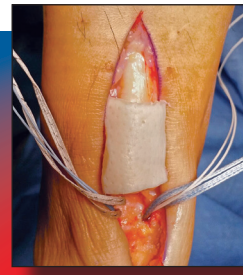

The Use of Acellular Dermal Matrices in Tendon Repair

These allografts offer many treatment advantages.

BY WINDY COLE, DPM

Goals and Objectives

After reading this article the podiatric physician will be able to:

1) Recognize the frequency of Achilles tendon ruptures and the potential complications.

2) Learn about the properties of acellular dermal matrices and their effectiveness in tendon augmentation.

3) Become knowledgeable in the surgical technique in employing ADMs in tendon repair.

4) Familiarize themselves with the Foot Function Index.

5) Denote the differences among ADM products.

6) Understand the histological pattern of healing in the tendon-ADM junction.

7) Understand the use of ADMs into surgical practice in the appropriate patients.

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Achilles tendon ruptures are quite common in the general population, especially among members of the older demographic occasionally active in sports. Operative treatments provide a lower re-rupture rate than non-operative treatments but the complication rate is a concern. The use of a human acellular dermal matrix (ADM) to augment the repair may reduce the complication rate while still demonstrating a low re-rupture rate and satisfactory functional outcomes. In this article, we present a detailed technique and evaluation of nine patients who underwent Achilles tendon repair with acellular dermal matrix augmentation. After non-viable tissue was removed, the primary repair of the tear or ruptured tendon was performed using a soft tissue fixation

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device. The repair was then augmented using one 5 x 5 cm piece of human acellular dermal matrix, which was attached using an interrupted stitch pattern.

The patient was non-weight-bearing for three to four weeks and then transitioned to a removable cast boot. Functional outcomes were evaluated using the Foot Function Index-Revised long form and any complications or re-ruptures were noted. After an average 18 months follow-up (12 months minimum), the average Foot Function Index-Revised long form score was 33.0% ± 4.2, which corresponded to reduced pain and positive functional outcomes in comparable studies in the literature. There were no cases of re-rupture or complications related to treatment after a minimum of two years post-operative duration noted in this case series. The successful outcomes presented here support further evaluation beyond this initial case series for using a human acellular dermal matrix as an augment in Achilles tendon repairs.

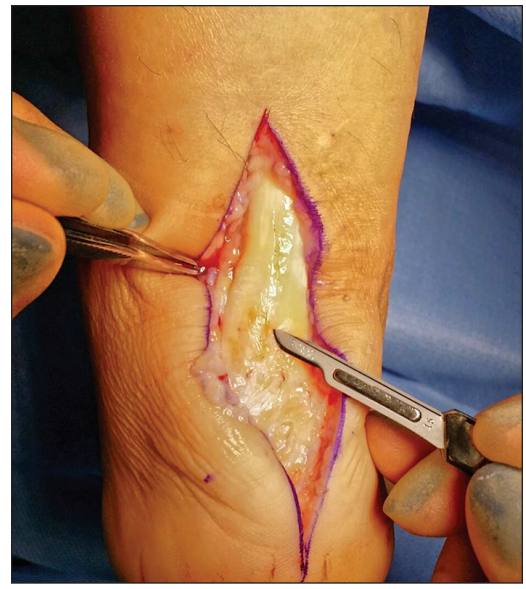

Figure 1: Skin and subcutaneous tissue were carefully dissected in one layer

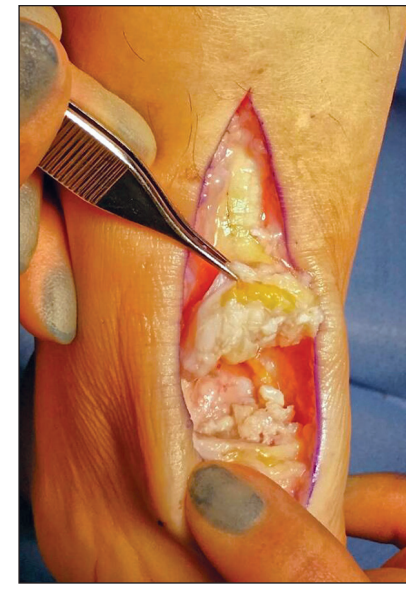

Figure 2: Chronic mucoid degeneration and hypertrophied tendon noted just proximal to the Achilles tendon insertion

Augmentation is used in tendon repair to strengthen the repair site and reduce the risk of a re-rupture.

