

THE BIOMECHANICS OF ALLOMEND® ACELLULAR DERMAL MATRIX: SUTURE RETENTION STRENGTH

Reginald Stilwell, B.S., C.T.B.S.
Ryan Delaney, M.S.
Lauren Castillo, B.S., C.T.B.S.
AlloSource®, Centennial, CO

The Biomechanics of AlloMend[®] Acellular Dermal Matrix: Suture Retention Strength

Reginald Stilwell, B.S., C.T.B.S., Ryan Delaney, M.S., Lauren Blume, B.S., C.T.B.S.
AlloSource[®], Centennial, CO

ABSTRACT

Acellular dermal matrices can successfully be used to replace or repair integumental soft tissue compromised by disease, injury or surgical procedures. These biomaterials are used surgically for a wide range of regenerative medicine applications, including sports medicine applications such as tendon augmentation, rotator cuff repair or superior capsular reconstruction, which call for especially robust and resilient dermal matrix materials that will resist suture pullout. Using standard testing protocols, AlloMend[®] Thick ADM exhibited a suture retention strength as strong as the force a 2-0 suture (typically used for these procedures) is expected to withstand.

Introduction

AlloMend ADM, AlloSource's acellular human dermal matrix (AlloSource[®], Centennial, CO), is produced through a proprietary process of cleaning, rinsing and decellularizing donated human dermal tissue, with significant removal of cellular debris (including DNA and RNA), proteins and antigens.¹ The process does not require the use of detergents or enzymes, thereby mitigating the possibility of harmful residuals in the tissue. Further, the product has been tested by standard ISO 10993-5 methodology and was found to be non-cytotoxic.

The decellularization process also inactivates microorganisms through cellular disruption and, as a result, the likelihood of inflammation or immunogenic rejection response by the recipient is further minimized.

The tissue undergoes a terminal e-beam sterilization procedure, resulting in a 10⁻⁶ Sterility Assurance Level (SAL), meeting the same stringent sterility levels required by the U.S. Food and Drug Administration for implantable biomedical devices.

Because of this sterilization, AlloMend ADM can be stored at room temperature for up to two years. Unlike some other acellular dermal matrices, the tissue is pre-hydrated and ready for immediate use without requiring a lengthy rehydration period. In addition, due to its elasticity and suppleness, AlloMend ADM can be easily placed in a variety of anatomical areas.

The AlloMend preparation process results in a three-dimensional, collagen-rich, biocompatible, non-cytotoxic matrix that retains its biomechanical properties. All of these steps and protocols help ensure that AlloMend ADM will be readily accepted by the recipient with subsequent revascularization and cell repopulation.

