclic load testing, as well as the maximum load and the linear stiffness resulting from tensile testing to failure. The level of statistical significance was set at  $P < 0.05$ .

## 3. Results

### 3.1. Cyclic load testing

Due to limited DVRT displacement (5–8 mm maximum displacement), only four paired shoulders yielded DVRT data throughout the 1000 load cycles. In the other five pairs of shoulders, the DVRT exceeded its linear range before 1000 cycles. The last cycle number at which the gap distance could be detected and the corresponding gap distance are shown in Table 1. In the four paired shoulders, the anterior gap distance was 1.4 mm (SD 1.1) in the augmentation group and 3.0 mm (SD 0.6) in the control group at 1000 cycles. The

posterior gap distance was 2.3 mm (SD 0.8) in the augmentation group and 2.7 mm (SD 0.8) in the control group at 1000 cycles. The statistical analysis could not be performed for the gap distances due to the limited sample number at 1000 cycles. In all nine samples of the augmentation group, stretching of the augmentation graft was observed during cyclic loading. In the five pairs of shoulders in which the DVRT exceeded its linear range before 1000 cycles, the amount of stretching of the graft was large under gross observation.

Among the nine pairs of shoulders, there was no obvious sign of destruction of the repair site, such as tendon pull-out from the anchor or anchor pull-out from the bone, following the cyclic testing.

### 3.2. Tensile testing to failure

The maximum load of the augmentation group (560.2 N, SD 95.5) was significantly greater than that of the control group (345.7 N, SD 60.8) in all nine paired shoulders ( $P < 0.01$ ), whereas the linear stiffness of the augmentation group (65.2 N/mm, SD 15.6) was significantly less than that of the control group (77.2 N/mm, SD 15.7;  $P < 0.01$ ).

In the control group, two suture anchors were used for the repair, and there were two tendon–bone junctions in each shoulder. Each tendon–bone junction failed with three different mechanisms (A: tendon cut-out at the suture of the reattachment site, B: suture breakage, and C: suture anchor pull-out from the bone). Three shoulders failed through mechanisms A and A, two shoulders failed through mechanisms A and B, two shoulders failed through mechanisms A and C, one shoulder failed through mechanisms B and B, and one shoulder failed through mechanisms C and C. In total, the failure mechanism was cut-out of the tendon in seven shoulders, suture breakage in three shoulders, and pull-out of the anchor from the bone in three shoulders. Cut-out of the tendon was the major failure mechanism in the control group.

In the augmentation group, the repair site failed through four different mechanisms. Four shoulders failed through a combination of cut-out of the tendon at the suture of the reattachment site and cut-out of the tendon at the suture of the augmentation graft. Two shoulders failed due to pull-out of the four suture anchors from the bone. In these two shoulders, the four anchors were pulled out from the bone with the bone fragment between the suture anchors, and the tendon had not been detached at the suture of the reattachment site. Two shoulders failed due to bone fracture at the site of the lateral suture anchors. In these two shoulders with fractures at the lateral anchors, the tendon ends remained at the reattachment site. One shoulder failed through a combination of cut-out of the tendon at the suture of the reattachment site and pull-out of the lateral anchors from the bone. The failure mechanisms of all of the samples are shown in Table 2. The augmentation graft itself was not ruptured in any of the nine samples.