Introduction

The Achilles tendon is one of the most common tendons to rupture despite being the thickest tendon in the human body.[1] Acute ruptures frequently occur while participating in sports, especially in patients over the age of 30 who are only occasional athletic participants.[2] Achilles tendon ruptures are frequently misdiagnosed, which delays needed treatment and creates neglected ruptures.[3] Both surgical and non-surgical treatments now advocate the use of braces over rigid casts to allow early mobilization,[4] but there is debate over the more effective treatment. One meta-analysis found a significantly lower re-rupture rate for surgical treatment but a significantly lower complication rate for non-operative treatment.[5]

Another review reported there were no significant differences for complication and re-rupture rates between the two treatment types, though several studies had lower re-rupture rates for surgical than non-surgical treatment.[4] These reviews, along with other literature,[6] indicate that surgical treatment is the preferable option but alternative techniques are needed to further decrease both re-rupture and complication rates.

Augmentation is used in tendon repair to strengthen the repair site and reduce the risk of a re-rupture. While augmentation has been used in other types of tendon repair, especially major rotator cuff repairs,[7] there are not as many reports of its use, including more rigorous randomized controlled trials, in Achilles tendon treatment. There are different types of tendon augmentation materials available, including autografts, xenografts, and allografts. Although there is no risk of cellular rejection with autografts, these grafts potentially increase the complexity and length of the surgery as well as possibly causing donor site morbidity and pain to the patient. While xenografts avoid donor morbidity, the foreign material can cause hypersensitive reactions with patients, and poor clinical results have led some investigators to discontinue their use for tendon augmentation.[8]

To avoid these respective complications, another alternative surgical treatment is the use of a human acellular dermal matrix (ADM) to augment the Achilles tendon repair. These allografts have been de-cellularized under the theory of providing a biocompatible scaffold that can be used for host revascularization and cellular growth.[9] There are only a few reports of ADM augmentation for Achilles tendon repair,[10-13] but these preliminary studies reported favorable outcomes without any re-ruptures, including difficult-to-heal neglected ruptures. ADMs have also shown favorable outcomes in

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different types of tendon augmentation, including rotator cuff repair[14-16] and distal biceps repair.[17] In general, ADMs have excellent handling characteristics as the tissue processing allows the graft to be stored fully hydrated at ambient temperatures.[18] Access to different sizes and thickness of ADMs is preferable during an augmented repair while using certain repair techniques;[12] and the hydrated, ambient temperature storage is an easy way to facilitate this access while negating waste and lengthy rehydration times. A low dose of gamma irradiation administered at low temperatures provides a sterility assurance level (SAL) of 1 x 10-6 medical device grade sterility, a process shown to have minimal impact on allograft tissue.[19]

ADMs are less expensive than xenografts.

The purpose of this case series was to evaluate the use of ADM to augment Achilles tendon repairs using a novel technique.

