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Achilles Tendon Augmented Repair Using Human Acellular Dermal Matrix: A Case Series

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ABSTRACT

Achilles tendon ruptures are common in the general population, especially among members of the older demographic occasionally active in sports. Operative treatments provide a lower incidence of rerupture than do nonoperative treatments, although surgical complications remain a concern. The use of a human acellular dermal matrix to augment Achilles tendon repair might reduce the incidence of complications. In the present case series, we describe the outcomes of 9 patients who underwent Achilles tendon repair with acellular dermal matrix augmentation. Functional outcomes were evaluated using the Foot Function Index-Revised long form, and the clinical results were recorded. After a mean average follow-up period of 14.4 (range 12.0 to 20.0) months, the mean Foot Function Index-Revised long form score was 33.0% ± 4.2%. No cases of rerupture or complications that required additional treatment occurred during the observation period. The outcomes we have presented support further evaluation beyond this case series for using a human acellular dermal matrix to augment Achilles tendon repairs.

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 during sports participation, especially in patients aged >30 years who are only occasional athletic participants (2). Achilles tendon ruptures can be misdiagnosed, which will delay treatment and results in neglected ruptures (3). Both surgical and nonsurgical treatments now advocate the use of braces instead of rigid casts to allow for early mobilization (4); however, debate has ensued regarding the most effective treatment. One meta-analysis found a significantly lower rerupture rate for surgical treatment but a significantly lower complication rate for nonoperative treatment (5). Another review reported no significant differences for complication and rerupture rates between the 2 treatment types, although several studies reported lower rerupture rates for surgical than for nonoperative treatment (4). These reviews, along with other reported data (6), indicate that surgical treatment is the preferable option but alternative techniques are needed to further decrease both rerupture and complication rates.

Augmentation has been used in tendon repair to strengthen the repair site and reduce the risk of rerupture. Although augmentation has been used in other types of tendon repair, especially major rotator cuff repairs (7), fewer studies have reported on its use, including more rigorous randomized controlled trials, with Achilles tendon treatment. Different types of tendon augmentation materials are available, including autografts, xenografts, and allografts. Although no risk of cellular rejection exists with autografts, these grafts potentially increase the complexity and length of the surgery and can also result in donor site morbidity and pain. Although xenografts avoid donor morbidity, the foreign material can cause hypersensitivity reactions with human patients, and the poor clinical results have led some investigators to discontinue their use for tendon augmentation (8).

To avoid these complications, another alternative surgical treatment is the use of a human acellular dermal matrix (ADM) to augment Achilles tendon repair. These allografts have been decellularized and serve as a biocompatible scaffold that can be used for host revascularization and cellular growth (9). Only a few studies have reported on ADM augmentation for Achilles tendon repair (10–13). These studies have described favorable outcomes without any reruptures, even in difficult to heal neglected Achilles tendon ruptures. One ADM in particular, ArthroFlex® (LifeNet Health, Virginia Beach, VA;

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hereafter referred to as AF-ADM), has shown favorable outcomes in different types of tendon augmentation, including rotator cuff repair (14–16) and distal biceps repair (17). This ADM is available in a variety of sizes and can be stored fully hydrated at ambient temperatures (18); thus, it is convenient to use, and no time is required to allow for rehydration of the graft. Moreover, low-dose gamma irradiation administered at low temperatures provides a sterility assurance level of 1×10^{-6}, medical device grade sterility, and is a process shown to have minimal effects on allograft tissue (19).

The purpose of the present case series was to evaluate the use of AF-ADM to augment Achilles tendon repairs using a simple technique for augmentation.

Patients and Methods

From September 2012 through December 2014, 9 patients from the author's practice (W.C.) underwent Achilles tendon repair with AF-ADM augmentation. The Achilles tendon tears were linear and confirmed by clinical examination and magnetic resonance imaging scans. All the patients were taken to the operating room and placed in the prone position. General anesthesia and popliteal nerve block were administered for patient comfort. A well-padded thigh tourniquet was applied and inflated to 350 mm Hg. The surgical limb was prepared with a chlorhexidine antiseptic and draped in a sterile manner.

