Use of DermaSpan™ Acellular Dermal Matrix As An Adjunct to Achilles Repair and Reconstruction

Author: Charles M Zelen,* DPM,[1] Atilla Poka,* M.D., James Carr,* M.D.

Study Completed September 2011

ABSTRACT

Tendon augmentation grafts have been shown to be successful in achieving enhanced stability in the repair of Achilles ruptures. A variety of materials have been utilized to augment Achilles tendon repairs. Experience has demonstrated that a graft material incorporating appropriate biological and mechanical properties is required to achieve a successful augment. The purpose of this biomechanical study is to compare load to failure of a standard Krackow repair of the Achilles versus a repair supplemented with DermaSpan Acellular Dermal Matrix (ACD) allograft applied circumferentially and attached to the Achilles with a running locking suture technique. Seven matched pairs of human cadaver legs were utilized. The Achilles tendons were isolated from cadaver legs at the musculotendinous proximally, and distally with its native insertion attached to a portion of the calcaneus. Achilles tendon ruptures were created 6 cm proximal to the calcaneal insertion. Tendons were repaired with a modified Krackow stitch. One of each matched pair was augmented with a 4 x 7 cm DermaSpan Acellular Dermal Matrix circumferentially around the tendon and sutured with a lateral trap running locking suture technique. This was followed by tensile testing to failure at a displacement rate of 2.54 mm/sec. The repair load to failure was determined and repair stiffness was calculated. The repair load to failure in the control group was 120.43N±45.80 compared to 355.87N±70.29 in the group augmented with the allogenic dermis ($p<0.00001$). The repair stiffness in the control group was 4.92±2.11N/mm which was statistically significantly less than the 18.56±5.29N/mm in the group augmented with allogenic dermis ($p<0.0001$). Addition of an allogenic repair patch with a running locking suture technique, at the time of the initial repair, shows a statistically significant biomechanical advantage over a Krackow repair, providing a load to failure nearly three times that of the suture repair alone. The increase in repair strength observed in this study suggests Achilles tendon repairs augmented with DermaSpan Acellular Dermal Matrix are capable of bearing more load at the immediate post operative timepoint.

Address Correspondence to: Charles Zelen, DPM FACFAS; Director Professional Education and Research Institute 222 Walnut Ave; Roanoke, VA 24016
email: cmzelen@periedu.com

[1] Private Practice; Foot and Ankle Associates of Southwest Virginia, Director Professional Education and Research Institute. Podiatry Section Chief Department; Department of Surgery Carilion Clinic; Podiatry Section Chief; Department of Orthopedics; HCA Lewis Gale Hospital.

*This is a Zimmer Biomet funded study. These are Zimmer Biomet paid consultants.

INTRODUCTION

The Achilles tendon is the thickest and strongest tendon in the human body. However, in spite of this, it is also one of the most frequently ruptured tendons, accounting for nearly 40% of all surgically repaired tendons.[1] There has been much advancement in the repair of Achilles tendons since 1929 when Quenu and Stojanovitch advocated that rupture of the Achilles tendon should be operated on without delay. Over the last 15 years there has been an increase in the use of biological and synthetic scaffolds to augment the repair of ligamentous and tendinous injuries. Today many of these tendon grafts exist as autografts, allografts, xenografts, and synthetic materials. Even given these advancements, there remains much debate about the appropriate course of treatment for acute and chronic Achilles tendon ruptures.[2]

Many early studies comparing surgical and conservative treatments favored a surgical treatment.[2] In the 1970s, Nistor advocated a nonsurgical approach stating that there was shorter morbidity time, fewer patient complaints, and no hospital stay; finding minor differences between the outcomes of surgical and nonsurgical treatments. Contrary to this, a review by Cetti demonstrated that the major complication rate was 3.5% in surgical repair compared to 18.1% in conservative therapies. Furthermore, re-rupture occurred at a higher incidence in nonsurgically treated patients (13.4%) compared to surgically treated patients (1.4%).[3]