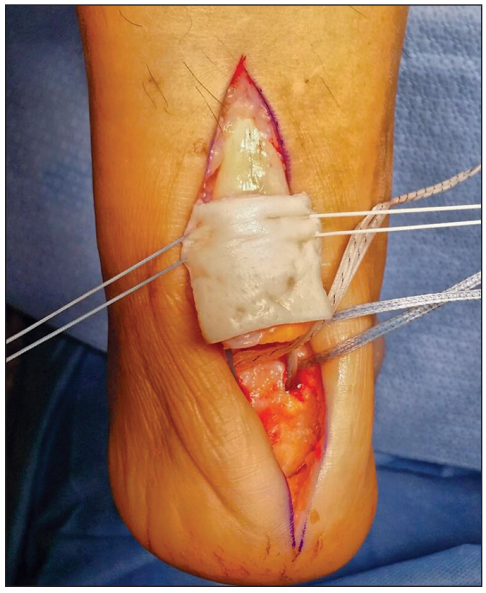

Figure 3a: ADM was tacked down proximally onto tendon

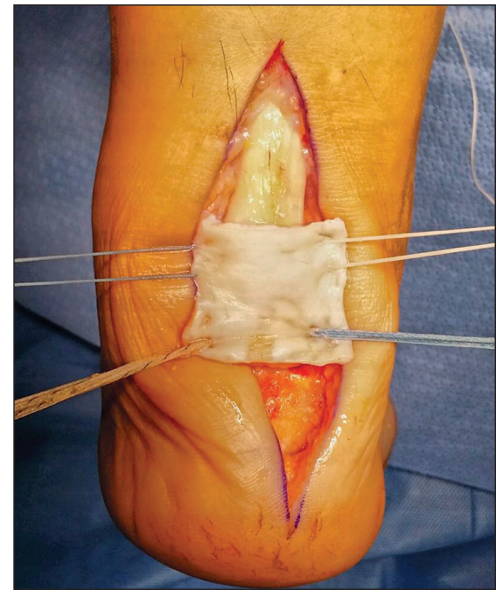

Figure 3b: ADM was tacked down distally onto tendon

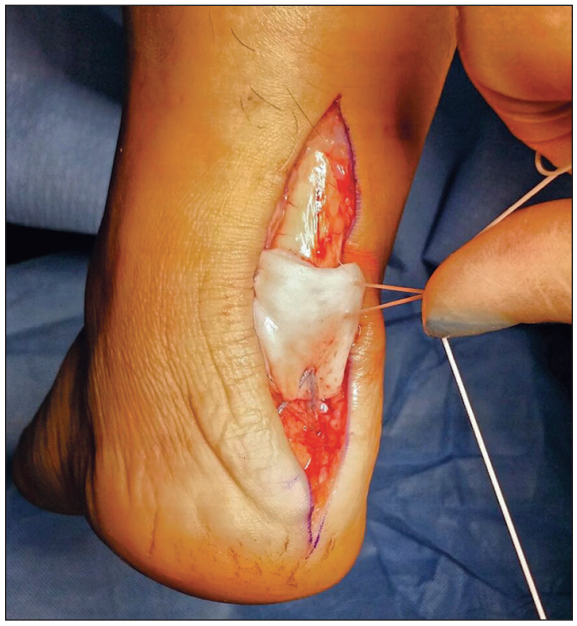

Figure 3c: Hand ties were used to secure ADM graft onto tendon

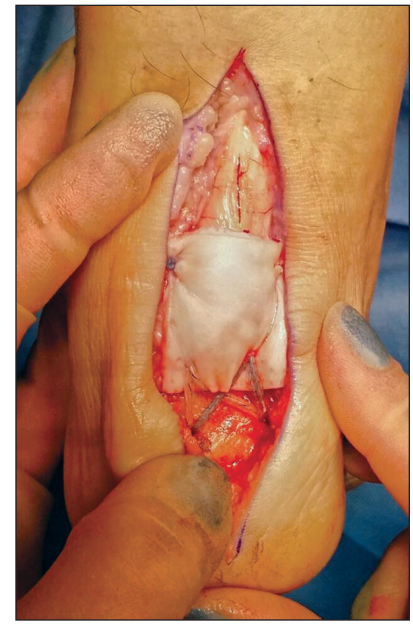

Figure 3d: Completed tendon/graft repair constru

Case Series

Methods and Materials

Nine patients underwent Achilles tendon repair with ADM augmentation from September 2012 through December 2014. Patients were medically cleared for surgical intervention after tendon tears or rupture was confirmed by magnetic resonance imaging (MRI). All patients were taken into the operating room and placed in a prone position. General anesthesia along with a local nerve block were administered for patient comfort. A well-padded thigh tourniquet was applied and inflated to 350 mmHg. The surgical limb was prepped with a chlorhexidine antiseptic and draped in a sterile manner.

A lazy-s incision was then created from proximal lateral to distal medial overlying the deformity. Skin and subcutaneous tissue were carefully dissected in one layer and retracted (Figure 1). All bleeders were electrocauterized as needed. Neurovascular structures were meticulously protected throughout the procedure. The Achilles paratenon

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was split centrally and carefully reflected medially and laterally. Hematoma, hypertrophied or devitalized tendon, and nonviable tissue were removed at this time (Figure 2). A primary repair of the tear or ruptured tendon was performed using 3-0 absorbable suture. If the tendon was ruptured at the insertion or if the tendon must be removed from the attachment on the calcaneus to perform a debridement and repair, it was re-attached using a soft tissue fixation device (Figures 3a-d).