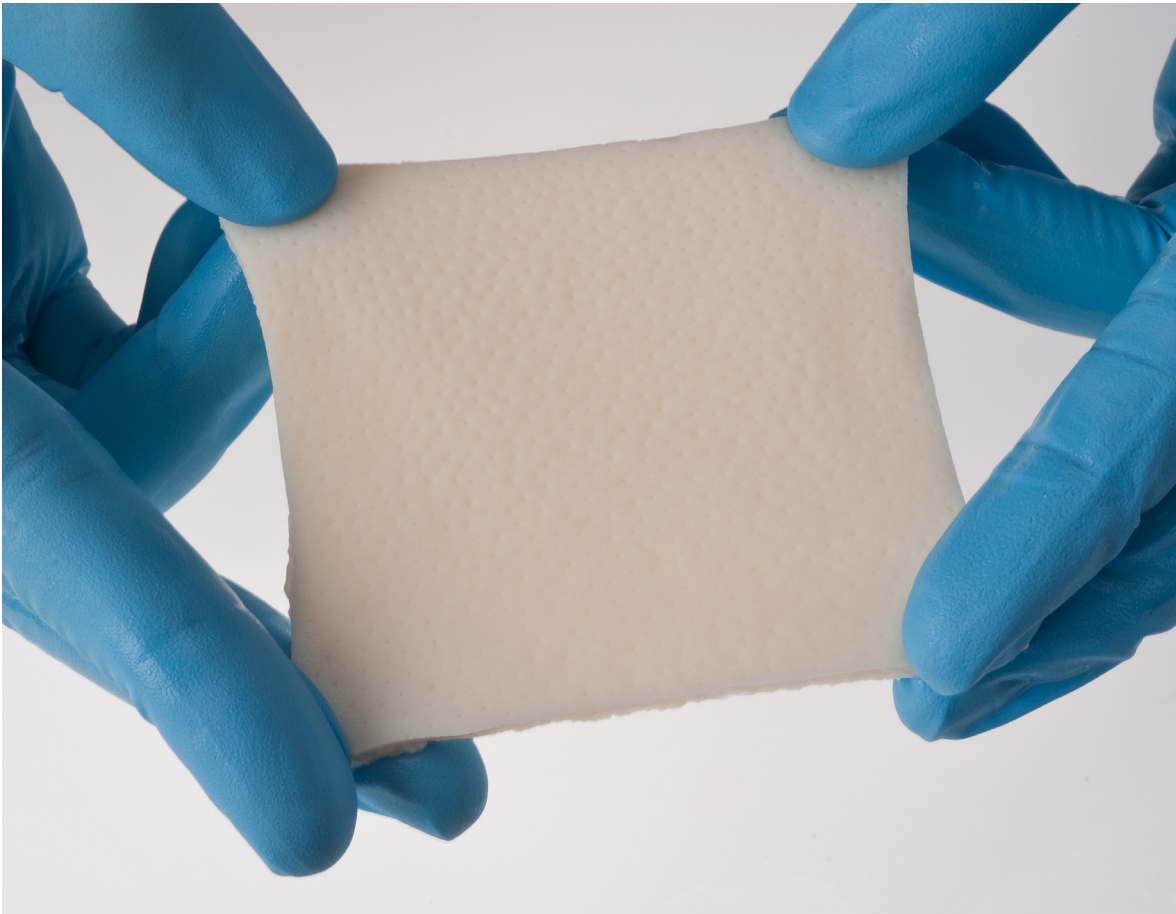


Figure 1. AlloMend ADM Tissue.

Objectives

Since the failure of a graft can lead to significant patient complications, dermal matrix tissue must be structurally resilient in two related ways:

1. *Tensile strength* – It must withstand stretching and pulling forces and maintain its function. As demonstrated in another study, AlloMend ADM exhibited ultimate tensile strength many times higher than the maximums required in extreme physiological conditions such as intra-abdominal placement.²
2. *Suture retention strength (suture pullout strength)* – It must resist tearing at the point of suture when forces pull at the suture.

The purpose of this study is to determine the suture retention load for AlloMend ADM.

Suture retention strength is the maximum pulling force measured in Newtons (N) on a suture that a tissue can bear at the point of suture before the suture tears through the tissue. Since AlloMend is offered in multiple thicknesses (Medium, Thick, Extra-Thick and Ultra-Thick configurations–M, T, XT and UT respectively), these measurements were undertaken to reflect the strength (N) at various points of tissue thickness (mm).

Process

AlloMend ADM grafts from seven different donors (41 samples total) were used in the study. They were prepared in a range of thicknesses ranging from 1.29 to 4.05 mm and cut into approximately 4.0 x 4.0 cm pieces.

All testing was performed using a MTS Model 820.050-SL or ADMET 2600 uniaxial testing apparatus (MTS Systems Corporation, Eden Prairie, MN, or ADMET, Norwich, CT) in accordance with accepted practices for measuring ultimate suture retention strength.^{3,4} In each case, the tissue was secured in the testing apparatus with 2.0 cm of hanging tissue remaining. A simple loop of Anthrex FiberWire 2/metric 5 suture was placed through the tissue approximately 1.0 cm from the edge. This particular suture is one of the strongest available and thus it was used in this test to ensure there would be no suture failure except if exposed to the most extreme forces.

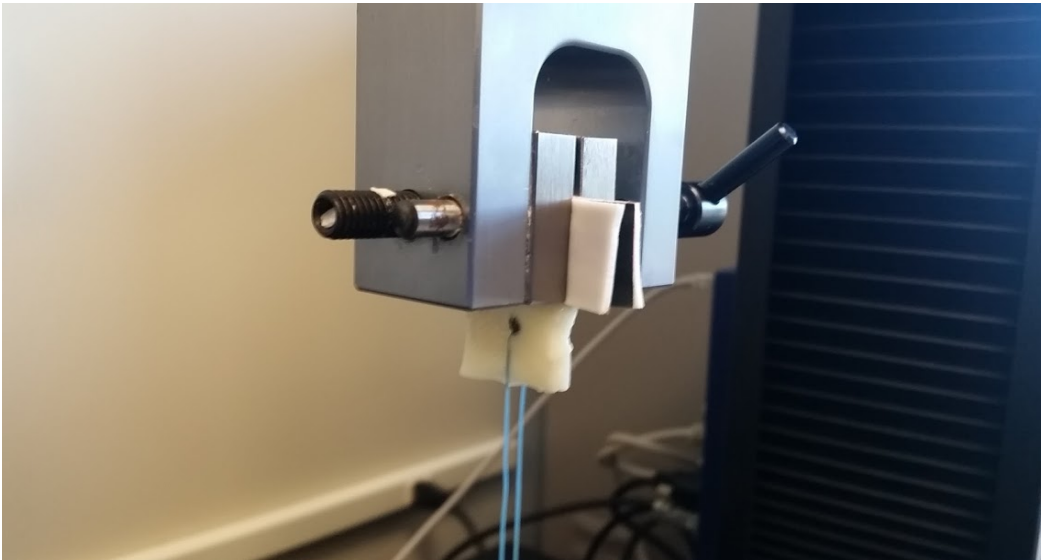


Figure 2. AlloMend Tissue Secured to ADMET Machine with Suture - Pretesting.

