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BASIC SCIENCE

Comparison of two different superior capsule reconstruction methods in the treatment of chronic irreparable rotator cuff tears: a biomechanical and histologic study in rabbit models

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Background: In the treatment of irreparable rotary cuff (RC) tears, the superior capsule of the shoulder is reconstructed using tensor fascia lata (TFL) or several allografts to prevent progressive joint degeneration. This study compared the healing qualities of acellular human dermal graft (HDG) and the TFL autograft in superior capsule reconstruction (SCR) from biomechanical and histologic perspectives.
Methods: Chronic retracted RC tear models were created bilaterally in 9 rabbits, and 7 rabbits with intact RC were used as a control group. SCR was performed 8 weeks after the tear using HDG in right shoulders and TFL in left shoulders. At 12 weeks after SCR, 2 shoulders from each experimental group were investigated for histologic healing, and 7 samples from the experimental and control groups were biomechanically tested.
Results: Complete healing was observed macroscopically in the glenoid and humeral sides of both groups. No difference was observed in the enthesis maturation scores between the experimental groups. Collagen fiber density was higher and the orientation was better in TFL group. Inflammatory cell infiltration was not seen in the TFL group, but inflammatory cell infiltration was pronounced in the HDG group. The mean pullout strengths of the TFL group, HDG group, and intact RC group were 139.7 ± 40.5 N, 123.9 ± 47.9 N, and 105.1 ± 11.8 N ($P = .187$), respectively. The mean stiffness values ($P = .711$), yield forces ($P = .404$), and displacements ($P = .135$) were also statistically not different between the groups.
Conclusion: In SCR, the healing qualities of HDG and TFL were similar in rabbit models.
Level of evidence: Basic Science Study; Biomechanics and Histology

Keywords: Superior capsule reconstruction; tensor fascia lata; human dermal allograft; biomechanics; healing; shoulder stability

The Bezmialem Vakif University Ethical Committee for Animal Studies approved this experimental animal study (2016/155).

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The superior shoulder capsule, which is a tiny membranous sleeve above the rotator cuff (RC) with insertion to the greater tubercle in 30% to 60% of people, has an important role in the stability of the shoulder.[10,18] Biomechanical cadaveric studies have showed that the superior capsule is one of the main static stabilizers in the superior stability of the shoulder.[11,16,18]

Although most RC tears heal with excellent results after open or arthroscopic repair, some chronic retracted tears cannot be repaired due to muscle atrophy or fatty degeneration.[2,5,6,14,19] In the treatment of irreparable RC tears, superior capsule reconstruction (SCR) is a recent and popular method that is performed arthroscopically or open to prevent progressive joint degeneration.[15-17] The main aim of the surgery is to make superior shoulder stability by tension effect of the superior capsule. The secondary aim is to maintain the spacer effects of the torn and defected supraspinatus and infraspinatus tendons over the humeral head with a different mechanism.

Several allografts, such as the acellular human dermal allograft (HDG) or autologous tensor fascia lata (TFL) graft, are used for this reason. Mihata et al[17] described SCR by using 6- to 8-mm autologous TFL; however, 3.0-mm HDG is mostly preferred in North America.[17,22] In a recent study, the mean acromiohumeral distance after SCR with TFL was increased from 4.6 mm to 8.7 mm, the mean active elevation was increased from 84° to 148°, the mean American Shoulder and Elbow Surgeons score was increased from 23.5 to 92.9 points, and postoperative magnetic resonance imaging (MRI) showed intact reconstruction without progression of muscle atrophy in 83% of the patients.[16] Denard et al,[4] however, reported the first preliminary results of arthroscopic SCR using HDG. Similar to the clinical studies by Mihata et al, they also found significant improvements in the clinical outcomes at a minimum of 1-year follow-up. They reported their success rate as 74.6%; however, the healing rate of the HDG was 45% based on the MRI, and the mean acromiohumeral distance was not increased compared with their preoperative measurements. These results not only showed the success and importance of SCR for the functions and stability of the shoulders but also raised the question about whether HDGs are inferior to TFL in their healing patterns in SCR. In addition, the thickness of the TFL and its fixation in 10° to 30° of glenohumeral abduction were shown to have important effects on superior stability.[17]

The initial shoulder stabilities after different SCR fixation methods have been demonstrated by in vitro biomechanical studies using cadavers. The main conclusions of the clinical studies of the SCR using TFL or HDG showed the importance of the graft healing, which is correlated to the success rate of the surgery and the clinical outcomes.[4,16] However, graft-to-bone healing patterns and their pullout strengths after healing still need to be explored. To our knowledge, no study to date has compared HDG and TFL in SCR after healing of the grafts, from biomechanical and histologic perspectives. We hypothesized that after SCR surgery, graft-to-bone healing of autologous TFL would be histologically better than acellular HDG and that TFL would provide greater fixation strength than HDG after healing. This study was designed to histologically and biomechanically compare healing qualities of HDG, which is an allograft for the human and a xenograft for the rabbit, and TFL autograft.

