



# Biomechanics of tensor fascia lata allograft for superior capsular reconstruction

Zachary D. Vredenburg, MD<sup>a</sup>, John P. Prodrorno, MD<sup>b</sup>, James E. Tibone, MD<sup>c</sup>, Taylor R. Dunphy, MD<sup>d</sup>, Joel Weber, MD<sup>e</sup>, Michelle H. McGarry, MS<sup>f</sup>, Seungbum Chae, MD<sup>f,g</sup>, Gregory J. Adamson, MD<sup>f</sup>, Thay Q. Lee, PhD<sup>f,\*</sup>

<sup>a</sup>Department of Orthopedic Surgery, SUNY Upstate Medical University, Syracuse, NY, USA

<sup>b</sup>Princeton Orthopaedic Associates, Princeton, NJ, USA

<sup>c</sup>Department of Orthopaedic Surgery, Keck School of Medicine of University of Southern California, Los Angeles, CA, USA

<sup>d</sup>Newport Orthopedic Institute, Newport Beach, CA, USA

<sup>e</sup>Evergreen Health Orthopedics & Sports Care, Kirkland, WA, USA

<sup>f</sup>Orthopaedic Biomechanics Laboratory, Congress Medical Foundation, Pasadena, CA, USA

<sup>g</sup>Department of Orthopaedic Surgery, Daegu Catholic University Hospital School of Medicine, Daegu, Republic of Korea

**Background:** We hypothesized that in a cadaveric massive rotator cuff tear (MCT) model, a fascia lata (FL) allograft superior capsular reconstruction (SCR) would restore subacromial contact pressure and humeral head superior translation without limiting range of motion (ROM). Therefore, the objective of this study was to compare these parameters between an intact rotator cuff, MCT, and allograft FL SCR.

**Methods:** Eight fresh cadavers were studied using a custom shoulder testing system. ROM, superior translation, and subacromial contact pressure were measured in each of 3 states: (1) intact rotator cuff, (2) MCT, and (3) MCT with SCR.

**Results:** Total ROM was increased in the MCT state at 60° of abduction ( $P = .037$ ). FL SCR did not restrict internal or external rotational ROM. Increased superior translation was observed in the MCT state at 0° and 30° of humeral abduction, with no significant difference between the intact cuff and FL SCR states. The MCT state significantly increased mean subacromial contact pressure at 0° of abduction with 30° and 60° of external rotation, and FL SCR restored this to intact levels. Peak subacromial contact pressure was increased for the MCT state at 0° of abduction with 30° and 60° of external rotation, as well as 30° of abduction with 30° of external rotation.

**Conclusion:** This study demonstrates a tensor FL allograft preparation technique for use in SCR. After MCT, FL SCR restores ROM, superior translation, and subacromial contact pressure to the intact state.

**Level of evidence:** Basic Science Study; Biomechanics

© 2020 Journal of Shoulder and Elbow Surgery Board of Trustees. All rights reserved.

**Keywords:** Superior capsular reconstruction; tensor fascia lata; biomechanics; allograft; rotator cuff tear; superior translation; subacromial contact pressure

Institutional review board approval was not required for this basic science study.

\*Reprint requests: Thay Q. Lee, PhD, Orthopaedic Biomechanics Laboratory, Congress Medical Foundation, 800 S Raymond Ave, Pasadena, CA, 91105.

E-mail address: [tqlee@congressmedicalfoundation.org](mailto:tqlee@congressmedicalfoundation.org) (T.Q. Lee).

Irreparable rotator cuff tears present a treatment dilemma, especially in young patients. Options in this patient population include tendon transfer, partial rotator cuff repair, débridement, patch interposition, subacromial spacer use, and reverse shoulder arthroplasty. Tendon

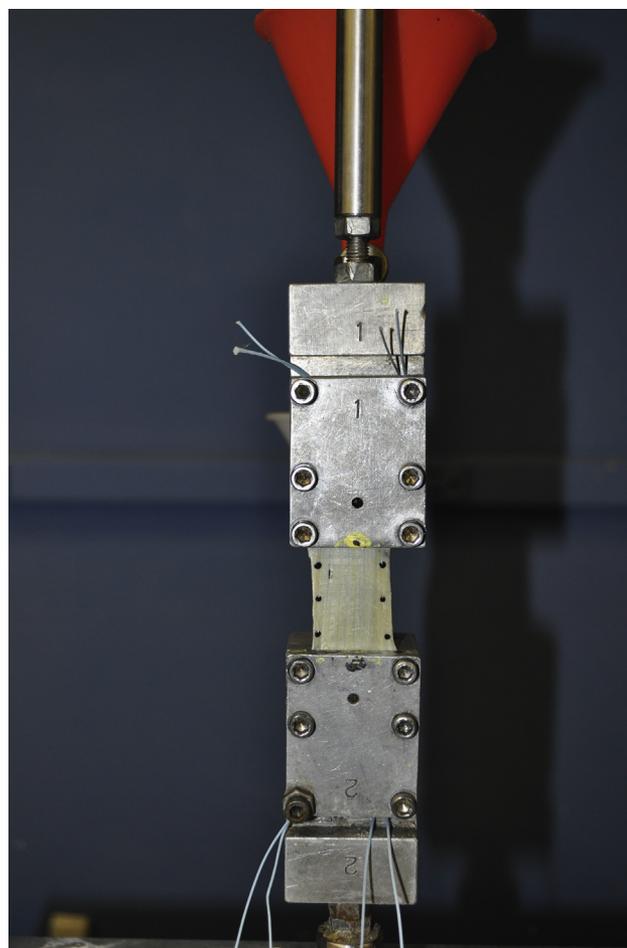
transfer, partial rotator cuff repair, and débridement have shown unpredictable outcomes. Long-term data are lacking regarding patch interposition and subacromial spacer use.<sup>6</sup> Despite improved functional outcomes, concerns regarding complications, function, and survivorship of reverse arthroplasty in the young patient with higher functional demands exist.<sup>7</sup> An alternative technique to address an irreparable rotator cuff tear is superior capsular reconstruction (SCR). SCR was initially described by Mihata et al<sup>10-12</sup> using a 5-mm-thick tensor fascia lata (TFL) allograft in biomechanical studies and subsequently using 6- to 8-mm autograft in clinical studies. An alternative technique uses 2- to 3-mm-thick human acellular dermal allograft.<sup>16,17</sup> Concerns with autograft harvest including donor-site morbidity and graft preparation have been considered, and alternative graft options have been explored. Clinical use of dermal allograft has become popular, with multiple commercial products available. Comparison of TFL and rotator cuff allograft to acellular dermal matrix allograft demonstrated biomechanical inferiority of the dermal matrix allograft.<sup>2,8</sup>