One 5 x 5 cm piece of ADM was cut to size to overlay the primary tendon repair (Figure 4). ADM was then sutured into place using an interrupted stitch pattern with 3-0 absorbable suture material. The soft tissue layers were re-approximated using atraumatic surgical technique (Figure 5). The wounds were dressed with a non-adherent layer, 10 x 10 cm gauze, and cast padding. A 10 cm below knee splint was applied with the foot in gravity equinus and the knee bent at 30 degrees. The patient was non-weight-bearing three to four weeks post-operative and transitioned into a removable cast boot when clinical indications of healing were present.

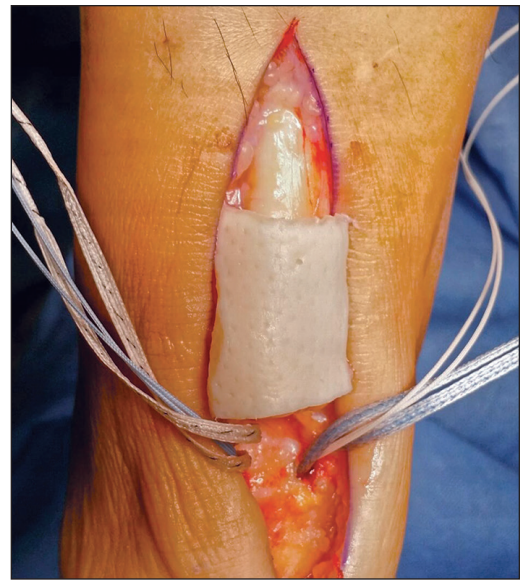

Figure 4: 5x5 cm ADM graft cut to size and placed over area of primary tendon repair

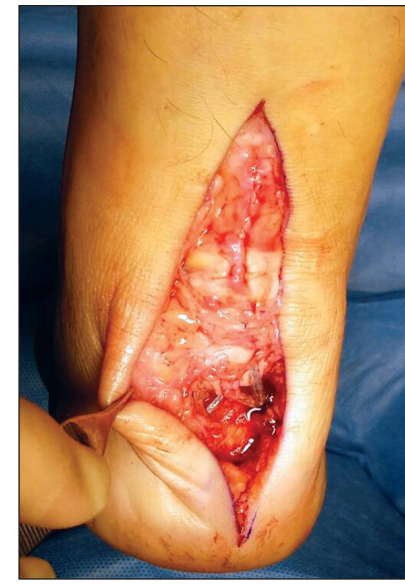

Figure 5: Careful re-approximation of the paratenon layer over the ADM repair

The Foot Function Index-Revised is a patient-completed survey used to score function after surgical intervention.