Materials and methods

The experiments used 25 shoulders of 16 New Zealand mature rabbits. The rabbits weighed from 2.8 to 3.5 kg. We performed SCR using autologous TFL in the left shoulders of 9 rabbits and used sterile decellularized HDG (ArthroFLEX; LifeNet Health, Virginia Beach, VA, USA) in the right shoulders of the same 9 rabbits. Although the acellular dermal graft was a kind of allograft for humans, the HDG in this animal study is a xenograft for the rabbits.

The experiments were completed in 3 stages. The first step was the creation of the massive cuff tear models, the second step included SCR using TFL or HDG, and the third step was biomechanical and histologic analyses performed on the healing tissues of the SCR models.

We divided the 25 shoulders of the 16 rabbits into 3 groups: a control group with intact supraspinatus and subscapularis tendons (n = 7), a TFL group (n = 9), and an HDG group (n = 9).

Creation of the massive RC defects

In the first stage of the experiments, we created massive supraspinatus and subscapularis tendon defects in both shoulders of the 9 rabbits to simulate massive, retracted, irreparable cuff tears in humans.[20] The rabbits were anesthetized using 10 mg/kg ketamine hydrochloride and 3 mg/kg xylazine hydrochloride. The bilateral shoulders were shaved, and surgical areas were prepared for the sterile environment using povidone-iodine and dressing. Through a 2-cm incision and a deltopectoral approach, supraspinatus and subscapularis tendons were identified and detached from their insertions on the proximal humerus, and their distal 5-mm lengthwise lateral segments were removed with underlying capsule, using the knife to create supraspinatus and subscapularis tendon defects (Fig. 1). After control

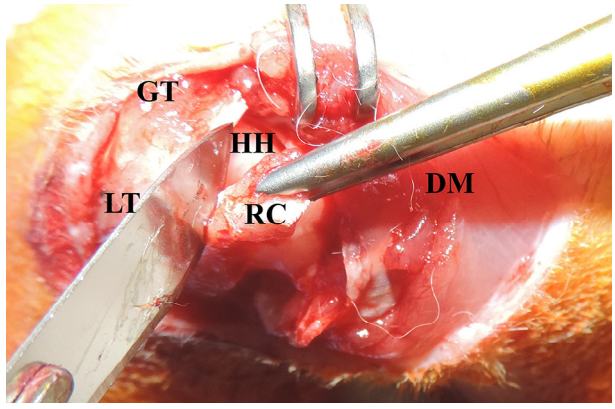

Figure 1 First step of the surgery in the right shoulder of a rabbit. The rotator cuff (*RC*) supraspinatus and subscapularis tendons were identified, and their 5-mm width segment was resected. *DM*, deltoid muscle; *HH*, humeral head; *GT*, greater tubercle; *LT*, lesser tubercle.