Over the years many operative methods have been proposed for the treatment of Achilles tendon ruptures, especially those untreated ruptures of greater than 4 weeks duration ranging from augmented and non-augmented repairs, percutaneous or minimally invasive repairs, and reconstructive repairs. Simple end to end and suture techniques are often inadequate for neglected repairs because of the deficit between ends that needs to be overcome. The ruptured Achilles can become so contracted as early as 3-4 days that end to end repair is not feasible.[4] In these instances more advanced augmented procedures must be utilized to ensure the repair has suitable biological and mechanical properties to facilitate healing. Many augmented procedures have been described including[2]: tendon transfers (plantaris, FDL, FHL, peroneus brevis, gastrocnemius flaps in many varieties, and Achilles tendon allografts). The issues with these types of procedures are that they increase surgery and tourniquet time, are technically more difficult, decrease function and strength, require larger or multiple incisions, and may entail donor site morbidity.[5,6] It is for these reasons surgeons have turned to exogenous materials. Early trials with synthetic materials were quite popular in the 1970's, 1980's and early 1990's because of their mechanical characteristics, providing strong repair constructs immediately post-operative. However, many of the materials were not suitable from the biological aspects, resulting in complications due to foreign body reactions, chronic inflammation, and osteolysis.[7]

It is for this reason a transition occurred to produce biological grafts that produce very little host response, can mechanically support a repair, and integrate and degrade into host tissues. The overall goal is to produce a graft that can assist as a tissue regeneration scaffold as opposed to reparation. Safety concerns regarding biological grafts are centered on disease transmission and sterility. Human derived allograft donors are required by the FDA to be screened and test for diseases such as HIV and hepatitis. Grafts are produced aseptically or sterilely. Aseptic processing is handling the material such that there is no introduction of additional bacteria. This does not necessarily mean that all bacteria are eradicated from the material. In order for a tissue allograft or medical device to be labeled as "sterile" an SAL of 10^{-6} (1 in a million chance material contains microbe) must be obtained.[8]

There are many reasons a biological implant can produce a host response. Most notably are presence of DNA material in the graft and the presence of the antigen α-Gal. Remnant porcine DNA has been implicated as the cause of severe inflammatory reactions.[9] All xenogeneic scaffolds, including those derived from porcine Small Intestine Submucosa (SIS), have been found to have high levels of α-Gal antigens. This antigen is found in most animal species with exception of humans and monkeys. In fact, humans produce large amounts of anti-Gal antibodies which are a probable reason for many of these xenogeneic grafts to be rejected or mount an inflammatory response.[10]

Grafts that are crosslinked, chemically or naturally, produce a reparative process. Reparative processes create a weaker construct prone to failure. This occurs because the body recognizes the graft as foreign and either breaks it down rapidly and fills in with scar tissue or breaks it down and encapsulates it. Encapsulation occurs due to immune cells penetrating the graft's extracellular matrix making the graft unable to remodel. This results in chronic inflammation consistent with a foreign body response.[11] The overall goal is to produce a graft that can assist as a tissue regeneration scaffold, as opposed to reparation. Regeneration occurs with non-crosslinked grafts. The body accepts the graft and integrates the graft via revascularization and cell repopulation.

DermaSpan Acellular Dermal Matrix is a three dimensional scaffold that is free of crosslinking to allow for a repair via revascularization and cellular population without encapsulation associated with its cross-linked counterparts.[12] Furthermore, DermaSpan is an allograft tissue that has been sterilized eliminating the con-

cern of contamination or a host response.[12] DermaSpan combines the desirable attributes of being human derived, is sterile, and is capable of cellular infiltration from the repair tissue onto the graft from the surrounding tissue sites.[12] The question still remains whether DermaSpan will provide an increase in the mechanical integrity of a suture-based repair, creating a more robust repair construct. The following study demonstrates how DermaSpan can be used as a supplement to a complex Achilles repair and gives greater repair strength at the time of initial repair compared to using a simple Krackow suture repair alone.