**Table 1**  
Anterior and posterior gap distances, maximum failure load, and linear stiffness of all the samples.

| Sample | Anterior gap distance (mm)/<br>number of cycles (cycles) |              | Posterior gap distance (mm)/<br>number of cycles (cycles) |              | Maximum failure load (N) |              | Linear stiffness (N/mm) |              |
|--------|----------------------------------------------------------|--------------|-----------------------------------------------------------|--------------|--------------------------|--------------|-------------------------|--------------|
|        | Control                                                  | Augmentation | Control                                                   | Augmentation | Control                  | Augmentation | Control                 | Augmentation |
| No.1   | 3.8/1000                                                 | 3.1/1000     | 3.1/1000                                                  | 2.6/1000     | 433.1                    | 555.8        | 68.5                    | 64.9         |
| No.2   | 2.7/1000                                                 | 0.7/1000     | 3.4/1000                                                  | 3.3/1000     | 354.0                    | 515.0        | 61.3                    | 55.2         |
| No.3   | 2.6/1000                                                 | 0.7/1000     | 2.7/1000                                                  | 2.0/1000     | 347.3                    | 671.2        | 67.6                    | 45.8         |
| No.4   | 2.7/1000                                                 | 1.1/1000     | 1.7/1000                                                  | 1.4/1000     | 442.9                    | 682.9        | 75.3                    | 67.1         |
| No.5   | 5.1/140                                                  | 4.9/140      | 6.7/880                                                   | 3.8/880      | 259.9                    | 397.9        | 97.2                    | 87.8         |
| No.6   | 5.3/14                                                   | 3.2/14       | 5.2/1000                                                  | 5.8/1000     | 336.4                    | 616.8        | 69.0                    | 66.9         |
| No.7   | 3.6/9                                                    | 1.2/9        | 2.3/1000                                                  | 0.6/1000     | 346.4                    | 623.4        | 83.6                    | 69.4         |
| No.8   | 4.2/260                                                  | 3.9/260      | 0.6/1000                                                  | 3.5/1000     | 297.3                    | 486.6        | 107.3                   | 86.4         |
| No.9   | 5.0/140                                                  | 4.7/140      | 3.7/1000                                                  | 2.1/1000     | 294.3                    | 492.5        | 65.3                    | 43.3         |

**Table 2**  
Failure mechanisms of all the samples.

| Sample | Control                            | Augmentation                               |
|--------|------------------------------------|--------------------------------------------|
| No.1   | Anchor pull-out                    | Tendon cut-out and lateral anchor pull-out |
| No.2   | Suture breakage                    | Fracture at lateral anchor                 |
| No.3   | Tendon cut-out and anchor pull-out | Tendon cut-out                             |
| No.4   | Tendon cut-out and suture breakage | Fracture at lateral anchor                 |
| No.5   | Tendon cut-out and anchor pull-out | Four anchors pull-out                      |
| No.6   | Tendon cut-out                     | Tendon cut-out                             |
| No.7   | Tendon cut-out                     | Tendon cut-out                             |
| No.8   | Tendon cut-out and suture breakage | Tendon cut-out                             |
| No.9   | Tendon cut-out                     | Four anchors pull-out                      |

#### 4. Discussion

To obtain a more secure initial fixation for rotator cuff repairs, an augmentation graft may protect the tendon reattachment. Muscle force is transferred to the greater tuberosity and is shared by the rotator cuff repair and the augmentation graft. The decreased load to the repair site due to the augmentation graft may help protect the rotator cuff repair site during the required healing period for the repair. In the present study, the biomechanical assessments of rotator cuff repairs with and without the augmentation graft were performed under both cyclic load testing and tensile testing to failure.

In the tensile testing to failure, the maximum load of the augmentation group was significantly greater than that of the control group. However, the linear stiffness of the augmentation group was significantly less than that of the control group. Two possible explanations for these results were developed: the low stiffness of the graft materials compared to the native tendon and the compression of the tendon at the repair site. During the operative procedure performed in this study, the augmentation graft was sutured to the tendon, pulled laterally to cover the reattachment site, and pulled inferiorly on the lateral aspect of the humerus with a 20-N load applied to the graft for 3 min. Subsequently, the graft was sutured to the anchor while a 10-N load was applied to the graft inferiorly. The application of the 20-N load for 3 min was added to decrease the elasticity of the augmentation graft. While the graft was pulled laterally and inferiorly, the tendon, which was sutured to the graft, was also pulled laterally. The tendon was compressed between the site sutured to the graft and the repair site, which was sutured to the bone. After the 20-N load was applied to the graft for 3 min, the stiffness of the graft was still less than that of the tendon. In the tensile testing, the compression of the tendon and the lower stiffness of the graft may have caused the augmentation group to have a lower stiffness than the control group.

