



# The Biomechanics of ProLayer<sup>™</sup> Acellular Dermal Matrix:

suture retention  
strength

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# ProLayer Acellular Dermal Matrix

## Abstract

Dermal acellular matrices may 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 and rotator cuff repair, which call for especially robust and resilient dermal matrix materials that will resist suture pullout. Using standard testing protocols, ProLayer ADM exhibited a suture retention strength as strong as the force a 2-0 suture (typically used for these procedures) is expected to withstand.<sup>1</sup>

## Introduction

ProLayer Acellular Dermal Matrix [Figure 1], 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.<sup>1</sup> The process does not require the use of detergents or enzymes, which may reduce 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.<sup>1</sup>

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.<sup>1</sup>

The tissue undergoes a terminal e-beam sterilization procedure, resulting in a 10<sup>-6</sup> 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 its terminal sterilization, ProLayer ADM can be stored at room temperature for up to two years. Unlike some other acellular dermal matrices, the tissue is prehydrated and ready for immediate use without requiring a lengthy rehydration period. In addition, due to its elasticity and suppleness, ProLayer ADM can be easily placed in a variety of anatomical areas.

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

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## Materials and methods

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 seen in other studies, ProLayer ADM exhibited ultimate tensile strength many times higher than the maximums required in extreme physiological conditions such as intra-abdominal placement.
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 ultimate suture retention load for ProLayer ADM.

### Tensile strength

Suture retention strength is the maximum pulling force (N) on a suture that a tissue can bear at the point of suture before the suture tears through the tissue. Since ProLayer is offered in multiple thicknesses (Medium, Thick and Extra Thick configurations—M, T and XT respectively) this measurement was standardized to reflect the strength (N) per mm thickness of the tissue.



Figure 1. ProLayer ADM Tissue

## Process

ProLayer ADM grafts from four different donors (29 samples total) were used in the study. They were prepared in a range of thicknesses ranging from 1.29 to 3.09mm and cut into approximately 4.0 x 2.0 cm pieces.

All testing was performed using an ADMET 2600 uniaxial testing apparatus (ADMET, Norwood, MA) in accordance with accepted practices for measuring ultimate suture retention strength.<sup>2,3</sup>

In each case, the tissue was secured in the ADMET tester with 2.0cm of hanging tissue remaining. A simple loop of FiberWire 2-0/metric 5 suture (Arthrex, Naples, FL) 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.

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.

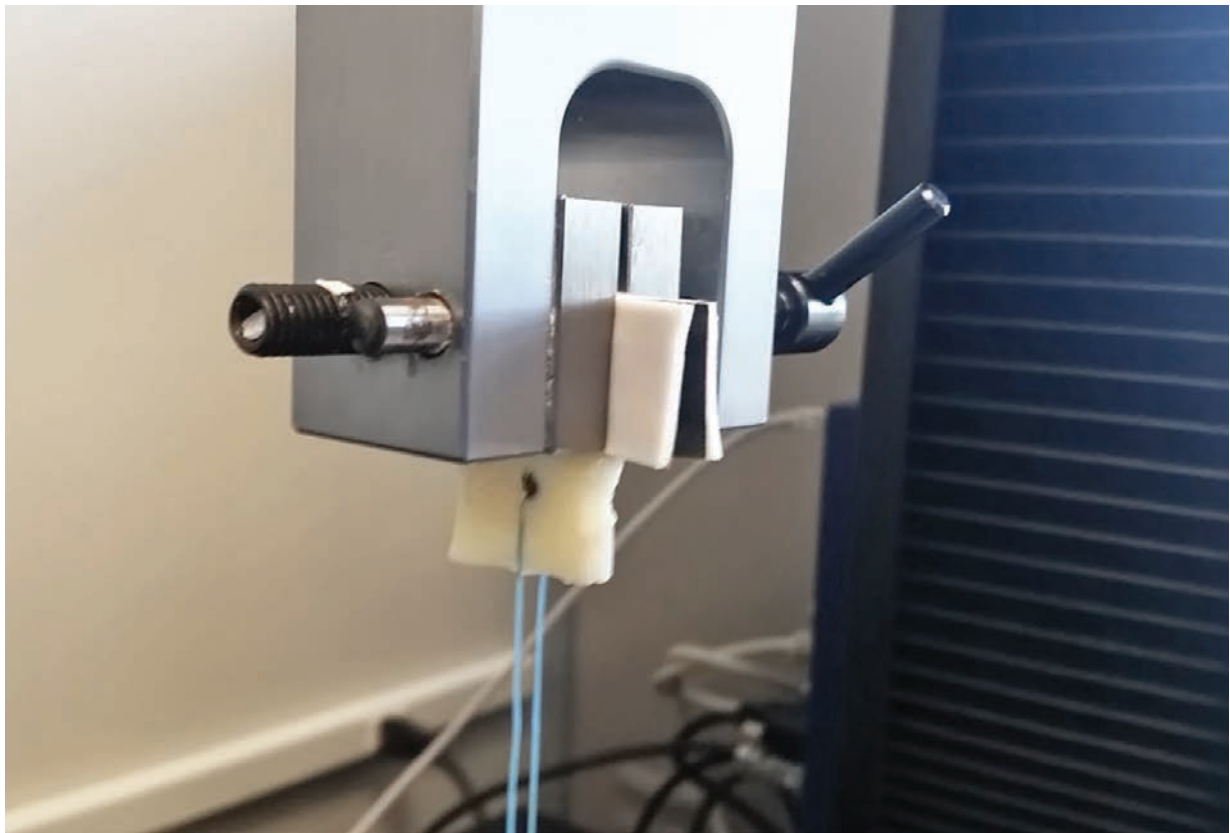


Figure 2. ProLayer tissue secured to ADMET machine with suture - pretesting.