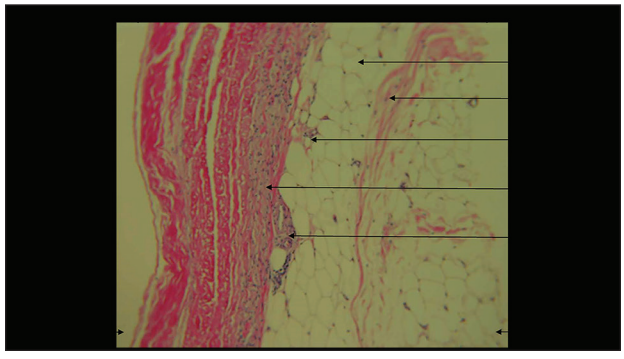

Figure 6: Histological section of tendon/graft interface low magnification

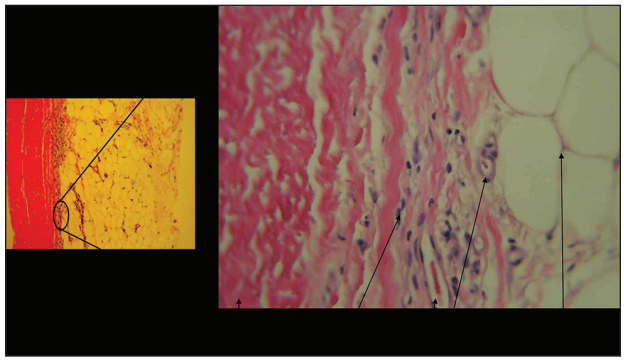

Figure 7: Histological section of tendon/graft interface high magnification

Outcome Measures

The Foot Function Index-Revised (FFI-R) long form was used to evaluate patients at an average of 18 months follow-up. This validated test[20] was scored using the method detailed in Riskowski, et al.[21] Any questions that were unanswered and left blank by the patient were not counted in the score of that individual patient. Additionally, Question #48 was missing from every version of the FFI-R long form that was available. This missing question was not factored into any of the patients' scores. In addition to the FFI-R, any potential complications or re-ruptures were noted.

Results

Nine patients underwent an Achilles tendon repair augmented with ADM. Patients ranged in age from 23-68 years old and consisted of four males and five females. All nine patients completed the Foot Function Index-Revised (FFI-R) long form with an average 18 months (minimum 12 months) follow-up. Table 1 shows the sub scores and cumulative score for each patient.

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The average score for patients 1-4 and 6-9 was 33% ± 4.2. Soon after the survey was completed, patient 5 was diagnosed with multiple sclerosis and this likely had a large effect on his answers. Since the diagnosis of multiple sclerosis was unrelated to the ADM augmentation, this patient's results were not included in the average score or data analysis. There have not been re-ruptures or complications seen for any patients at post-operative time periods ranging 29.4 to 56.8 months.

Discussion

All nine patients successfully underwent augmented Achilles tendon repair surgery. No patients showed any sign of infection or had an adverse reaction to the ADM augment. One patient was removed from data analysis due to the diagnosis of an unrelated condition that would have severely affected the results.

No patients showed any sign of infection or had an adverse reaction to the ADM augment.

The FFI-R long form was developed in response to criticisms of the original FFI. The FFI-R long form is considered highly accurate with a reliability of 0.96 and a construct validity of 0.306 correlated with a 50-foot walk time.[20] A thorough search of the literature did not return any reports of Achilles tendon repairs that were evaluated using the FFI-R long form. This absence was also supported by a recent meta-analysis.[22] While the lack of similar studies makes comparison difficult, the results presented here could provide a baseline for evaluation with future studies. Although it is not an ideal substitute, other foot and ankle studies have reported scores of 31.1 ± 9.8,[23] 31 ± 10,[24] and 35.2,[25] respectively, which correlated with reduced pain and positive functional outcomes. The similarity in scores

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TABLE 1:

Foot Function Index-Revised Long Form Scores

	Pain Score	Stiffness Score	Difficulty Score	Activity Score	Personnel Score	Cumulative Score
Patient 1	24%	25%	25%	40%	24%	27%
Patient 2	48%	38%	35%	40%	29%	36%
Patient 3	24%	28%	25%	40%	29%	29%
Patient 4	26%	25%	25%	49%	29%	30%
Patient 5*	91%	81%	81%	30%	74%	73%
Patient 6	28%	38%	25%	58%	35%	35%
Patient 7	43%	50%	25%	40%	24%	33%
Patient 8	52%	44%	25%	58%	35%	39%
Patient 9	43%	31%	25%	49%	35%	35%
Total**	36%	35%	26%	47%	30%	33.0% ± 4.2
Rao et al. (22)						31.1% ± 9.8
Rao et al. (23)						31% ± 10
Fishman et al. (24)						35.2%

**After the survey was completed, Patient 5 was diagnosed with multiple sclerosis which may invalidate their answers.*

***Does not include results from Patient 5.*

Tendon (from page 139)

suggests that the average score reported here of 33 ± 4.2 may indicate a level of success. In addition, the smaller standard deviation score may show a higher degree of consistent outcomes among the Achilles tendon repair patients, a favorable finding.