MATERIALS AND METHODS

Seven matched pairs of fresh frozen human cadaver legs were used. The tendons were harvested from patients without pre-existing known Achilles tendon disruptions or disorders. Direct inspection revealed that all tendons were grossly normal in appearance without calcifications or tendinosis. The Achilles tendons were excised from cadaver legs proximally at the junction with the gastrocnemius-soleus muscle and distally a block of the calcaneus was excised insuring the insertion point of the Achilles tendon was preserved. The calcaneus was transected proximally to the Achilles tendon insertion point ensuring a minimum of 1 cm of bone was present between the transaction and the Achilles tendon. Each calcaneal bone block was potted in poly(methylmethacrylate) bone cement (Cobalt™ HV bone cement, Biomet, Warsaw, IN) in a fixture adapted to fit on a mechanical test system, ensuring that the insertion point of the Achilles tendon was exposed. The proximal end of each Achilles tendon was placed into a custom gripping fixture (Figure 1).

Specimens were placed on an Instron 8511 mechanical test system (Instron, Norwood, MA) and pre-loaded to 5N. Each Achilles tendon was cyclically loaded in tension for 10 cycles from 5N to 30N at 12.5N/sec to precondition the tendon back to a simulated in situ state. The load and displacement data from each Achilles tendon was recorded. Immediately after preconditioning each tendon, simulated Achilles tendon ruptures were created 6 cm proximal to the calcaneal insertion by a simple transverse transection utilizing a scalpel. All tendons were repaired using eight modified Krackow locking loop stitches [Krackow, JBJS, 1986] (four evenly spaced sutures over a 2 cm span on the medial and lateral sides of the tendon) utilizing No. 2 suture on both the proximal and distal halves of the simulated repair (Figure 2).

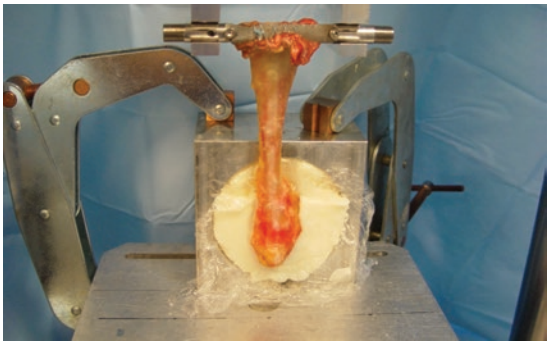

Figure 1
Test set up on the Instron 8511 mechanical test system. The calcaneal block was potted in poly (methylmethacrylate) bone cement ensuring the insertion point of the Achilles tendon was exposed. The proximal end of the Achilles tendon was placed in a custom gripping fixture and additional sutures were added to ensure the tendon did not slip.

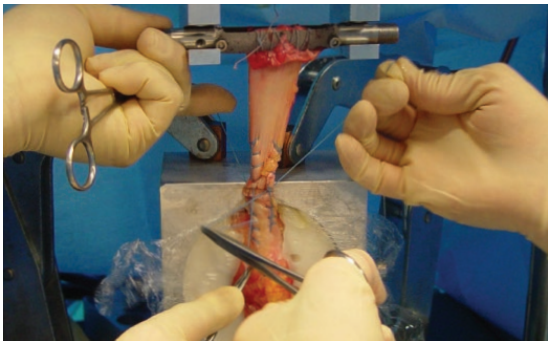

Figure 2
Eight modified Krackow locking loop stitches were utilized to in the simulated repairs. Four evenly spaced sutures were performed over a 2 cm span on the medial and lateral sides of the tendon.

Approximately 4 to 6 cm of free suture was left exposed on the starting and ending points of the Krackow suturing (four free ends total; two on each the proximal and distal sides of the simulated rupture). Four surgical knots (double loop on the first, single loop on the remaining) were utilized to tie the proximal and distal portions of the tendon rupture together via the free suture ends (Figure 3).