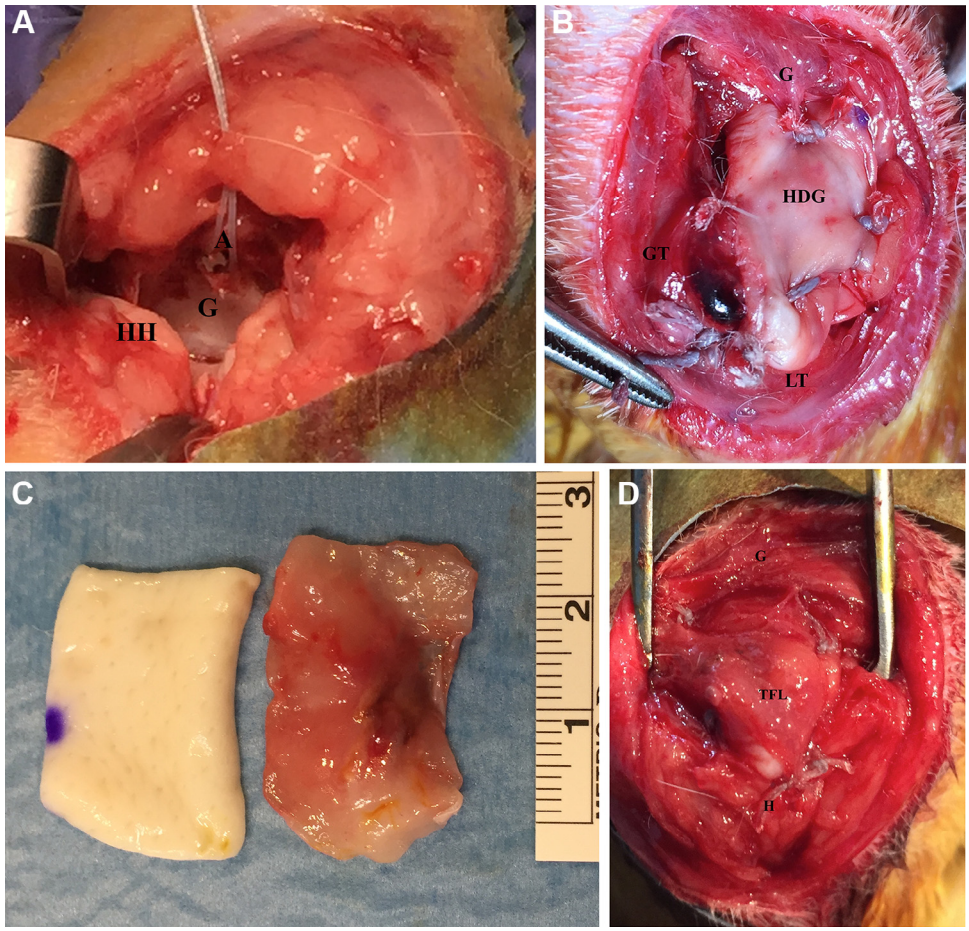

Figure 2 (**A**) Placement of a metal suture anchor (*A*) into the supraglenoid area. *G*, glenoid; *HH*, humeral head. (**B**) Superior capsule reconstruction (SCR) using human dermal graft (*HDG*). *G*, glenoid side; *LT*, lesser tubercle; *GT*, greater tubercle. (**C**) Acellular human dermal graft (on the left) and tensor fascia lata autograft (on the right) used for SCR in the study. (**D**) SCR using autologous tensor fascia lata (*TFL*). *G*, glenoid side; *H*, humeral side.

of hemorrhage, the fascia and skin were closed and dressed. The same procedures were applied bilaterally. After the operations, the animals were placed in separate cages without any restriction of mobilization. For infection prophylaxis, 50 mg/kg cefazolin sodium was provided, and naproxen sodium was administered for pain relief over the next 24 hours.

To simulate chronic retracted, massive cuff tears of humans in the animal models, we waited 8 weeks before SCR.[3]

SCR procedure

The second stage of the experiment was SCR, which was performed 8 weeks after the tears were created. At this stage, all of the rabbits were anesthetized again, and under sterile conditions and infectious prophylaxis with cefazolin sodium, the superior rim of the glenoid and the greater tuberosity were reached through a deltopectoral approach. In all shoulders, the glenohumeral joint cartilages were apparent when the deltoid muscle retracted. There was neither a native capsule nor a neocapsule. We placed a 2.0-mm metal suture anchor with permanent braided sutures into the supraglenoid area of the scapula and inserted a 2-0 mm nonabsorbable polyfilament transosseous suture through the greater tuberosity for fixation of the grafts for SCR (Fig. 2, *A*).

For the right shoulders, acellular HDG with dimensions of 20 mm in length, 10 mm in width, and 1.26 to 1.75 mm in thickness were used as the graft. First, the dermal graft was tightly attached to the superior of the glenoid using 2 sutures of the metal anchor, and the lateral end of the graft was attached to the area between the greater and lesser tuberosity using a previously inserted transosseous suture with the mattress technique while holding the shoulder in 20° to 30° of abduction[15,23] (Fig. 2, *B*). After 1 anterior and 1 posterior side-to-side stitches were added for fixation of the graft, the wound was closed and dressed.

For the left shoulder, we first harvested the TFL autograft. A 3-cm longitudinal incision was made over the TFL of the left tight tensor fascia, and the fascia, with dimensions of 20 mm × 10 mm, were harvested using a knife and scissors (Fig. 2, *C*). We folded the graft in half to double its thickness. The thickness of the HDG was between 1.26 and 1.75 mm, as the manufacturer reported, and we doubled the TFL to obtain a similar thickness. With the same technique as the right shoulder, the TFL was fixed to the superior of the glenoid and the tuberosities (Fig. 2, *D*). The incisions were closed and dressed, and the rabbits were put in their own cages.

Harvesting the specimens

The third stage of the experiment was euthanizing the animals for histologic evaluations and biomechanical tests of the healing qualities of the SCR methods and biomechanical tests of the intact control group. For healing time, we waited 8 weeks after the SCR, and then, all of the animals were euthanized using intracardiac high-dose ketamine hydrochloride and xylazine hydrochloride.[9] After disarticulations of the scapulothoracic and elbow joints, we removed all of the soft tissues and capsule around the shoulder joint, but left intact the scapula, the humerus, and the reconstructed superior capsule, which was previously attached to the superior of the glenoid and the tuberosities.

The 7 rabbits in the control group (with intact RC tendons) were euthanized with the same technique to compare their shoulders with the experimental groups. Only the supraspinatus and subscapularis tendons were left intact, and other soft tissues around the shoulder joint, including the capsule, were cut.

Outcome measures

The primary outcome of this study was the ultimate failure load of the SCR, which was measured with a load-to-failure test. The secondary outcomes were stiffness values, yield forces, and amount of displacement of the SCR constructs at the failure in the mechanical tests and gross and histologic healing patterns of the grafts to the bones.

Gross evaluations

After the animals were euthanized, all of the shoulders were evaluated macroscopically for healing defects and partial or complete healing.

Histologic evaluations

A pathologist, who was blinded to the reconstruction methods, investigated 4 bilateral shoulders from 2 rabbits from the experimental groups for the graft-to-tendon healing qualities of the glenoid and humeral sides of the grafts.

In the gross evaluations, samples were macroscopically evaluated for complete or partial healing at the graft-to-bone junction.

For the histologic analyses, samples were fixed with 10% neutral-buffered formalin for 2 days and decalcified in 10% formic acid for 6 days, washed in water, and processed for standard paraffin embedding. Mega paraffin blocks were used for the specimens. Serial sections (5-μm-thick slices) were cut from the mega blocks using a microtome. The sections were stained with hematoxylin and eosin, Masson's trichrome, and silver stain for light microscopic examination (Eclipse-Ci; Nikon Instruments, Melville, NY, USA). Photographs were captured with an Eclipse 80i-DS-Ril digital camera (Nikon Instruments).