Reports have shown operative treatment has less than one third the rate of re-rupture (3.5%) versus non-operative care (12.6%) but has also demonstrated a substantial risk of complications with about one-third of patients affected (34.1%).[5] While the literature indicates operative treatment is the preferred choice for Achilles tendon repair, alternative operative techniques should be pursued that reduce the complication rate while further lowering the risk of re-rupture. Augmented repair with an ADM may be able to accomplish both of these objectives. Even taking the small patient population into account, the complete lack of either re-ruptures or complications reported here is noteworthy.

Lee[10] explored the use of a different human acellular dermal matrix, in a preliminary case series. Nine patients had neglected Achilles tendon ruptures repaired with ADM augmentation and were followed through 20-30 months post-operative. After at least 20 months post-operative, no patients experienced a re-rupture compared with the historical average of 3.5%. Four complications were noted, one uncomplicated deep vein thrombosis and three patients with diabetes had superficial wound dehiscence, but it is unlikely any of these were related to the ADM usage. Following this initial success, Lee[11] published a study describing the outcome of nine patients with acute Achilles tendon rupture who were repaired with ADM augmentation. After a follow-up of 21 to 30 months, no patient experienced a re-rupture or complication.

Each of these case series are small but together represent a moderate patient size sample with long-term follow-up that showed a 0% rate of re-rupture and very low complication rate associated with the use of ADM augmentation. Huang, et al.[13] also published on the use of allografts to augment the repair of acute Achilles tendon rupture in 59 patients. Instead of an inlay or onlay augmentation, the allograft was woven around the native tendon. After a 2.1 years follow-up, satisfactory results were reported with no occurrence of re-rupture. Interestingly, one patient appeared to have experienced an allergic reaction three days following surgery.

Even taking the small patient population into account, the complete lack of either re-ruptures or complications reported here is noteworthy.

In the case of the re-ruptured Achilles tendon, the ADM is thought to have incorporated well into the paratenon interface.

Immunogenic reactions are rare in processed allograft tendons and may reflect a concern about the manner of tissue processing as previously raised.[19,26] The reaction was resolved using a five-day course of intravenous anti-allergy treatment. No other complications were reported. Ofili, et al.[27] used Achilles tendon allografts to repair neglected Achilles tendon ruptures in 14 patients with an average 6.9 months between the time of injury and surgery. Favorable outcomes were reported with all patients able to bear weight and perform a single heel rise. Although the allograft may not have been used as augmentation, the lack of complications, except for a single case of delayed healing, provide further support for the safe use of allografts in Achilles tendon repair procedures.

There are several soft tissue products available for use in augmented repairs. Although there is a shortage of comparative clinical studies for ADM usage in augmented Achilles tendon repair, bench top studies have shown differences in the biomechanical properties of several different products.[18,28] In both, a suture pull-out strength comparison test and ultimate load to failure comparison test, ADMs demonstrated similar or greater strength than other products of the same thickness, SportsMesh (BioMet Sports Medicine, LLC, Warsaw, IN) or OrthADAPT (Pegasus Biologics, Inc., Irvine, CA).[18,28] Other biomechanical studies have demonstrated the strength of tendon repairs augmented with ADM versus an unaugmented repair control.[29,30] Beitzel, et al.[29] found rotator cuff repairs performed on cadaveric fresh frozen shoulders augmented with ADM on top had a significantly higher load to failure (575.8 ± 22.6 N, p = 0.025) versus the control (438.9 ± 98.8 N).

Eshan, et al.[30] explored the use of 1.0 mm and 1.5 mm thick ADM to augment repairs of scapholunate ligaments with intact scapholunate ligaments serving as the control in cadaveric tests. During tensile testing, the 1.0 mm augment failed at the suture-matrix interface and the 1.5 mm augmented repair failed at the suture-bone anchor interface. In contrast, the intact control failed at mid-substance, which showed the strength provided the tendon by AF-ADM augmentation.

The limitations of this case series include a small patient population. However, these results are not meant to be generalizable but rather serve

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as a preliminary investigation into the use of ADM for augmented Achilles tendon repairs.

The successful outcomes presented here, including the lack of re-ruptures or complications after a minimum two years post-operative, with an average of 18 months follow-up for FFI-R long form scores, support further evaluation beyond this initial case series for using ADM as an augment in Achilles tendon repairs.