A lazy-S incision was then created from proximally and laterally to distally and medially, overlying the deformity. Skin and subcutaneous tissue were carefully dissected in 1 layer and retracted (Fig. 1). All bleeding vessels were electrocauterized, as needed. Neurovascular structures were meticulously protected throughout the procedure. The Achilles paratenon was split centrally and reflected medially and laterally. Hematoma, hypertrophied or devitalized tendon, and nonviable tissue were then removed (Fig. 2). A primary repair of the torn tendon was performed using 3-0 absorbable suture. If the tendon was ruptured at the insertion or if the tendon had to be removed from the attachment into the calcaneus to perform debridement and repair, it was reattached using a soft tissue fixation device (Arthrex SpeedBridge™; Arthrex, Naples, FL; Fig. 3). Next, one 5×5-cm piece of AF-ADM (LifeNet Health) was cut to size to overlay the primary tendon repair (Fig. 4). The AF-ADM was sutured in place using an interrupted stitch pattern with 3-0 absorbable suture. The soft tissue layers were then reapproximated (Fig. 5), and the wound was dressed with a petrolatum-impregnated nonadherent layer, 10×10-cm gauze, and cast padding. A 10-cm below-the-knee splint was applied, with the foot in gravity equinus and the knee bent at 30°. The patients remained non-weightbearing for 3 to 4 weeks postoperatively and was transitioned into a removable cast boot when the clinical indications of healing were sufficient.

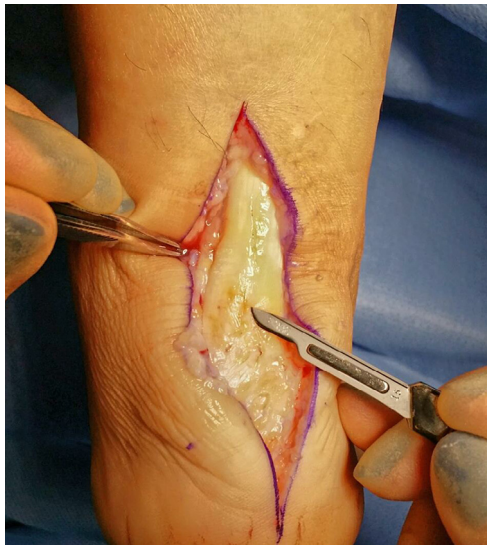

Fig. 1. Skin and subcutaneous tissue was carefully dissected in 1 layer and retracted.

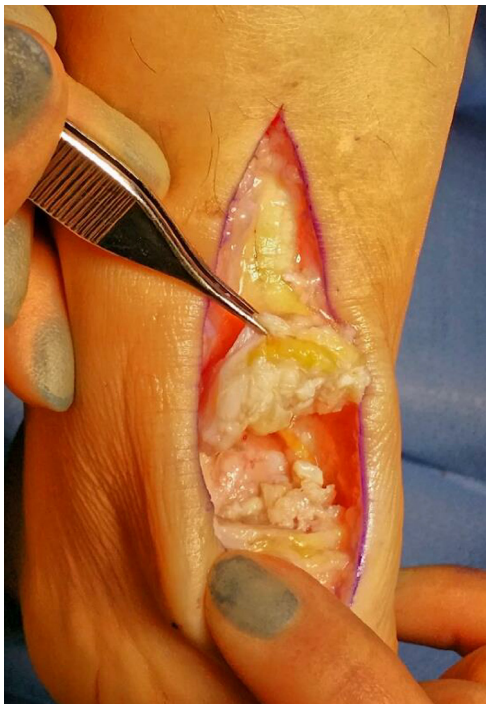

Fig. 2. All hematoma, hypertrophied or devitalized tendon, and nonviable tissue were removed.