A pathologist blinded to the study design scored the maturation of enthesis and assessed the graft-to-bone healing. Enthesis was scored using the criteria listed in Table I. The phase of graft-to-bone healing was determined by evaluating fiber formation with Masson's trichrome and silver stain. In addition, to quantitatively evaluate the graft-to-bone healing, a scoring scale was used including collagen fiber density, collagen fiber orientation, inflammatory cell infiltration, increased vascularity on light microscope, and Sharpey fibers between the graft and bone on a polarized light microscope (Table II).[10]

Table I Enthesis maturation scoring system for graft-to-bone healing

Score	Definition
1	The insertion had continuity without fibrous tissue or bone ingrowth
2	The insertion had continuity with fibrous tissue ingrowth but no fibrocartilage cells
3	The insertion had continuity with fibrous tissue ingrowth and fibrocartilage cells but no tidemark
4	The insertion had continuity with fibrous tissue ingrowth, fibrocartilage cells, and a tidemark

Table II Quantitative analyses of graft-to-bone healing

Characteristic	Grading	Score
Collagen fiber density	Low	1
	Medium	2
	High	3
Collagen fiber orientation	None	0
	Some	1
	Mostly	2
	Completely	3
Inflammatory cell infiltration	None	0
	Mild	1
	Moderate	2
	Severe	3
Vascularization	None	0
	Mild	1
	Moderate	2
	Abundant	3
Sharpey fibers	0%	0
	25%	1
	50%	2
	75%	3

Biomechanical evaluations

Seven bilateral shoulders from the experimental groups were biomechanically tested for the healing qualities of the SCR methods, and 7 shoulders in the control group were tested for the tensile strength of the intact supraspinatus and subscapularis tendons. The mechanical tests were performed on the day of euthanasia.

We embedded the medial part of the scapula and two-thirds distal part of the humerus into polyvinylchloride pipes, which were 5 cm in diameter, using polyester putty. The polyvinylchloride pipes were fixed to the universal biomechanical test machine (MTS mini Bionix II; Eden Prairie, MN, USA) at a right angle. The scapular side was fixed to the load cell, and the humeral side was fixed to the mechanical loading arm using fixture attachments (Fig. 3). The tensile linear force was exerted on the humerus through fixture attachments in the direction of perpendicular to the humeral diaphysis and parallel to the rotation axis of the scapula to simulate neutral abduction of the shoulder. According to the test protocol, after 10 N

Figure 3 Scapular and humeral sides were fixed to the biomechanical test machine at right angles.

of preloading in 2 minutes, 60 cyclic loadings from 5 N to 50 N were applied with 0.25-Hz frequency.[3] After cyclic loading, the failure load was applied with a velocity of 1 mm/s to measure the maximum pullout strengths. Failure was defined as a sudden decrease in the load-displacement curve, occurrence of a fracture in the bony parts, or a complete tear in the soft tissue. The outcome parameter of the biomechanical tests was ultimate failure load, which is the measured pullout strength of the healed SCR, the yield force, and vertical displacements at failure. Elongation at failure was defined as the amount of vertical displacement of the loading arm of the test machine at failure. This measurement does not show only the amount of elongation of the SCR because of the other parts of the construct but can give comparable values for each group.

Statistical analyses

We made a power analysis during the study design to determine the number of shoulders for the biomechanical tests. We thought that among the parameters, failure load could increase the number of required shoulders mostly. Thus, for a maximum of 50-N differences in the failure load between the groups and about 30 N of standard deviation, we calculated the number of required shoulders for each group as 7 (for 95% confidence level and 80% power). We used the Kruskal-Wallis test for the comparisons between the groups because the ranges of standard deviations were large and the values did not show normal distribution.

Results

Gross evaluation

Macroscopically, complete healing was observed in the glenoid and humeral sides in all samples from both groups. No defect was detected in any part of the graft-to-bone junction on either side.

Histologic analyses

From each experimental group, 2 pairs of shoulders were used for histologic analyses (Fig. 4). The insertion had continuity with fibrous tissue ingrowth and fibrocartilage cells (Fig. 5, *A*) but no tidemark in either group, so no difference was observed in the enthesis maturation scores between the experimental groups (3 points for each sample). Collagen fibers were found in both groups with Masson's trichrome stain and appeared in the late phase of healing (Table III; Fig. 5, *B* and Fig. 6, *B*). However, collagen fiber density was greater and orientation was better in the TFL group (3 points vs. 2 points). Minimal reticular fiber formation was detected at the graft-to-bone junctional areas of both groups with silver stain