While the mechanism which allows ADMs to integrate with host tissue is not fully understood, the author will now detail a separate case with the aim of providing a greater understanding of how the ADM scaffold is incorporated in tendon repair. In this histological case study, a patient underwent primary Achilles tendon repair with ADM augmentation between the tendon and paratenon. The ADM graft was removed two months post-operative following re-rupture of the native tendon due to a fall, and an extensive histology analysis was conducted on the integrated ADM.

The second surgery following re-injury provided a fortuitous opportunity to explore the remodeling composition of the ADM following augmented tendon repair. Furthermore, a literature investigation was undertaken to determine how ADMs incorporate into the tendon structure and what mechanism could be responsible for influencing the strength of repair. These results are presented here.

Case Notes

A 35–year-old patient underwent an end-to-end primary repair of an Achilles tendon rupture. The severed ends of tendon re-approximated with sutures and ADM were placed between the tendon and paratenon to augment the repair. The post-operative course was unremarkable and the surgical site healed well. At two months post-operative, the patient fell and re-ruptured his Achilles tendon. The re-rupture occurred at the primary repair site, and surgical intervention was necessary to address the injury. Approximately one month after the re-rupture, the area was surgically opened, and histology specimens were obtained from the ADM-paratenon interface. Upon removal, it was noted that the ADM had adhered to the host tissue and that the rupture had transected both the host tendon and ADM graft. At this revision surgery, ADM was again used to augment the repair. The patient's post-op progress was satisfactory and the repair successful.

Histology Analysis

Multiple sections of explanted tissue were prepared for histological evaluation. The specimens were taken from the area of Achilles tendon sutures. The histology slides were prepared and analyzed by the Biology Lab at the University of Padua (Italy). Alcian Blue and Periodic acid–Schiff (PAS) stains were used on all slides. Alcian Blue followed by PAS stain can be useful in detecting glycosaminoglycans,[31] which are synthesized by fibroblasts[32] and facilitate wound repair.[33]

Histology Results

Sections were taken at eight weeks post-operative. All sections showed excellent attachment of the paratenon to the ADM with no evidence of any inflammatory response seen in any area. Low magnification images showed large areas of the graft-paratenon interface (Figure 6), while the high magnification images concentrated on remodeling features (Figure 7). Active infiltration of cells were seen from the paratenon into the graft (Figures 1, 2), and the infiltrating cells appeared mesenchymal (likely synovial based on morphology) in nature (Figure 7). Neo-vascularization was seen within cell-infiltrated areas (Figure 6). Robust vascularization was also observed in the graft-paratenon interface (Figure 7). Revitalization of the graft, with new blood vessel and cell formations, was directional from the paratenon side, and up to 60% of the graft depth appeared vitalized with new cells in some areas.

Discussion

As expected, the remodeling was being driven from the direction of the paratenon. Typically, tenoblasts and tenocytes are 90-95% of the total cellular elements of the tendon while the remaining 5-10% includes synovial cells of the tendon sheath on the tendon surface and vascular cells in the endo and epitenon.[34] ADM demonstrated high levels of biocompatibility as evidenced by the absence of inflammation within the graft and host tissue, the infiltration of appropriate host cells into the graft matrix, and the presence of active vascularization within and around the graft. While these results are consistent with healthy incorporation demonstrated in the literature,[35] it is important not to generalize the results of this case study.

Understanding the mechanisms by which ADMs incorporate with host tissue plays an important role in increasing the strength and consistency of repairs.

Understanding the mechanisms by which ADMs incorporate with host tissue plays an important role in increasing the strength and consistency of repairs. Furthermore, several studies have shown that different ADMs demonstrate varying degrees of re-cellularization, re-vacularization, and ultimately incorporation. Many of these authors have concluded that the different sterilization and manufacturing processes are responsible for the varying levels of integration displayed by ADMs. As suggested by some of the reviewed studies,[36] the integration properties of ADMs may be due to the unique process used to de-cellularize and sterilize the matrix. Residual DNA content is an indicator of the thoroughness of the de-cellularization process, which is important because cellular

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remnants in ADMs may hinder the healing process and promote a less desirable host response.[37]