The failure mechanism in the augmentation group indicated the protection of the tendon reattachment by the dermal graft. The augmentation graft was not ruptured in any of the shoulders in the augmentation group. This result demonstrated that the material used in this study is strong enough for use as an augmentation graft. In the control group, the cut-out of the tendon at the reattachment site was the major failure mechanism. In the augmentation group, the cut-out of the tendon was not found in four shoulders (two shoulders failed due to the pull-out of four suture anchors, and two shoulders failed due to bone fracture at the site of the lateral suture anchors). In these four shoulders, the reattachment site, where the cuff end was fixed on the bone with the sutures, might have been protected by the augmentation graft until the application of the maximum load.

The present study demonstrated the advantage of the augmentation graft technique with respect to the maximum load that could be endured. Recently, Barber et al. reported the biomechanical assessment of the augmentation graft technique using the same material as

that of the graft (Barber et al., 2008). In that study, the augmentation graft was sutured to the same suture anchors that were used for the reattachment of the tendon. The results revealed no differences in cyclic load testing with and without augmentation, and the maximum load in the augmentation group was greater than that in the control (without augmentation) group.

The present study has several limitations. The cadavers used in this study were aged (84.4 years old), although the cadaveric specimens with rotator cuff tear were excluded. This age related rotator cuff degeneration was not examined histologically. Due to limited DVRT displacement, only four paired shoulders yielded DVRT data throughout the 1000 cycles. In the other five pairs of shoulders, the DVRT exceeded its linear range in less than 1000 cycles. The displacement during the failure test was measured with the machine actuator; however, the stiffness of the construct may not equal the stiffness of the repair site. Finally, this was a zero time-point evaluation using a human cadaveric model. Therefore, the in vivo effects of the dermal graft augmentation are unknown.

#### 5. Conclusions

The dermal graft augmentation of the rotator cuff repair increased the maximum load following the repair. However, augmentation did not increase the stiffness of the repair site. Future studies are warranted to evaluate whether differences in graft material stiffness are important. The translation of the present study to an in vivo model would also provide evidence of whether the results are clinically applicable.

#### Conflict of interest statement

Concerning conflict of interest: One author (SS) is a consultant to Wright Medical. His role on the input for this study as a coauthor was under a funding contract agreement; he is currently a consultant to Wright Medical. A second author (JS) is a consultant and shareholder of Tornier. No other authors have anything to report concerning a conflict of interest.

#### Acknowledgments

This study was supported by funding from Wright Medical Technology (Arlington, TN, USA). Wright Medical had no involvement in the study design, specimen collection, analysis or interpretation of the data, the writing of the manuscript, or the decision to submit the manuscript for publication.

#### References

- Barber, F.A., Herbert, M.A., Coons, D.A., 2006. Tendon augmentation grafts: biomechanical failure loads and failure patterns. *Arthroscopy* 22, 534–538.
- Barber, F.A., Herbert, M.A., Boothby, M.H., 2008. Ultimate tensile failure loads of a human dermal allograft rotator cuff augmentation. *Arthroscopy* 24, 20–24.
- Burkhart, S.S., Johnson, T.C., Wirth, M.A., Athanasiou, K.A., 1997. Cyclic loading of transosseous rotator cuff repairs: tension overload as a possible cause of failure. *Arthroscopy* 13, 172–176.
- Fini, M., Torricelli, P., Giavaresi, G., Rotini, R., Castagna, A., Giardino, R., 2007. In vitro study comparing two collagenous membranes in view of their clinical application for rotator cuff tendon regeneration. *J. Orthop. Res.* 25, 98–107.
- Kim, D.H., Elattrache, N.S., Tibone, J.E., Jun, B.J., DeLaMora, S.N., Kvitne, R.S., et al., 2006. Biomechanical comparison of a single-row versus double-row suture anchor technique for rotator cuff repair. *Am. J. Sports Med.* 34, 407–414.
- Park, M.C., Tibone, J.E., Elattrache, N.S., Ahmad, C.S., Jun, B.J., Lee, T.Q., 2007. Part II: Biomechanical assessment for a footprint-restoring transosseous-equivalent rotator cuff repair technique compared with a double-row repair technique. *J. Shoulder Elbow Surg.* 16, 469–476.
- Wong, I., Burns, J., Snyder, S., 2010. Arthroscopic Graftjacket repair of rotator cuff tears. *J. Shoulder Elbow Surg.* 19, 104–109.