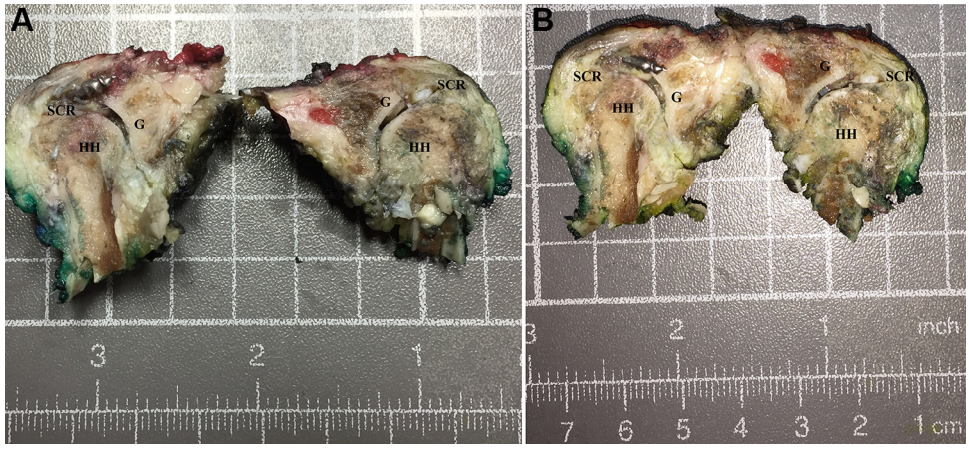

Figure 4 (**A**) Macroscopic evaluation of the specimen from the tensor fascia lata group showed intact and healed superior capsule reconstruction (*SCR*). (**B**) Macroscopic evaluation of the specimen from the human dermal graft group showed intact and healed superior capsule reconstruction. *G*, glenoid; *HH*, humeral head.

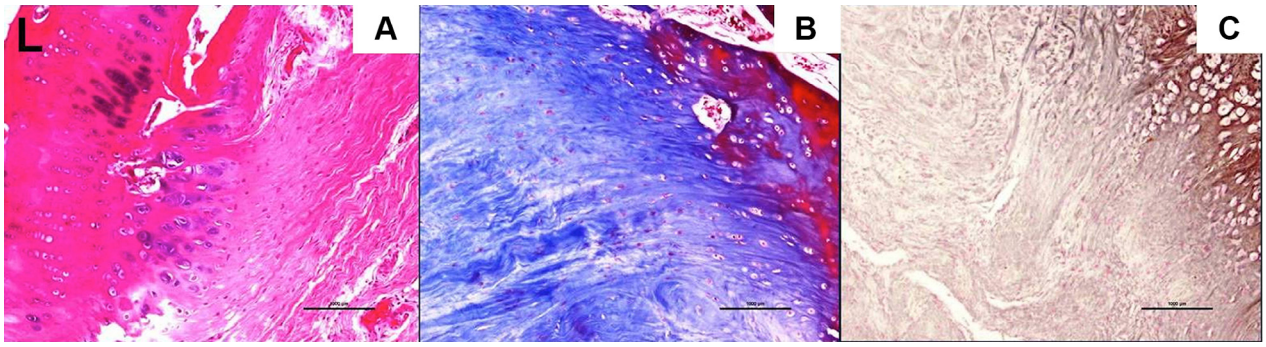

Figure 5 (**A**) Tendon-to-bone insertion area on a specimen from the tensor fascia lata (TFL) group, glenoidal side. The insertion has continuity with fibrous tissue ingrowth and fibrocartilage cells. Dense, organized, and wavy collagen fibers are observed (hematoxylin and eosin stain, original magnification ×100). (**B**) Tendon-to-bone insertion area of the glenoidal side in the TFL group. Dense collagen fibers with wavy pattern are demonstrated (Masson's trichrome stain, original magnification ×100). (**C**) Minimal reticuler fiber formation is visualized in the tendon-to-bone insertion area of the glenoidal side in the TFL group (silver stain, original magnification ×100).

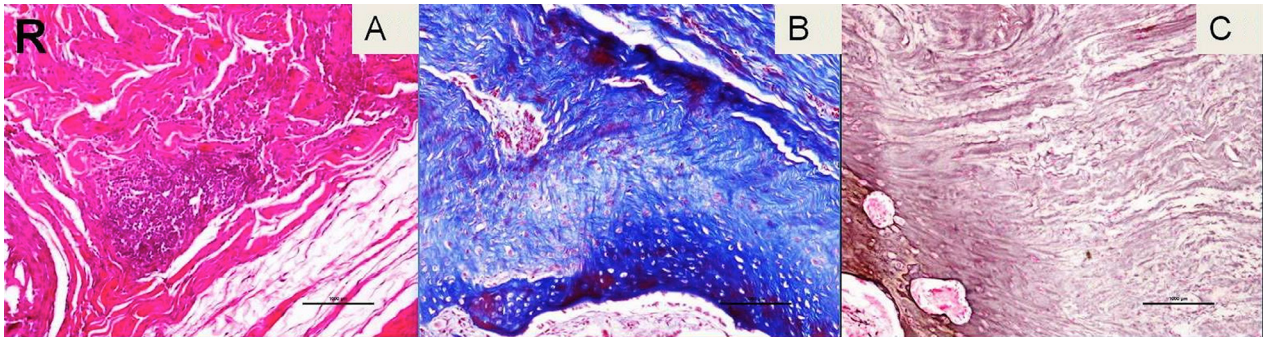

Figure 6 (**A**) Tendon-to-bone insertion area of a specimen from the human dermal graft group (HDG), humeral side. Abundant inflammatory cell infiltration is noticed into collagenous matrix (hematoxylin and eosin stain, original magnification ×100). (**B**) Tendon-to-bone insertion area of the glenoidal side in the HDG group. Dense collagen fibers with wavy pattern are demonstrated with Masson's trichrome stain (Masson's trichrome stain, original magnification ×100). (**C**) Tendon-to-bone insertion area in the HDG group, glenoidal side. Minimal reticuler fiber formation is visualized (silver stain, original magnification ×100).