A tension test was executed at 20.0 mm/min until the point of complete suture pullout. The maximum load on the tissue just prior to suture pullout was recorded for each sample.

Results

As would be expected, the suture pullout strength for each sample was closely correlated to the thickness of the AlloMend ADM graft, as demonstrated in Figure 3.

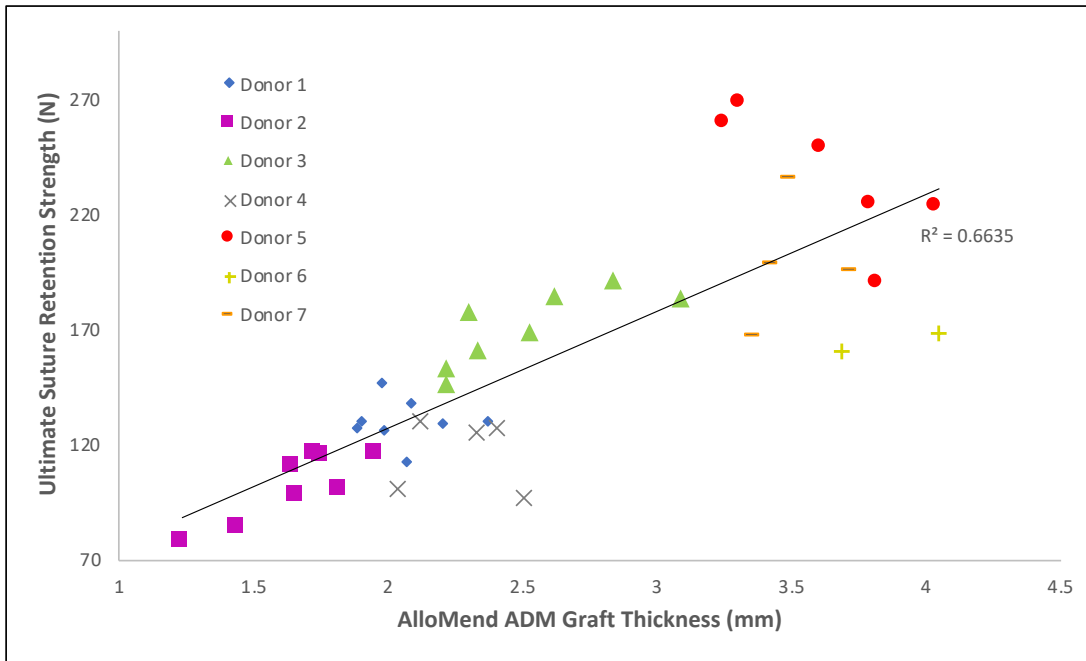


Figure 3. Relation between Graft Thickness and Suture Pullout.

An analysis of suture pullout strength per unit of thickness yielded a mean value of 61.4 N/mm. The most commonly used AlloMend ADM products are from the AlloMend T configuration (from 1.0–2.0 mm). Therefore, depending on their precise thicknesses, the tissue grafts in this range can be expected to have an ultimate suture pullout strength of between 61 and 123 N. The thickest graft, AlloMend UT (from 3.0–4.0 mm) extended the range up to 161 to 270 N.

Implications

As noted, sports medicine procedures such as tendons, augmentation rotator cuff repairs, and superior capsular reconstruction are among the most challenging when it comes to maintaining sutured graft structural viability⁵. Various brands of 2–0 sutures commonly used in these procedures exhibit ultimate tensile strengths of between 69 and 125 N. As noted, AlloMend's Thick (T) ADM tissue has a suture pullout strength of between 61 and 123 N. Thus, in procedures utilizing 2–0 sutures, this tissue can be expected to be approximately as strong as the suture. When using a tissue at the high end of the AlloMend T configuration, the suture would be more likely to fail than the graft itself if the suture was stretched or pulled to the extreme.

Conclusion

AlloMend ADM can meet and exceed all surgical requirements in terms of secure placement in the course of soft tissue repair. It offers optimal suture retention and tensile strength while retaining essential flexibility and pliability characteristics allowing for secure placement and suturing. These attributes, along with its assured terminal sterility, room temperature storage and a pre-hydrated format, make AlloMend ADM an ideal extracellular dermal matrix tissue for a wide range of clinical applications.

References

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6278 S Troy Cir
Centennial, CO 80111
USA

MAIN 720. 873. 0213
TOLL FREE 800. 557. 3587
FAX 720. 873. 0212

allosource.org