Outcome Measures

The Foot Function Index-Revised (FFI-R) long form was used to evaluate patients at an average follow-up point of 14.4 (range 12.0 to 20.0) months. This validated test (20) was scored by summing the answers in each subsection and dividing by the maximum possible score for that section as detailed by Riskowski et al (21). Any questions that were unanswered and left blank by the patient were not counted in the score for that patient. Budiamn-Mak et al (20) examined the internal consistency reliability of the FFI-R with missing data using the classic test theory. It was determined that the reliability of the test was similar regardless of whether the absent values were substituted with mean data or the missing data were kept without substitution. Additionally, question 48, part of the activity limitation subsection, was missing from our version (version 3) of the FFI-R long form. The numbering on the form went from question 47 to question 49 without any further information. This missing question was not factored into any of our patients' scores. Because the scores were calculated using the maximum possible score for each subsection, the excluded question did not result in lower scores for our subjects. In addition to the FFI-R, any potential complications or reruptures were noted.

Results

Nine patients underwent Achilles tendon repair augmented with AF-ADM. The patients ranged in age from 23 to 68 years and in-

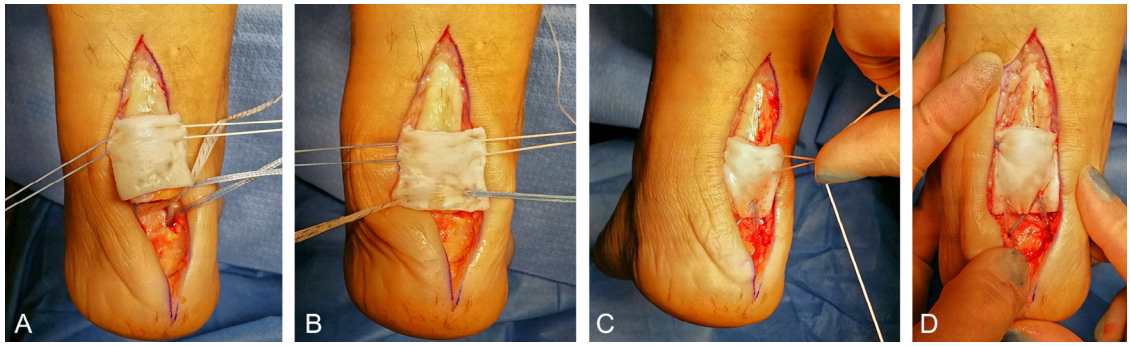

Fig. 3. (*A–D*) Intraoperative images demonstrating the sequential use of a soft tissue fixation device to reattach the Achilles tendon and ArthroFlex® (LifeNet Health) human acellular dermal matrix onto the calcaneus.

cluded 3 males (33.3%) and 6 females (66.7%). Their mean body mass index was 28.0 ± 7.7 kg/m^2. Six injuries (63.7%) involved the right lower extremity and 3 (33.3%) involved the left lower extremity. Four (44.4%) of the injuries had been caused by trauma and five (55.6%) by "wear and tear." All the injuries involved partial tears. A statistical description of the case series is presented in Table 1.

All 9 patients completed the FFI-R long form at an average follow-up point of 14.4 (range 12.0 to 20.0) months. The domain scores and cumulative score for each patient are listed in Table 2. The mean score for all patients was 37.4% ± 13.9%. Soon after the survey was completed, multiple sclerosis was diagnosed in patient 5, which likely influenced that patient's answers. The removal of patient 5's scores changed the mean score to 33.0% ± 4.2%. The diagnosis of multiple sclerosis was unrelated to the AF-ADM augmentation. No reruptures or complications were seen in any of the patients postoperatively with a minimum follow-up period of 2 years.

Discussion

All 9 patients successfully underwent augmented Achilles tendon repair surgery. No patient showed any signs of infection or had an adverse reaction to the AF-ADM. In 1 patient, multiple sclerosis was diagnosed, an unrelated condition. This likely explained the outlier effect on the scores, which decreased from 37.4 to 33.0 when this subject's scores were removed from the analysis. The removal also decreased the standard deviation from 13.9 to 4.2, demonstrating the substantial effect of this single patient's scores.

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 person reliability of 0.96 and a construct validity of 0.306, correlating with a 50-ft walk time (20). A thorough search of the reported data did not return any reports of Achilles tendon repairs evaluated using the FFI-R long form. This absence was also supported by a recent meta-analysis (22). Although the lack of similar studies made comparisons difficult, the absence also denotes the importance of small pilot studies. The present results could be used by future investigators in the development of more rigorous randomized controlled trials or prospective cohort studies.