Table III Histologic scores of the specimens from the human dermal graft group and the tensor fascia lata group for the humeral and glenoid insertions of the grafts*

Characteristic	Human dermal graft		Autologous tensor fascia lata	
	Humeral	Glenoid	Humeral	Glenoid
Collagen fiber density	2	2	3	3
Collagen fiber orientation	1	2	3	3
Inflammatory cell infiltration	3	2	0	0
Vascularization	2	2	2	3
Sharpey fibers	2	3	3	3

* The scores (see Table II) were the same for 2 specimens from the human dermal graft group and the same for 2 specimens from the tensor fascia lata group.

(Fig. 5, *C* and Fig. 6, *C*). Reticular fibers appeared during the early phase of the regeneration. These histologic findings meant complete graft-to-bone healing for both groups.

Inflammatory cell infiltration was not seen in the glenoid or tuberosity insertions of the samples from the TFL group, which indicates complete healing. In the HDG group, however, inflammatory cell infiltration was more pronounced, especially in the lesser tuberosity insertion area, which demonstrates delayed healing or inflammatory response to HDG (Fig. 6, *A*).

Biomechanical tests

Seven samples from the experimental and control groups were biomechanically tested. All of the specimens passed cyclical loading tests and underwent failure load for the

Table IV Results of the biomechanical test

Group	Failure load	Stiffness	Yield load	Displacement
	(N)	(N/mm)	(N)	(mm)
TFL				
Mean	139.7	23.8	142.1	14.7
SD	40.5	13.7	43.6	7.1
Median	115.0	19.7	120.0	14.2
HDG				
Mean	123.9	19.5	123.7	13.3
SD	47.9	8.9	49.0	5.4
Median	102.0	23.3	101.0	12.8
Intact RC				
Mean	105.1	25.2	105.1	11.7
SD	11.8	3.1	11.9	3.3
Median	105.0	25.1	101.0	11.2
P value*	.187	.711	.404	.135

TFL, tensor fascia lata; *SD*, standard deviation; *HDG*, human dermal graft; *RC*, rotator cuff
* Kruskal-Wallis test.

measurement of their ultimate failure loads. We noted failure modes of all the specimens. In the HDG group, the samples failed by superior capsule tear in 4 specimens and by scapular neck fracture in 3 specimens. In the TFL group, superior capsules were torn in 5 specimens, the proximal humerus was broken in 1, and neck of the scapula was broken in 1 during failure. In the control group, intact RC was torn through its muscular part in each specimen.

The mean failure loads of the TFL, HDG, and intact RC groups were 139.7 N, 123.9 N, and 105.1 N, respectively ($P = .187$; Table IV). The mean yield loads of the TFL, HDG, and intact RC groups were 142.1 N, 123.7 N, and 105.1 N, respectively ($P = .404$), the mean stiffness values were 23.8 N/mm, 19.5 N/mm, and 25.2 N/mm, respectively ($P = .711$), and the mean amounts of displacements in the constructs were 14.7 mm, 13.3 mm, and 11.7 mm, respectively ($P = .711$). Although the mean failure load of the TFL group was the highest and the mean failure load of the HDG group was higher than the intact RC group, the differences between the groups were not statistically significant.

Discussion

SCR is a popular technique that has promising short-term results in the treatment of chronic, massive, irreparable RC tears.[16] The superior capsule of the shoulder is an anatomically and histologically distinct layer and is different from the tendon layer that attaches to a substantial area of the greater tuberosity (30%-61%).[18] The superior capsule and supraspinatus are important stabilizers and depressors of the humeral head that provide a stable fulcrum for the deltoid muscle.[11] Superior glenohumeral translation at 5° and 30° of abduction has been shown biomechanically in cases of superior capsular defects that cause superior humeral escape.[11] Another biomechanical cadaveric study showed that SCR with a collagen graft restored the superior stability in massive, irreparable RC tear models.[17]

Different types of grafts are available for the treatment of massive irreparable RC tears, such as TFL autograft, HDG, xenografts, and synthetic patch augmentations[1,7,8,16] TFL and HDG are the main and best options for SCR. However, no study to date has analyzed and compared the histologic and biomechanical properties of the graft options and their healing outcomes. This animal study biomechanically and histologically analyzed HDG and TFL for SCR.

From a biomechanical point of view, a cadaveric study by Mihata et al[15] compared SCR using fascia lata allografts with SCR using HDG. Their results showed HDG only partially restored superior glenohumeral stability, whereas the fascia lata allograft fully restored superior glenohumeral stability.[15] The biomechanical assessment in our study found the mean pullout strength of the TFL group was the highest, and that of the HDG group was higher than the intact RC group; however, these differences were not statistically significant. There were no significant differences between the groups in mean displacements of the constructs at failure.