For these reasons, biomechanical assessments have explored alternative graft options. Patellar tendon allograft has demonstrated the ability to reduce superior translation of the humeral head and peak subacromial contact pressure without restricting range of motion or resulting in significant graft deformation.<sup>4</sup> Prior studies have not assessed TFL allograft of 6 to 8 mm in thickness using a similar preparation technique to that described with autograft by Mihata et al.<sup>9-11</sup> The ideal fascia lata (FL) graft preparation technique in terms of irradiation and cold storage has also not been assessed in prior biomechanical studies. Thus, the first objective was to determine the optimal allograft irradiation and storage method. Subsequently, we used this method with the objective of mimicking the autograft preparation technique of Mihata et al<sup>9-11</sup> to achieve a similarly sized graft and then study its biomechanical properties.

## Materials and methods

### Mechanical performance of different graft preparations

First, a study was performed to compare FL allograft preparation and compare the performance of different graft preparation techniques under cyclic loading and load-to-failure testing. Paired TFL allografts were received aseptically from 8 donors (5 male and 3 female donors; mean age, 42.4 years [range, 15-80 years]) and assigned to 1 of 4 preparations: (1) fresh frozen, (2) fresh frozen and gamma irradiated, (3) freeze dried, or (4) freeze dried and gamma irradiated (JRF Ortho [Centennial, CO, USA] and Community Tissue Services [Dayton, OH, USA]). FL allografts were débrided to remove extraneous soft tissue, fat, and muscle and received a proprietary bioburden reduction treatment. Allografts from the right limb were packaged and stored frozen at  $\leq -65^{\circ}\text{C}$ .



**Figure 1** Load-to-failure testing setup showing 2 × 5-cm graft clamped in cryo-clamps on Instron material testing machine (Norwood, MA, USA) after graft preparation.

Allografts from the left limb were packaged and lyophilized for 16 hours to remove moisture. Allografts from each limb were then bisected; the distal half received low-dose gamma irradiation (1.05-1.65 Mrad; Steris, Groveport, OH, USA), whereas the proximal half of the FL received no irradiation. Grafts were sectioned into 2 × 5-cm segments. Sixteen graft segments of each graft preparation were tested. The thickness was measured with a micrometer (model No. CD-S8"CT; Mitutoyo, Kawasaki, Japan). Each corner was sutured, and the grafts were clamped in cryo-clamps on both sides to prevent graft slippage during testing. The clamps were set at a distance of 3 cm apart to standardize the length of the graft. Six black paint markers were placed along the graft to serve as digitizing markers for measuring displacement using a video digitizing system (Fig. 1). The specimens were preloaded to 5 N and then cycled from 5 to 50 N for 20 cycles, followed by load to failure. All loads were applied at a rate of 20 mm/min. The specimens were video recorded during testing; then, the displacement between the markers was measured using WINalyze software (Mikromak Service, Berlin, Germany). Total nonrecoverable deformation was measured at cycles 1 and 20. Yield/ultimate extension, yield/ultimate load, yield energy, stiffness, elastic modulus, toughness, ultimate stress, ultimate strain, ultimate change in width, and ultimate energy were measured.



**Figure 2** Preparation of tensor fascia lata allograft. The septum is harvested from the upper-left region in the top left image; the posterior aspect of the tensor fascia lata is at the superior aspect of the image.



**Figure 3** Prepared tensor fascia lata allograft sized to 55 mm long  $\times$  40 mm wide.

## FL allograft SCR

### Cadaver preparation

Eight shoulders (5 male and 3 female shoulders) with an average age of 73.9 years (standard deviation, 8.3 years) were harvested and structures were sutured based on the technique described in previous studies.<sup>4</sup> All shoulders were macroscopically intact without any gross pathology. Shoulders were dissected of all soft tissues, leaving intact the glenohumeral joint as well as the tendons of the pectoralis major, deltoid, latissimus dorsi, biceps, supraspinatus, infraspinatus, teres minor, and subscapularis. The humerus was sectioned with a sagittal saw 2 cm below the deltoid tuberosity. The tendons were tagged with No. 2 FiberWire (Arthrex, Naples, FL, USA) with looped knots to load the tendons to simulate muscle loading. We placed 2 tags in the supraspinatus, 3 in the subscapularis, 2 in the infraspinatus, and 1 in the teres minor. Three

tags were placed in the deltoid insertion. Two tags each were then placed in the pectoralis major insertion and the latissimus dorsi insertion on the humerus. The scapula was attached to a metal plate placed in the infraspinatus fossa using 3 bolts.