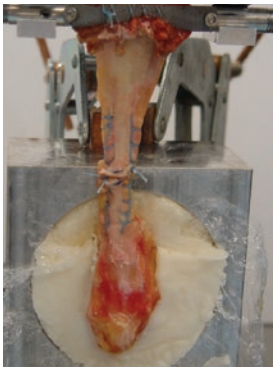

Figure 3
The final simulated repair. Four surgical knots (double loop on the first, single loop on the remaining) were utilized to tie the proximal and distal portions of the tendon rupture together via the free suture ends.

The matched pairs of Achilles tendons were randomly assigned such that each Achilles tendon received one of two treatments: Control Repair – modified Krackow repair alone or Augmented Repair – application of a circumferential augmentation to the modified Krackow repair with the DermaSpan Acellular Dermal Matrix (Biomet, Warsaw, IN; provided by Tissue Banks International, Baltimore, MD). To apply the augmentation grafts, 4 cm x 7 cm x 0.8 mm patches of DermaSpan were reconstituted in sterile saline per the manufacturer's Instructions for Use and were attached to the repaired Achilles tendon with Lateral Trap Sutures.[2] The DermaSpan graft was centered over the simulated tendon rupture site and the four corners of the graft were temporarily attached to the tendon with a simple sutures using 2-0 suture. Next, nine Lateral Trap Sutures were performed with 2-0 suture. The Lateral Trap Sutures were applied with continuous evenly spaced suturing per each medial and lateral side of the graft and were inserted into the graft approximately 5 mm from the medial and lateral edges. The temporary corner sutures were removed once the Lateral Trap Sutures were applied (Figure 4).

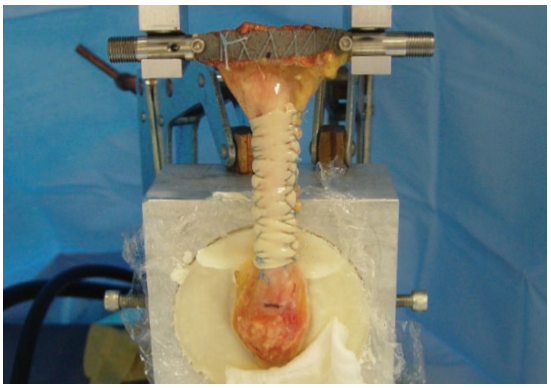

Figure 4
Simulated repair augmented with the DermaSpan ACD. Nine Lateral Trap Sutures were applied with continuous evenly spaced suturing per each medial and lateral side of the graft and were inserted into the graft approximately 5 mm from the medial and lateral edges.

After the repairs were completed, each Achilles tendon was subsequently pre-loaded at 5 N and cyclically loaded in tension for 10 cycles from 5 N to 30 N at a rate of 12.5 N/sec on. The load and displacement data was recorded for the cyclic loading. This was followed by tensile testing to failure at a displacement rate of 2.54 mm/sec. The load and displacement data was recorded. The repair load to failure was determined by the location at which the first suture failed as noted as the point at which the load-displacement curve deviated from the linear progression. The mean repair failure load and standard deviation for the control and augmented repairs were calculated based on the failure load data. Repair stiffness was calculated from the linear region of the load-displacement curves. The mean repair stiffness and standard deviation for the control and augmented repairs were calculated based on the stiffness data. Paired t-tests were performed to compare the repair load to failure and the repair stiffness with and without augmentation. Statistical significance was placed at $p<0.05$.

RESULTS

All repaired tendons exhibited load-displacement curves that were expected for a nonlinear material. Each curve exhibited a heal region that transitioned into a linear region. The failures all occurred within the linear region of the load-displacement curve. The repair load to failure (Figure 5A) in the control group was 120.43 N± 45.80 compared to 355.87 N± 70.29 in the group augmented with DermaSpan ACD ($p < 0.00001$). The repair stiffness (Figure 5B) in the control group was 4.92± 2.11 N/mm which was statistically significantly less than the 18.56 ± 5.29 N/mm in the group augmented with DermaSpan ACD ($p < 0.0001$). In all tendons, the Krackow repair suture was observed to be the initial mode of failure.