In a biomechanical study on RC healing, in which the mechanical testing methods were not the same but similar, the mean ultimate failure loads of the healed RCs at 8 weeks were 148.4 ± 31 N in microfracture group and 101.4 ± 26 N in control group without microfracture.[3] In our study, the mean failure loads of the TFL, HDG, and intact RC groups were 139.7 ± 40.5 N, 123.9 ± 47.9 N, and 105.1 ± 11.8 N, respectively. Although it may not be accurate to compare the results of SCR to the RC repair in rabbit models, we observe that the results of failure strengths are very similar in both studies, especially when the results of RC repair group without microfracture was compared with the intact RC group in our study. The amount of elongations of the tendons in the above study is almost half of the elongations in our study. This could have resulted from differences in the testing methods.

There are currently no studies evaluating the histologic outcomes and findings of SCR in the healing capacities of the grafts on the glenoid and tuberosity surfaces. In our current study, the enthesis maturation scores and the vascularity response to injury and treatment were similar among groups. Inflammatory cell infiltration was not seen in the glenoid or tuberosity insertions of the TFL, which indicates a completed healing process. In the HDG group, however, inflammatory cell infiltration was pronounced and severe, especially in the lesser tuberosity insertion area. Although inflammatory cell infiltration is typical in the early phase of the healing process, it demonstrates delayed healing in the late phase that is caused by host reaction. Collagen fibers were found in both groups, and they appear in the late phase of healing. Collagen fiber density was higher and orientation was better in the TFL group than in the HDG group. Minimal reticular fiber formation that appears during the early phase of regeneration was detected at graft-to-bone junctional areas

in both groups. The histologic findings showed both groups had complete graft-to-bone healing; nevertheless, the healing process with TFL was relatively better.

Several types of allografts have been used in different fields of orthopedics for a long time, and some potential problems, such as healing, disease transmission, and high costs, are their well-known disadvantages compared with autografts. Although HDG could be considered as a xenograft for the rabbit, it might be acting as an allograft because of its acellularity. However, there is concern with xenografts regarding the potential for an inflammatory response and subsequent failure to heal.[24] Inflammation can occur due to residual cell damage.[26]

Clinical results indicating the stability of TFL are encouraging. Mihata et al[16] reported the outcomes after a minimum of 2 years of follow-up of the SCRs using TFL graft in 24 shoulders. All shoulders had irreparable RC tears and were evaluated during shoulder arthroscopy. All of the measured outcomes improved significantly for the patients, and only 15% of patients had retears in the follow-up interval.[16] Denard et al[4] published a clinical study examining the minimum 1-year follow-up outcomes of 59 patients in whom dermal allografts were used in arthroscopic SCR and found a successful outcome in approximately 70%. However, only 45% of the dermal allografts were healed at the 1-year follow-up according to MRI, and this healing rate was lower than the healing rate of TFL (83%) in the study of Mihata et al. One reason for the lower rate of healing in HDG could be related to healing problems of the allografts in the orthopedic procedures compared with autografts.[12,13,25] Pennington et al[21] reported 1-year outcomes of arthroscopic SCR using HDG of 86 patients and found significant improvements in visual analog scale pain scores and American Shoulder and Elbow Surgeons scores, the acromiohumeral interval on radiographs, and muscle strengths and ROM of the shoulders. The rate of patient satisfaction was 90% in their series.

Some limitations must be considered when generalizing our results to human populations. First, this study was conducted on rabbits, and rabbits have similar but also different anatomic properties compared with humans. The healing rates of the tissues in rabbits are also not same as in human physiology.

Second, the histopathology scores were not statistically analyzed because of the low sample number for each group, and immunohistochemistry evaluations were not performed.

Third, other allograft and synthetic graft options were not evaluated.

Fourth, we did not perform biomechanical tests in different direction of the forces, which could simulate shoulder movements in other directions, especially in the inferosuperior direction.

Lastly, the 2-0-mm metal anchor could be large for the glenoid of the rabbits; however, we believe that it did not affect fixation of the grafts and, therefore, our healing process and the results. We also did not notice any glenoid bony failure during the insertion of the anchors.

Conclusion

HDG and the TFL autograft had similar biomechanical and histologic results in rabbit models. We believe that this study can provide guidelines for graft options that are used in SCR. Further biomechanical and clinical studies are needed.