### TFL graft preparation

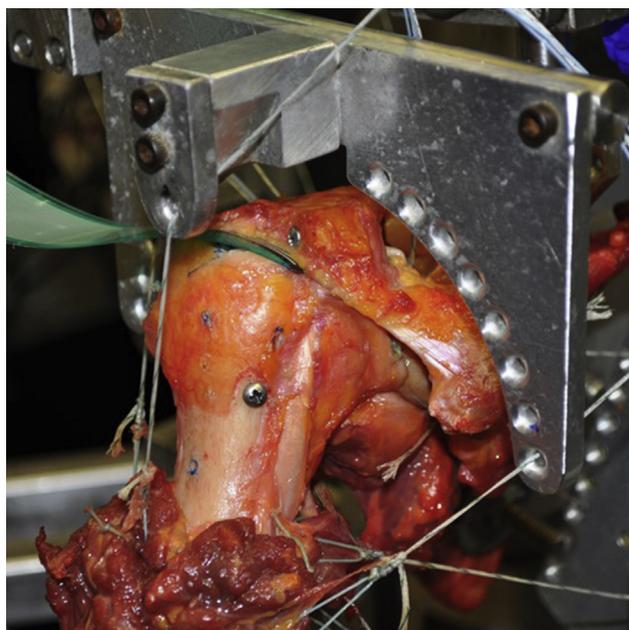
Eight fresh-frozen TFL allografts, 6 male and 2 female donors with an average age of 59.8 years (standard deviation 15.4 years), were débrided to remove extraneous soft tissue, fat, and muscle. Grafts (JRF Ortho and Community Tissue Services) received bioburden reduction treatment, were packaged and stored frozen at  $\leq -65^{\circ}\text{C}$ , and received a low dose of gamma irradiation (1.05–1.65 Mrad). Following treatment, the TFL allografts were prepared to create a sandwich technique, similar to that performed by Mihata et al<sup>11</sup> using TFL autograft. The intramuscular septum was sectioned at the junction of the anterior portion, along the posterior edge of the TFL. The septum was cut to create a 40  $\times$  55-mm rectangle. The TFL tissue was cut down to an 80  $\times$  110-mm rectangle, with the long axis down the length of the TFL, from the position as far posterior as possible. A posterior location was preferred as the segment of tissue in this location tends to be thicker. The TFL was then folded along its long axis to create a doubled layer of 40  $\times$  110 mm. The rectangle of septum was placed on top of these layers, and the TFL graft was folded along the short axis to create a 40  $\times$  55-mm rectangle. This graft section then measured 40  $\times$  55 mm, with 2 layers of TFL, a layer of septum in the center, and then 2 more layers of TFL to create a 5-layered graft. It was sutured with 2 simple sutures of No. 2 FiberWire along the 40-mm, shorter dimension at the open edge, 4 simple sutures along each of the longer dimensions (55 mm), and 3 mattress sutures along the long axis in the center of the graft (Figs. 2 and 3). The folded edge of the graft was not sutured. The graft thickness for the medial, central, and lateral portions of the graft was measured using a digital micrometer and averaged.

### Biomechanical testing

The intact cadaveric shoulder was secured to the shoulder testing system with the scapula in  $0^{\circ}$  of abduction and  $20^{\circ}$  of anterior tilt



**Figure 4** Left shoulder mounted on custom shoulder testing system in 60° of glenohumeral abduction.



**Figure 5** Right shoulder showing Tekscan sensor placed in subacromial space for measurement of subacromial contact pressure.

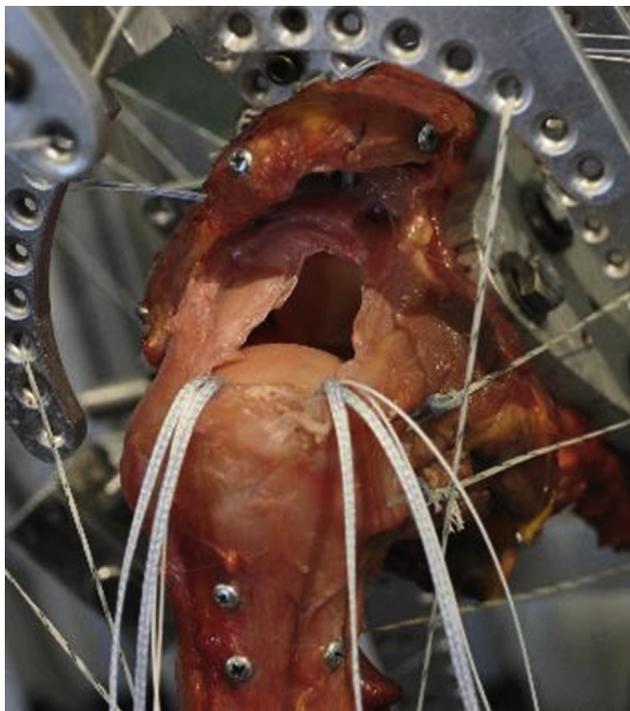
(Fig. 4). Muscle loading plates were adjusted to align with the scapula and fossa of each muscle. Sutures were tied through the loading plates onto the tendons of each muscle. These sutures are then loaded onto individual pulleys for muscle force application. An intramedullary rod was inserted into the distal humerus and secured with 6 screws. The rod was placed through a hollow potentiometer to measure rotational range of motion. This potentiometer was then secured to the arc of the testing system.