Reports have shown that operative treatment has less than one third the rate of rerupture (3.5%) compared with nonoperative care (12.6%) but has also demonstrated a substantial risk of complications, with about one third of patients affected (34.1%) (5). Although the

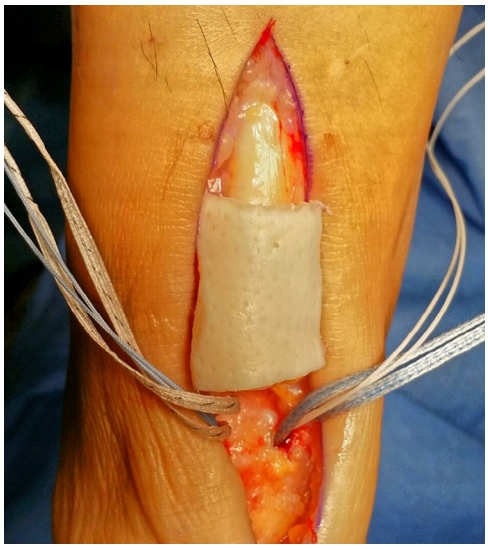

Fig. 4. One 5 × 5-cm piece of ArthroFlex® (LifeNet Health) human acellular dermal matrix was cut to size to overlay the primary tendon repair.

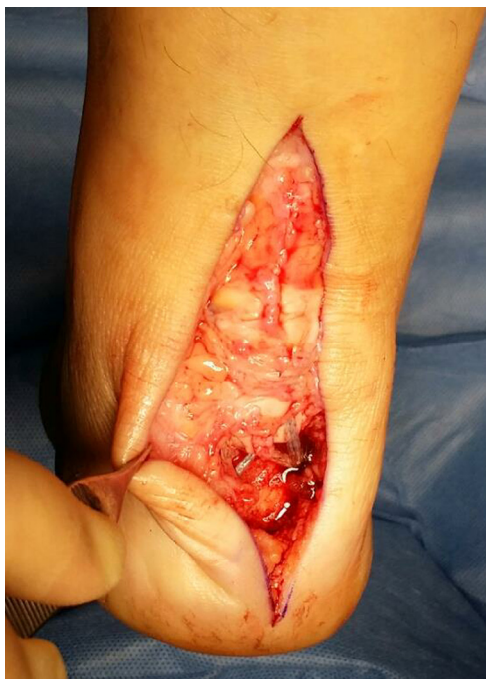

Fig. 5. The soft tissue layers were reapproximated using an atraumatic surgical technique.

Table 1
Statistical description of the case series (N = 9 patients)

Characteristic	Value
Age (y)	
Mean ± standard deviation	58.3 ± 12.5
Range	37.0 to 73.0
Sex (n)	
Female	6 (66.7)
Male	3 (33.3)
BMI (kg/m^2)	
Mean ± standard deviation	28.0 ± 7.7
Range	22.0 to 46.0
Anatomic side	
Left	3 (33.3)
Right	6 (63.7)
Cause of injury	
Trauma	4 (44.4)
Wear and tear	5 (55.6)
Achilles injury type, partial tear	9 (100)
Follow-up duration (mo)	
Mean	14.4
Range	12.0 to 20.0

Data in parentheses are percentages.
Abbreviation: BMI, body mass index.

reported data have indicated that operative treatment is the preferred choice for Achilles tendon repair for many patients, alternative operative techniques should be pursued that reduce the complication rate and further lower the risk of rerupture. Augmented repair with an ADM might be able to accomplish both these objectives. Even considering the small patient population, the complete lack of either rerupture or postoperative complications in our patients is noteworthy.