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References

1. Audenaert E, Van Nuffel J, Schepens A, Verhelst M, Verdonk R. Reconstruction of massive rotator cuff lesions with a synthetic interposition graft: a prospective study of 41 patients. Knee Surg Sports Traumatol Arthrosc 2006;14:360-4. http://dx.doi.org/10.1007/s00167-005-0689-7
2. Bedi A, Dines J, Warren RF, Dines DM. Massive tears of the rotator cuff. J Bone Joint Surg Am 2010;92:1894-908. http://dx.doi.org/10.2106/JBJS.I.01531
3. Bilsel K, Yildiz F, Kapicioglu M, Uzer G, Elmadag M, Pulatkan A, et al. Efficacy of bone marrow-stimulating technique in rotator cuff repair. J Shoulder Elbow Surg 2017;26:1360-6. http://dx.doi.org/10.1016/j.jse.2017.02.014
4. 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. http://dx.doi.org/10.1016/j.arthro.2017.08.265
5. Gerber C, Fuchs B, Hodler J. The results of repair of massive tears of the rotator cuff. J Bone Joint Surg Am 2000;82:505-15.
6. Goutallier D, Postel JM, Bernageau J, Lavau L, Voisin MC. Fatty muscle degeneration in cuff ruptures. Pre- and postoperative evaluation by CT scan. Clin Orthop Relat Res 1994;(304):78-83.
7. Gupta AK, Hug K, Berkoff DJ, Boggess BR, Gavigan M, Malley PC, et al. Dermal tissue allograft for the repair of massive irreparable rotator cuff tears. Am J Sports Med 2012;40:141-7. http://dx.doi.org/10.1177/0363546511422795
8. Gupta AK, Hug K, Boggess B, Gavigan M, Toth AP. Massive or 2-tendon rotator cuff tears in active patients with minimal glenohumeral arthritis: clinical and radiographic outcomes of reconstruction using dermal tissue matrix xenograft. Am J Sports Med 2013;41:872-9. http://dx.doi.org/10.1177/0363546512475204
9. Gupta R, Lee TQ. Contributions of the different rabbit models to our understanding of rotator cuff pathology. J Shoulder Elbow Surg 2007;16:S149-57. http://dx.doi.org/10.1016/j.jse.2007.05.002
10. Hee CK, Dines JS, Dines DM, Roden CM, Wisner-Lynch LA, Turner AS, et al. Augmentation of a rotator cuff suture repair using rhPDGF-BB and a type I bovine collagen matrix in an ovine model. Am J Sports Med 2011;39:1630-9. http://dx.doi.org/10.1177/0363546511404942
11. Ishihara Y, Mihata T, Tamboli M, Nguyen L, Park KJ, McGarry MH, et al. Role of the superior shoulder capsule in passive stability of the

glenohumeral joint. J Shoulder Elbow Surg 2014;23:642-8. http://dx.doi.org/10.1016/j.jse.2013.09.025
12. Leroux TS. Editorial commentary: superior capsule reconstruction with dermal allograft: effective marketing or the real deal? Arthroscopy 2018;34:102-4. http://dx.doi.org/10.1016/j.arthro.2017.10.033
13. MARS Group. Effect of graft choice on the outcome of revision anterior cruciate ligament reconstruction in the Multicenter ACL Revision Study (MARS) Cohort. Am J Sports Med 2014;42:2301-10. http://dx.doi.org/10.1177/0363546514549005
14. Melis B, Nemoz C, Walch G. Muscle fatty infiltration in rotator cuff tears: descriptive analysis of 1688 cases. Orthop Traumatol Surg Res 2009;95:319-24. http://dx.doi.org/10.1016/j.otsr.2009.05.001
15. Mihata T, Bui CN, 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. http://dx.doi.org/10.1016/j.jse.2017.07.019
16. 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. http://dx.doi.org/10.1016/j.arthro.2012.10.022
17. 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. http://dx.doi.org/10.1177/0363546512456195
18. 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. http://dx.doi.org/10.1016/j.jse.2011.04.034
19. Oh JH, Kim SH, Choi JA, Kim Y, Oh CH. Reliability of the grading system for fatty degeneration of rotator cuff muscles. Clin Orthop Relat Res 2010;468:1558-64. http://dx.doi.org/10.1007/s11999-009-0818-6
20. Otarodifard K, Wong J, Preston CF, Tibone JE, Lee TQ. Relative fixation strength of rabbit subscapularis repair is comparable to human supraspinatus repair at time 0. Clin Orthop Relat Res 2014;472:2440-7. http://dx.doi.org/10.1007/s11999-013-3439-z
21. 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. http://dx.doi.org/10.1016/j.arthro.2018.01.009
22. Petri M, Greenspoon JA, Millett PJ. Arthroscopic superior capsule reconstruction for irreparable rotator cuff tears. Arthrosc Tech 2015;4:e751-5. http://dx.doi.org/10.1016/j.eats.2015.07.018
23. Sethi P, Franco WG. The role of superior capsule reconstruction in rotator cuff tears. Orthop Clin North Am 2018;49:93-101. http://dx.doi.org/10.1016/j.ocl.2017.08.015
24. Walton JR, Bowman NK, Khatib Y, Linklater J, Murrell GA. Restore orthobiologic implant: not recommended for augmentation of rotator cuff repairs. J Bone Joint Surg Am 2007;89:786-91. http://dx.doi.org/10.2106/JBJS.F.00315
25. Wasserstein D, Sheth U, Cabrera A, Spindler KP. A systematic review of failed anterior cruciate ligament reconstruction with autograft compared with allograft in young patients. Sports Health 2015;7:207-16. http://dx.doi.org/10.1177/1941738115579030
26. Zheng MH, Chen J, Kirilak Y, Willers C, Xu J, Wood D. Porcine small intestine submucosa (SIS) is not an acellular collagenous matrix and contains porcine DNA: possible implications in human implantation. J Biomed Mater Res B Appl Biomater 2005;73:61-7. http://dx.doi.org/10.1002/jbm.b.30170