The arc allowed the plane of abduction to be defined and the humerus to be secured at varying degrees of glenohumeral abduction. The arc was positioned to define the scapular plane as the plane of abduction. Rotational range of motion, superior translation, and subacromial contact pressures were measured at 0°, 30°, and 60° of glenohumeral abduction. Range of motion and humeral head position were measured in a balanced muscle loading state: supraspinatus, 10 N; subscapularis, 10 N; infraspinatus, 10 N; teres minor, 5 N; pectoralis major, 20 N; latissimus dorsi, 20 N; and deltoid, 40 N. Next, unbalanced muscle loading was applied in which the load was removed from the pectoralis and latissimus and doubled on the deltoid, effectively translating the humerus superiorly. Superior translation and subacromial contact pressures were then measured in an unbalanced state.<sup>4</sup> Humeral head position was recorded with a MicroScribe 3DLX device (Revware, Raleigh, NC, USA) at 0°, 30°, 60°, and 90° of external rotation. Subacromial contact pressures were measured using a Tekscan sensor (model 4000; Tekscan, Boston, MA, USA). This sensor was placed in the subacromial space to measure contact force, contact area, and peak pressure (Fig. 5). Peak pressure was defined as the highest pressure across a 2 × 2-pixel area of loading.

After completion of the aforementioned testing, a rotator cuff defect was created; the supraspinatus and the anterior half of the infraspinatus were sectioned to simulate an irreparable rotator cuff tear. Biomechanical testing was then repeated in the massive cuff tear state. Next, SCR was performed using the prepared TFL allografts, and the shoulder was again tested.

### Superior capsular reconstruction

The biceps was left in place, and two 4.5-mm metal Corkscrew FT anchors (Arthrex) were placed along the glenoid rim: one just in front of the biceps at an angle replicating that in anterior portal placement and one as far posterior as possible, just at the posterior

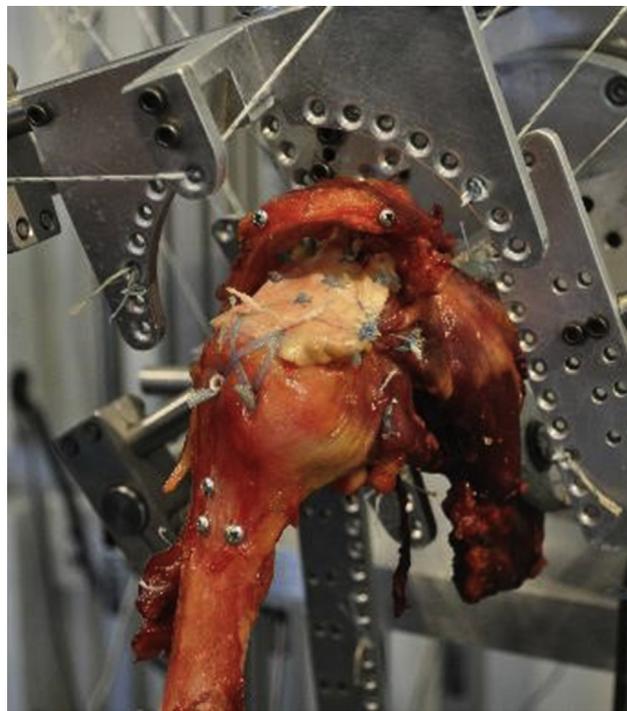


**Figure 6** Massive cuff tear in left shoulder with glenoid and medial humeral anchors placed for superior capsular reconstruction.

edge of the tear, to mimic that in Neviaser portal placement. Both anchors were placed far medial to avoid glenoid penetration. The medial row of humeral anchors was placed, using preloaded 4.75-mm Bio-SwiveLock anchors (Arthrex), 5 mm from the anterior and posterior margins of the tear at the footprint. Measurements were then taken at 20° of abduction to confirm the distances between the anchors for appropriate tension through the graft. These measurements were applied to the graft location of anchors for tensioning.

The glenoid anchors were fixed by passing 1 end of each No. 2 FiberWire pair through the cuff 5 mm from the edge and tying a sliding-locking knot, followed by 4 half-hitch stitches, leaving 4 simple stitches to 2 anchors. The medial-row humeral anchors (Fig. 6) were passed with all 4 sutures through 1 hole in the graft, 2 FiberTape suture limbs (Arthrex), and 1 FiberWire suture limb. The FiberWire pull stitches were then used to seal the medial footprint via a double-pulley technique.<sup>1</sup> The graft was fixed in 45° of shoulder abduction so that it was not over-tensioned to tearing at 0° of abduction.<sup>12</sup> The FiberTapes from these anchors were then used to place 2 lateral-row 4.75-mm Bio-SwiveLock devices in a suture bridge technique. The posterior graft was secured to the anterior margin of the posterior rotator cuff using 2 simple side-to-side stitches with No. 2 FiberWire (Fig. 7). Biomechanical testing of the shoulder was then repeated in the FL SCR state.

For both the graft preparation comparison and the cadaveric testing comparison, a within-subject repeated-measures analysis of variance was performed to determine whether a significant difference was detected based on graft preparation type or testing condition. If a significant difference was detected, pair-wise comparisons were performed with Bonferroni correction for multiple comparisons. The significance level was set at  $P < .05$ .



**Figure 7** Left shoulder after completion of superior capsular reconstruction.

## Results

### Mechanical performance of different graft preparations

No significant difference in thickness was observed between graft preparations ( $P = .31$ ). We found no significant change in length at peak load on cyclic loading for cycle 1 ( $P = .93$ ) or cycle 20 ( $P = .44$ ). No significant difference in nonrecoverable deformation was found between grafts for cycle 1 ( $P = .65$ ) or cycle 20 ( $P = .58$ ). Graft stiffness showed no significant difference ( $P = .99$ ) (Table I). Moreover, there was no significant difference in yield load between grafts ( $P = .96$ ). For this study, fresh-frozen gamma-irradiated allograft was chosen as this provides a readily available, quick-to-thaw graft that has been adequately sterilized.

### FL allograft SCR

Average graft thickness using the sandwich preparation technique was  $6.8 \pm 0.6$  mm. No significant differences in internal or external rotational range of motion were identified between states (Table II). Total range of motion was increased in the massive cuff tear state at 60° of glenohumeral abduction ( $P = .037$ ). FL SCR did not show significant differences in total humeral rotational range of motion.