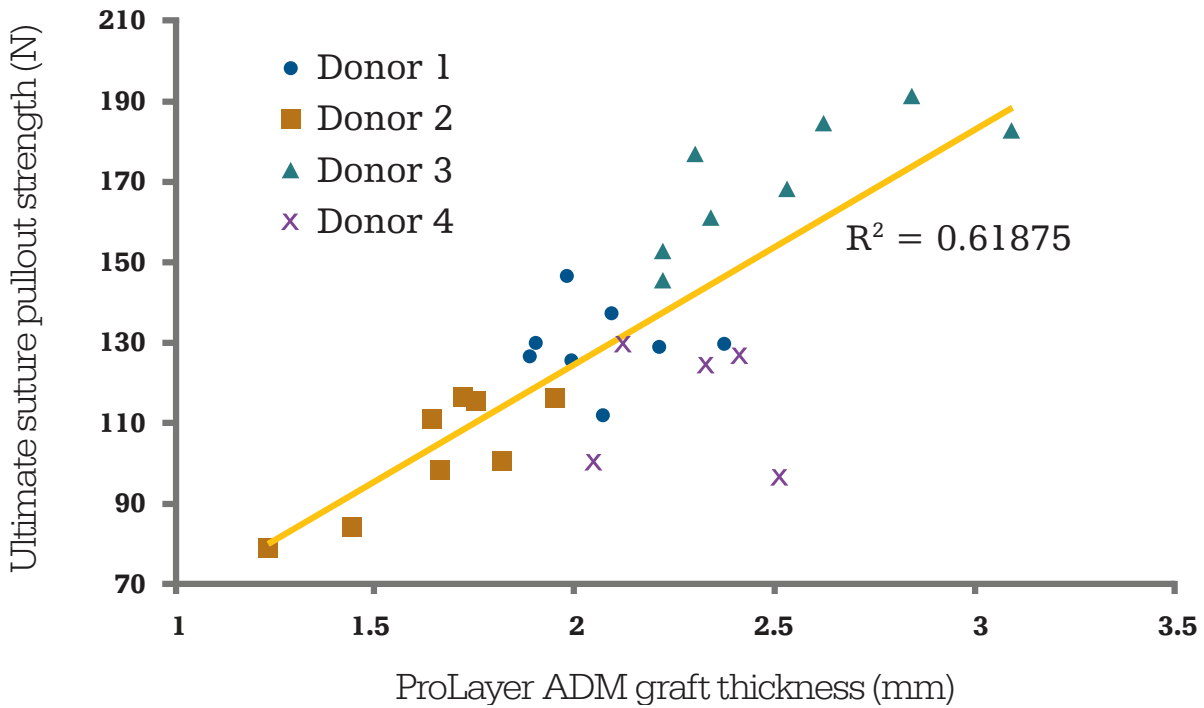


Figure 3. Relation between graft thickness and suture pullout.

**Results**

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

An analysis of suture pullout strength per unit of thickness yielded a mean value of 62.4 N/mm. The most commonly used ProLayer ADM products are from the Thick configuration (from 1.0–2.0mm). Therefore, depending on their precise thicknesses, the tissue grafts in this range were designed to have an ultimate suture pullout strength between 62 N and 124 N.

**Implications**

As noted, sports medicine tissue procedures such as tendon and rotator cuff repairs are among the most challenging when it comes to maintaining sutured graft structural viability. Various brands of 2-0 sutures commonly used in these procedures exhibit ultimate tensile strengths of between 69 and 125 N.<sup>4</sup> ProLayer ADM Thick (T) tissue has been shown to allow for a suture pullout strength of between 62 N and 124 N. Thus, in procedures utilizing 2-0 sutures, this tissue has been shown to be as strong as the suture. When using a tissue at the high end of the Thick configuration, the suture may be more likely to fail than the graft itself if the suture was stretched or pulled to the extreme.

**Conclusion**

ProLayer ADM was designed to offer optimal suture retention and tensile strength while retaining essential flexibility and pliability characteristics allowing for secure placement and suturing. These attributes, along with its validated terminal sterility, room temperature storage and a pre-hydrated format, are designed to make ProLayer ADM an ideal extracellular dermal matrix tissue for a wide range of clinical applications.

## References

1. Data on file at AlloSource.
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3. Mine, Yoshinari. Suture retention strength of expanded polytetrafluoroethylene (ePTFE) graft. Diss. Okayama University, 2010.
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