Lee (10) explored the use of a different human acellular dermal matrix, GraftJacket™ Regenerative Tissue Matrix (Wright Medical Technology, Inc., Arlington, TN; hereafter referred to as GJ-ADM), in a case series. Nine patients had neglected Achilles tendon ruptures repaired with GJ-ADM augmentation and were followed up for 20 to 30 months postoperatively. After ≥20 months postoperatively, no patients had experienced rerupture compared with the historical average of 3.5%. Four complications were noted, including 1 case of deep vein thrombosis and superficial wound dehiscence in 3 patients with diabetes. Thereafter, Lee (11) reported a study describing the outcome of 9 patients with acute Achilles tendon rupture who underwent repair with GJ-ADM augmentation. After a 21- to 30-month follow-up period, no patient had experienced a rerupture or complication. Huang et al (13) also reported 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 follow-up period of 2.1 years, satisfactory results were reported with no reruptures. One patient appeared to have experienced an allergic reaction 3 days after surgery. Immunogenic reactions are rare in association with processed allograft tendons and might reflect a concern about the method of tissue processing, as previously reported (19,23). The reaction resolved after a 5-day course of intravenous corticosteroid treatment. No other complications were reported. Ofili et al (24) used Achilles tendon allografts to repair neglected Achilles tendon ruptures in 14 patients with an average of 6.9 months between the injury and surgery. Favorable outcomes were reported, with all patients able to bear weight and perform a single-leg heel rise. Although the allograft might not have been used as augmentation, the lack of complications, except for a single case of delayed healing, provides further support for the safe use of allografts in Achilles tendon repair procedures.

Several soft tissue products are available for use in augmented repairs. Although a shortage of comparative clinical studies for ADM usage in augmented Achilles tendon repair exists, bench top studies have shown differences in the biomechanical properties of several different products (18,25). In both a suture pull-out strength comparison test and ultimate load to failure comparison test, AF-ADM demonstrated similar or greater strength than the same thickness of GJ-ADM, SportsMesh (BioMet Sports Medicine, LLC, Warsaw, IN), and OrthADAPT (Pegasus Biologics, Inc., Irvine, CA) (18,25). Other biomechanical studies have demonstrated the strength of tendon repairs augmented with AF-ADM versus an unaugmented repair control (26,27). Beitzel et al (26) found rotator cuff repairs performed on cadaveric fresh frozen shoulders augmented with AF-ADM had a significantly greater load to failure (575.8 ± 22.6 N; $p = .025$) compared with that of the control (438.9 ± 98.8 N). Eshan et al (27) explored the use of 1.0-mm and 1.5-mm thick AF-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 midsubstance, suggesting that augmentation increased the strength of the tendon.

The limitations of the present case series included the small patient population, unblended outcomes assessors, and the lack of a comparison group. Also, question 48 was missing from the FFI-R, which could potentially threaten the validity of our results. Finally, 2 of us (B.S., M.M.) are affiliated with LifeNet Health, a nonprofit organization that manufacturers AF-ADM. The potential bias was minimized by ensuring all decisions about patient care, including outcomes, was determined by the primary investigator (W.C.). Furthermore, these results were not meant to be generalizable but rather to serve as a preliminary investigation regarding the use of AF-ADM for augmented Achilles tendon repairs. This information could be used in the

Table 2
Foot Function Index-Revised long form scores

Pt. No.	Pain Score (%)	Stiffness Score (%)	Difficulty Score (%)	Activity Score (%)	Personnel Score (%)	Cumulative Score (%)
1	24	25	25	40	24	27
2	48	38	35	40	29	36
3	24	28	25	40	29	29
4	26	25	25	49	29	30
5*	91	81	81	30	74	73
6	28	38	25	58	35	35
7	43	50	25	40	24	33
8	52	44	25	58	35	39
9	43	31	25	49	35	35
Total	42.1 ± 21.4	39.9 ± 17.7	32.4 ± 18.6	44.7 ± 9.4	35.0 ± 15.3	37.4 ± 13.9
Total without Pt. 5	36.0 ± 11.6	34.8 ± 9.1	26.3 ± 3.5	46.5 ± 8.2	30.1 ± 4.3	33.0 ± 4.2

Abbreviation: Pt. No., patient number.
* Multiple sclerosis was diagnosed in patient 5.

future development of randomized controlled trials and prospective cohort studies focusing on repair of the injured Achilles tendon. The results we have observed in the present series of patients suggest that the method is safe and without reruptures or complications.

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