With a superiorly directed force, superior translation was significantly increased in the massive rotator cuff tear state at 0° of abduction with 0°, 30°, and 60° of external rotation

**Table I** Load-to-failure characteristics of 4 different graft preparations for fascia lata

	Fresh frozen	Fresh frozen and gamma irradiated	Freeze dried	Freeze dried and gamma irradiated	<i>P</i> value
Stiffness, N/mm	318.0 ± 74.2	313.9 ± 79.5	320.9 ± 96.7	364.6 ± 235.4	.99
Yield load, N	445.0 ± 109.4	448.7 ± 102.5	431.7 ± 128.4	428.2 ± 137.7	.96
Extension at yield load, mm	1.5 ± 0.2	1.5 ± 0.2	1.5 ± 0.2	1.5 ± 0.4	.98
Energy absorbed to yield load, Nmm	500.8 ± 155.9	480.3 ± 138.5	467.6 ± 182.3	478.0 ± 220.0	.99
Ultimate load, N	490.2 ± 93.9	513.8 ± 117.4	477.5 ± 130.1	487.2 ± 168.0	.91
Extension at ultimate load, mm	1.9 ± 0.3	1.9 ± 0.3	1.8 ± 0.3	1.9 ± 0.5	.96
Energy absorbed to ultimate load, Nmm	738.2 ± 217.7	806.1 ± 252.1	714.8 ± 316.7	786.0 ± 393.2	.91

Data are presented as mean ± standard error of mean.

**Table II** Humeral rotational range of motion for each testing condition and glenohumeral abduction angle

Glenohumeral abduction	Intact, °	MCT, °	Fascia lata SCR, °
Internal rotation			
0°	6 ± 3	7 ± 3	8 ± 3
30°	13 ± 3	15 ± 3	16 ± 3
60°	7 ± 4	11 ± 4	10 ± 4
External rotation			
0°	88 ± 7	96 ± 8	98 ± 8
30°	106 ± 8	109 ± 7	111 ± 7
60°	108 ± 7	112 ± 7	111 ± 6
Total range of motion			
0°	94 ± 9	104 ± 8	105 ± 8
30°	119 ± 7	124 ± 6	126 ± 5
60°	115 ± 8	122 ± 7*	121 ± 6

MCT, massive rotator cuff tear; SCR, superior capsular reconstruction. Data are presented as mean ± standard error of mean.

\* *P* < .05 compared with intact condition.

and at 30° of abduction with 0°, 30°, and 60° of external rotation (Fig. 8). These values were all restored to the intact state after FL SCR was performed. The massive cuff tear state significantly increased mean subacromial contact pressure at 0° of abduction with 30° and 60° of external rotation, and FL SCR restored this to the intact condition (Table III). Peak subacromial contact pressure was increased in the massive rotator cuff tear state at 0° of abduction with 30° and 60° of external rotation and at 30° of abduction with 30° of external rotation (Table IV).

## Discussion

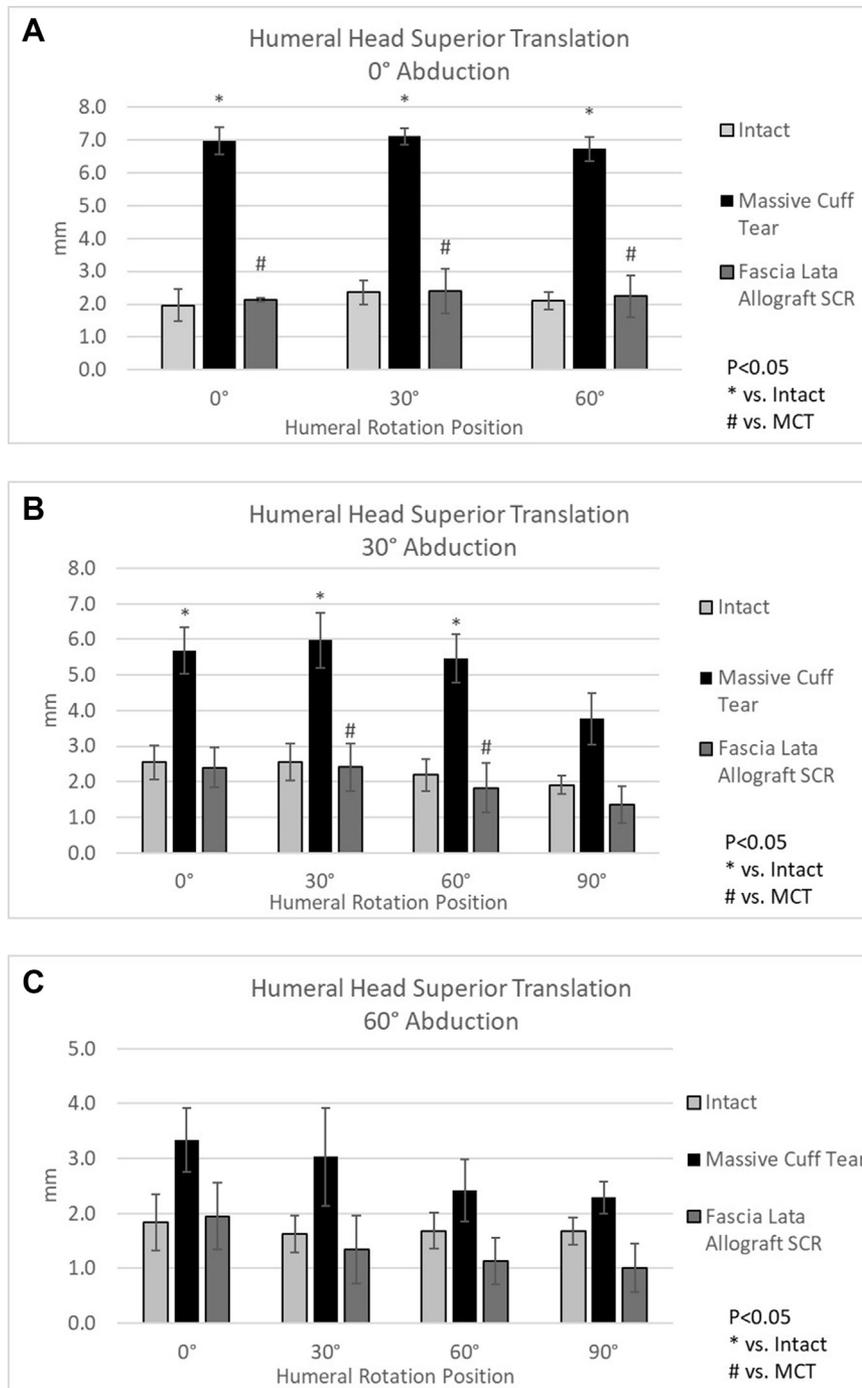
The initial study on the mechanical performance of different graft preparations demonstrated no biomechanical difference across the different graft preparations. Thus, fresh-frozen gamma-irradiated allograft was chosen for our