Conclusions

The histological results from our single patient cannot be generalized but do corroborate the findings presented here from laboratory studies and clinical case series. While data from a larger patient population would be more beneficial, this would also be difficult to obtain in tendon repair procedures where a second operation is not standard practice. Our histological analysis was only made possible due to an accidental fall of the patient, which made revision surgery necessary. The histological findings presented demonstrated that the remodeling of ADM in a tendon reconstruction procedure is similar to the matrix integration observed in a wound repair procedure. **PM**

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Tendon *(from page 142)*

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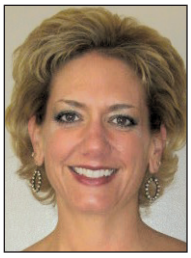

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CME EXAMINATION

SEE ANSWER SHEET ON PAGE 145.

1) Which is a true statement regarding Achilles tendon ruptures?

A) Ruptures are quite common in the general population.
B) Frequency increases in the older population occasionally active in sports.
C) Operative treatments result in a lower re-rupture rate than non-operative treatments.
D) All of the above.

2) Why is ADM thought to be superior to xenograft to augment tendon repair?

A) ADMs are less expensive than xenografts.
B) Xenografts have a higher risk for cellular rejection or hypersensitivity reactions.
C) Xenografts are less readily available than ADMs.
D) ADMs are more difficult to surgically incorporate into tendon repairs.

3) What characteristic(s) of ADM allow for successful use in tendon repair surgery?

A) ADMs have excellent handling properties and suture retention strength.
B) ADMs do not come in different sizes and thicknesses.
C) Room temperature storage allows for ease of facilitation of use.
D) Both a and c

4) Which of these statements about the surgical repair of Achilles tendon ruptures are true?

A) A lazy s incision was used to avoid vital neurovascular structures.
B) Hematoma and non-viable tissues were removed during surgery.
C) Careful dissection and re-approximation of the paratenon using atraumatic technique is essential.
D) all of the above are true.

5) The Foot Function Index-Revised is:

A) Outdated and no longer in use.
B) A patient-completed survey used to score function after surgical intervention.
C) Taken at several month intervals for an average final score.
D) Not easily validated because patients lie.

6) In the 9-patient case series presented, which statements are true:

A) No patient showed any signs of complication or infection post-op.
B) There were no reported re-ruptures in this patient cohort.
C) One patient was removed from the data analysis due to the diagnosis of an unrelated condition that could severely affect the results.
D) All of the above are true.

7) This case series is felt to be significant because:

A) There was a large patient population.
B) The results were meant to be generalizable.
C) It is intended to serve as a preliminary investigation of ADM augmentation in Achilles tendon repair.
D) The procedure was performed on more women than men.

Continued on page 144

8) In the case of the re-ruptured Achilles tendon, the ADM is thought to have:

A) Incorporated well into the paratenon interface.

B) Caused the rupture of the tendon.

C) Contributed to an aggressive inflammatory response.

D) Made no difference in healing.

9) Upon histological examination of the explanted tissues which of the following statements are true?

A) The ADM had not adhered to the host tissues.

B) An exuberant inflammatory reaction was appreciated upon examination.

C) Revitalization of the graft, with new blood vessel and cell formations, was directional from the paratenon side.

D) The ADM appeared devitalized and inactive.

10) All of the following have been demonstrated to be true about ADMs except:

A) ADM demonstrated high levels of biocompatibility as evidenced by the absence of inflammation within the graft and host tissue.

B) Revitalization of the graft, with new blood vessel and cell formations, was noted through histological analysis.

C) The use of a human acellular dermal matrix (ADM) to augment the repair may reduce the complication rate while still demonstrating a low re-rupture rate and satisfactory functional outcomes.

D) All of the above are true.

SEE ANSWER SHEET ON PAGE 145.

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EXAM #2/18
The Use of Acellular Dermal Matrices in Tendon Repair
(Cole)

Circle:

1.	A	B	C	D	6.	A	B	C	D
2.	A	B	C	D	7.	A	B	C	D
3.	A	B	C	D	8.	A	B	C	D
4.	A	B	C	D	9.	A	B	C	D
5.	A	B	C	D	10.	A	B	C	D

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3) I will apply the knowledge I learned from this lesson ____

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A B C D

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