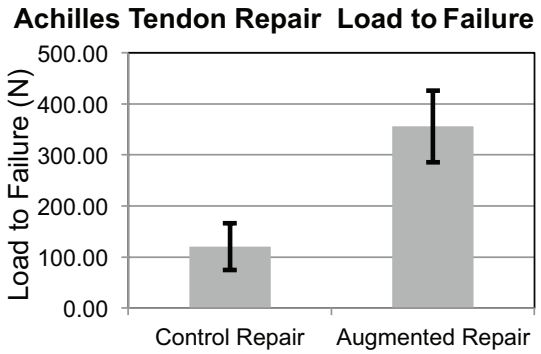

Figure 5A

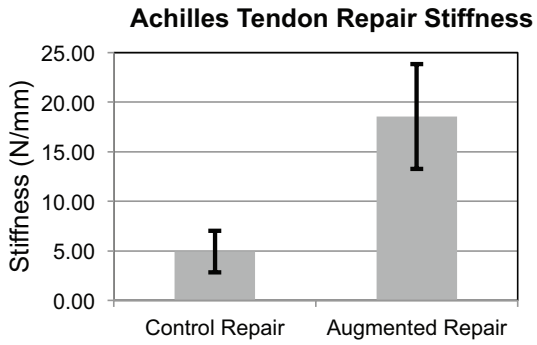

Figure 5B
Figure 5A Load to Failure and Figure 5B Repair Stiffness of Achllles tendon repairs comparing suture alone (Control) or suture augmented with allogenic dermis (augmented). The augmented repair resulted in 3.0 times increase in load to failure and 3.8 times increase in repair stiffness at $p<0.05$.

DISCUSSION

Achilles tendon ruptures generally may be due to distal tendon hypovascularity, repetitive microtrauma, steroid use, and/or degenerative changes. A rapid return to activity is enhanced by a rehabilitation program that allows early range of motion and promotes exercise to regain strength as soon as possible. Stronger repair constructs may facilitate this goal.[13] This study compared the immediate strength and stiffness of Achilles tendons repaired using a modified Krackow repair either augmented with DermaSpan Acellular Dermal Matrix or unaugmented. The DermaSpan scaffold is derived from human dermis and is composed of elastin, collagen, proteoglycans, and preserved blood vessel channels which permit revascularization and cellular repopulation.[12] DermaSpan is provided as a sterile, non-crosslinked allogenic acellular dermis. Since the material is sterile, it virtually eliminates the possibility for transmission of contaminant to the recipient. The modified Krackow repair proved to be a strong construct for Achilles tendon rupture repair, but augmentation of the modified Krackow repair using DermaSpan ACD with a running suture technique significantly increased this strength. The augmentation of the modified Krackow repair with DermaSpan ACD, at the time of the initial repair, resulted in a load to failure nearly three times greater than an unaugmented repair and repair stiffness 3.8 times that of an unaugmented repair. The increase in repair strength observed in this study suggests Achilles tendon repairs augmented with DermaSpan Acellular Dermal Matrix are capable of bearing more load at the immediate post operative timepoint.

CONCLUSION

Addition of a DermaSpan Acellular Dermal Matrix with a running locking suture technique, at the time of the initial repair, clearly shows a statistically significant biomechanical advantage over a standard modified Krackow repair. The increase in repair strength observed in this study* suggests Achilles tendon repairs augmented with DermaSpan Acellular Dermal Matrix are capable of bearing more load at the immediate post operative timepoint.

*The study was performed in a laboratory; clinical studies may result in different results.

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2390.1-US-en Rev.0219

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