study as this provides a readily available, quick-to-thaw graft that has been adequately sterilized.

This study demonstrates findings comparable to those of Croom et al<sup>4</sup> using patellar tendon allograft for SCR. The thickness of the prepared FL allograft of 6.8 ± 0.6 mm in this study approximates the 4- to 9-mm thickness of the native superior capsule identified by Nimura et al,<sup>13</sup> whereas the graft thickness was 4.3 mm using patellar tendon in the study of Croom et al. In their study, range of motion was significantly increased for internal rotation at 60° of abduction, external rotation at 0°, 30°, and 60° of abduction, and total rotation at 0°, 30°, and 60° of abduction vs. the intact state. In our study, FL SCR did not show significant differences in total humeral range of motion. In the study of Croom et al, superior translation under an unbalanced load was increased from the intact state after SCR with patellar tendon at 0° and 30° of glenohumeral abduction with 0°, 30°, 60°, and 90° of external rotation. Their study demonstrated a reduction in peak contact pressures following patellar tendon SCR; our study similarly showed a reduction in peak contact pressures following FL SCR.

The FL SCR in this study restored superior translation and subacromial contact pressure to the intact state. Peak subacromial contact pressures have been demonstrated clinically to relate to shoulder functional scores. Nordt et al<sup>14</sup> reported that in patients with impingement syndrome, the position of maximum impingement pain generally correlated with the position of maximum contact pressure. In our study, both peak and mean contact pressures were restored to no difference from the intact state following FL SCR.

It is difficult to extrapolate what clinical outcomes to expect using this technique. Only limited studies have reported the clinical results of using FL autograft or acellular dermal matrix allograft for SCR. Mihata et al<sup>10</sup> showed an improvement of 56.9 points in the American Shoulder and Elbow Surgeons score in patients without pseudoparalysis undergoing SCR with TFL autograft and a 95% graft healing rate on magnetic resonance imaging at an average of 5 years' follow-up. Significant improvements in strength and range of motion were also obtained in their study.



**Figure 8** Humeral superior translation from balanced to unbalanced muscle loading: 0° of glenohumeral abduction (A), 30° of glenohumeral abduction (B), and 60° of glenohumeral abduction (C). \*Statistical difference from intact condition ( $P < .05$ ). #Statistical difference from massive cuff tear condition ( $P < .05$ ). SCR, superior capsular reconstruction; MCT, massive rotator cuff tear.

Similar results have been demonstrated using acellular dermal matrix allograft. American Shoulder and Elbow Surgeons scores improved by 33.9 and 30.0 in studies by Denard et al<sup>5</sup> and Pennington et al,<sup>15</sup> respectively, with strength and range-of-motion improvements in forward flexion and external rotation. In a recent systematic review including data from these studies as well as 7 other studies, Catapano et al<sup>3</sup> did not demonstrate a clinical difference

between TFL autograft and acellular dermal matrix allograft. However, only 3 articles reviewed included >40 patients, and the total numbers of TFL autograft and acellular dermal matrix allograft reconstructions were 141 and 209, respectively. Only 12 complications were recorded across all studies, and the total number of patients included made it difficult to show any difference in the rate of clinical or magnetic resonance imaging failure (3.4%-

**Table III** Average subacromial contact pressure for each measurement position and specimen condition

Measurement position	Intact, kPa	Massive cuff tear, kPa	Fascia lata allograft SCR, kPa
0° of GH abduction			
0° of ER	110.1 ± 23.9	101.3 ± 46.0	112.9 ± 21.1
30° of ER	155.7 ± 20.4	287.8 ± 26.8*	105.4 ± 7.1†
60° of ER	164.3 ± 16.6	254.9 ± 12.9*	110.5 ± 7.9†
30° of GH abduction			
0° of ER	121.8 ± 16.0	168.3 ± 50.0	102.6 ± 17.7*
30° of ER	140.4 ± 21.5	213.7 ± 31.5	113.4 ± 12.5†
60° of ER	147.8 ± 21.3	187.8 ± 20.3	127.2 ± 16.5†
90° of ER	103.4 ± 25.4	104.5 ± 16.5	86.2 ± 11.9
60° of GH abduction			
0° of ER	128.4 ± 22.3	118.5 ± 28.0	125.5 ± 47.0
30° of ER	176.1 ± 44.0	208.2 ± 37.8	177.0 ± 35.2
60° of ER	127.7 ± 25.0	150.7 ± 38.7	117.3 ± 24.7
90° of ER	93.9 ± 20.7	101.5 ± 14.2	75.3 ± 15.0

SCR, superior capsular reconstruction; GH, glenohumeral; ER, external rotation.

Data are presented as mean ± standard error of mean.

\* Statistical difference from intact condition ( $P < .05$ ).

† Statistical difference from massive cuff tear condition ( $P < .05$ ).

**Table IV** Peak subacromial contact pressure for each measurement position and specimen condition

Measurement position	Intact, kPa	Massive cuff tear, kPa	Fascia lata allograft SCR, kPa
0° of GH abduction			
0° of ER	285.5 ± 86.6	349.0 ± 263.4	380.0 ± 67.4
30° of ER	586.3 ± 101.7	1027.7 ± 98.3*	328.6 ± 59.1†
60° of ER	535.3 ± 89.7	951.6 ± 85.8*	316.8 ± 31.9†
30° of GH abduction			
0° of ER	388.3 ± 79.3	530.4 ± 197.5	289.7 ± 78.8
30° of ER	398.6 ± 68.1	819.1 ± 120.4*	350.6 ± 49.6†
60° of ER	495.8 ± 90.1	720.4 ± 128.1	434.9 ± 69.9†
90° of ER	263.3 ± 100.8	271.6 ± 74.5	222.2 ± 61.8
60° of GH abduction			
0° of ER	406.8 ± 107.8	343.7 ± 115.3	450.2 ± 223.2
30° of ER	563.3 ± 160.2	615.2 ± 129.6	559.9 ± 123.8
60° of ER	410.6 ± 128.4	402.9 ± 134.9	356.7 ± 131.4
90° of ER	243.8 ± 82.1	291.5 ± 77.3	251.9 ± 114.0

SCR, superior capsular reconstruction; GH, glenohumeral; ER, external rotation.

Data are presented as mean ± standard error of mean.

\* Statistical difference from intact condition ( $P < .05$ ).

† Statistical difference from massive cuff tear condition ( $P < .05$ ).

36.1%) or revision (0%-10.4%). Overall, good short-term functional results have been seen with both techniques, but longer-term and larger studies are needed to assess the clinical outcomes of each.

Graft preparation and thickness differences with this technique vs. other techniques described in the literature could have an impact on outcomes after SCR. It should be noted that in prior biomechanical studies, the TFL allograft harvested from specimens was very thin, with no intermuscular septum. Thus, when the graft was folded over 2-3 times, it achieved a thickness of only

around 5 mm; the technique was therefore different from that described for TFL autograft preparation by Mihata et al.<sup>9,12</sup> In addition, there have been some noted outcome differences between the TFL autograft technique described by Mihata et al and the dermal allograft techniques described by other authors, but the overall number of reported cases makes it difficult to describe one technique as clearly superior.<sup>5,10-12,15</sup> It is possible that graft thickness differences between 6 and 8 mm for the TFL autograft and between 2 and 3 mm for the dermal allograft may contribute to these differences. In

our study, graft preparation mimicked this TFL autograft preparation as much as possible and resulted in an average graft thickness  $>6$  mm. Moreover, this study used treated grafts, which were not assessed in prior studies, and a preparation technique that would be reproducible in a clinical setting. Our grafts were treated for bioburden reduction, frozen at  $\leq -65^{\circ}\text{C}$ , and irradiated with 1.05-1.65 Mrad of low-dose gamma irradiation. Grafts undergoing this treatment were shown to be biomechanically equivalent to freeze-dried and nonirradiated grafts.

This FL allograft technique does provide potential benefits over the TFL autograft technique previously described by Mihata et al.<sup>9-11</sup> First, allograft avoids the morbidity associated with autograft harvest, avoiding an additional incision site, pain at the harvest site, and hip and thigh dysfunction. Second, it avoids the possibility of failed autograft harvest and the FL allografts can be prepared prior to patient anesthesia, thus saving operative time. Of note, graft preparation was consistently performed in under 30 minutes. Pre-shaped and prepared grafts are commercially available for other applications; this could potentially extend to commercial preparation to provide a prepared TFL allograft to the surgeon. Third, the frozen gamma-irradiated FL allograft is an inexpensive and, in our region, readily available graft option. Fourth, the contained sandwich fold technique used offers a potential opportunity for delivery of biological adjuncts. It should also be noted that we were able to achieve an acceptable and consistent thickness of allograft.

There are some limitations to this study. A limited sample size of 8 specimens means it is possible this study is underpowered to identify a small difference between the intact and FL SCR states. However, the identification of differences between the intact and massive rotator cuff tear states that returned to no difference vs. the intact state following FL SCR is reassuring. Graft size width and length were uniform, with variation in the thickness of the graft based on the cadaveric specimen. This study was not large enough to identify or stratify differences based on graft thickness, and the graft thicknesses were relatively uniform, with an average of  $6.8 \pm 0.6$  mm; this is something that could be assessed in future studies. It is also not known how the biomechanics of this allograft would change over time as our study only assessed the biomechanical properties at time 0 in a cadaveric model. The time required for graft preparation is also not insignificant as compared with a prepackaged acellular dermal matrix allograft. Further studies could be designed to determine the differences in overall cost as well as patient outcomes between different graft options. Another area for future study would be a direct biomechanical comparison, including cyclic loading, of FL allograft using this technique vs. patellar tendon allograft as both are

readily available graft options and have been studied separately.

## Conclusion

This study demonstrates a simple and clinically translatable TFL allograft preparation technique for use in SCR. After massive rotator cuff tear, this FL SCR technique restores range of motion, superior translation, subacromial mean contact pressure, and subacromial peak contact pressure to the intact state.

## Disclaimer

Support for this project was provided by the following: Arthrex (Naples, FL, USA), which donated anchors; JRF Ortho (Centennial, CO, USA), which donated tensor fascia lata grafts; and Community Tissue Services (Dayton, OH, USA), which donated cadaveric specimens and tensor fascia lata grafts.

Thay Q. Lee is a paid consultant for and receives research support from Arthrex. All the other authors, their immediate families, and any research foundations with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.

## References

1. Arrigoni P, Brady PC, Burkhart SS. The double-pulley technique for double-row rotator cuff repair. *Arthroscopy* 2007;23:675. <https://doi.org/10.1016/j.arthro.2006.08.016>
2. Barber FA, Aziz-Jacobo J. Biomechanical testing of commercially available soft-tissue augmentation materials. *Arthroscopy* 2009;25:1233-9. <https://doi.org/10.1016/j.arthro.2009.05.012>
3. Catapano M, de Sa D, Ekhtiari S, Lin A, Bedi A, Lesniak BP. Arthroscopic superior capsular reconstruction for massive, irreparable rotator cuff tears: a systematic review of modern literature. *Arthroscopy* 2019;35:1243-53. <https://doi.org/10.1016/j.arthro.2018.09.033>
4. Croom WP, Adamson GJ, Lin CC, Patel NA, Kantor A, McGarry MH, et al. A biomechanical cadaveric study of patellar tendon allograft as an alternative graft material for superior capsule reconstruction. *J Shoulder Elbow Surg* 2019;28:1241-8. <https://doi.org/10.1016/j.jse.2018.12.015>
5. Denard PJ, Brady PC, Adams CR, Tokish JM, Burkhart SS. Preliminary results of arthroscopic superior capsule reconstruction with dermal allograft. *Arthroscopy* 2018;34:93-9. <https://doi.org/10.1016/j.arthro.2017.08.265>
6. Deranlot J, Herisson O, Nourissat G, Zbili D, Werthel JD, Vigan M, et al. Arthroscopic subacromial spacer implantation in patients with massive irreparable rotator cuff tears: clinical and radiographic results of 39 retrospective cases. *Arthroscopy* 2017;33:1639-44. <https://doi.org/10.1016/j.arthro.2017.03.029>
7. Ek ET, Neukom L, Catanzaro S, Gerber C. Reverse total shoulder arthroplasty for massive irreparable rotator cuff tears in patients younger than 65 years old: results after five to fifteen years. *J Shoulder*

- Elbow Surg 2013;22:1199-208. <https://doi.org/10.1016/j.jse.2012.11.016>
8. Mihata T, Bui CNH, Akeda M, Cavagnaro MA, Kuenzler M, Peterson AB, et al. A biomechanical cadaveric study comparing superior capsule reconstruction using fascia lata allograft with human dermal allograft for irreparable rotator cuff tear. *J Shoulder Elbow Surg* 2017;26:2158-66. <https://doi.org/10.1016/j.jse.2017.07.019>
  9. Mihata T, Lee TQ, Hasegawa A, Kawakami T, Fukunishi K, Fujisawa Y, et al. Arthroscopic superior capsule reconstruction can eliminate pseudoparalysis in patients with irreparable rotator cuff tears. *Am J Sports Med* 2018;46:2707-16. <https://doi.org/10.1177/0363546518786489>
  10. Mihata T, Lee TQ, Hasegawa A, Kunimoto F, Kawakami T, Fujisawa Y, et al. Five-year follow-up of arthroscopic superior capsule reconstruction for irreparable rotator cuff tears. *J Bone Joint Surg Am* 2019;101:1921-30. <https://doi.org/10.2106/JBJS.19.00135>
  11. Mihata T, Lee TQ, Watanabe C, Fukunishi K, Ohue M, Tsujimura T, et al. Clinical results of arthroscopic superior capsule reconstruction for irreparable rotator cuff tears. *Arthroscopy* 2013;29:459-70. <https://doi.org/10.1016/j.arthro.2012.10.022>
  12. Mihata T, McGarry MH, Pirolo JM, Kinoshita M, Lee TQ. Superior capsule reconstruction to restore superior stability in irreparable rotator cuff tears: a biomechanical cadaveric study. *Am J Sports Med* 2012;40:2248-55. <https://doi.org/10.1177/0363546512456195>
  13. Nimura A, Kato A, Yamaguchi K, Mochizuki T, Okawa A, Sugaya H, et al. The superior capsule of the shoulder joint complements the insertion of the rotator cuff. *J Shoulder Elbow Surg* 2012;21:867-72. <https://doi.org/10.1016/j.jse.2011.04.034>
  14. Nordt WE III, Garretson RB III, Plotkin E. The measurement of subacromial contact pressure in patients with impingement syndrome. *Arthroscopy* 1999;15:121-5.
  15. Pennington WT, Bartz BA, Pauli JM, Walker CE, Schmidt W. Arthroscopic superior capsular reconstruction with acellular dermal allograft for the treatment of massive irreparable rotator cuff tears: short-term clinical outcomes and the radiographic parameter of superior capsular distance. *Arthroscopy* 2018;34:1764-73. <https://doi.org/10.1016/j.arthro.2018.01.009>
  16. Petri M, Greenspoon JA, Millett PJ. Arthroscopic superior capsule reconstruction for irreparable rotator cuff tears. *Arthrosc Tech* 2015;4:e751-5. <https://doi.org/10.1016/j.eats.2015.07.018>
  17. Tokish JM, Beicker C. Superior capsule reconstruction technique using an acellular dermal allograft. *Arthrosc Tech* 2015;4:e833-9. <https://doi.org/10.1016/j.eats.2015.08.005>