AlloMend® Acellular Dermal Matrices

Acellular dermal matrices can be used in a variety of potential highly stressed anatomies such as rotator cuff repair, superior capsule reconstruction, Achilles tendon rupture and abdominal wall reconstruction.[1-6] Summaries of AlloSource's AlloMend scientific studies are listed below.

The Biomechanics of AlloMend Acellular Dermal Matrix:

- Suture Retention Strength[1]
- Ultimate Tensile Strength[7]
- Growth Factor Study[8]
- Biocompatibility Study[9]

The Biomechanics of AlloMend Acellular Dermal Matrix: Suture Retention Strength

Suture retention strength is the maximum pulling force (Newtons) on a suture that a tissue can bear at the point of suture, before the suture tears through the tissue.[1] 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, in Newtons, per mm thickness of the tissue.[1] The analysis shown in Table 1 demonstrated that suture retention strength is directly correlated to graft thickness. AlloMend UT showed suture retention strength at 161-270N.

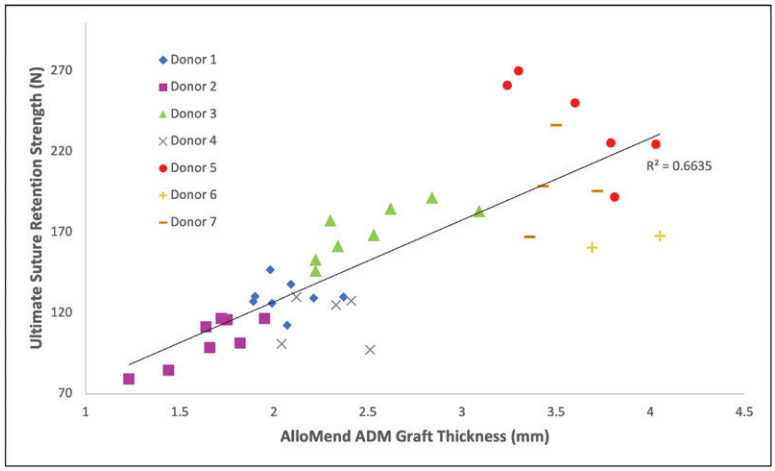
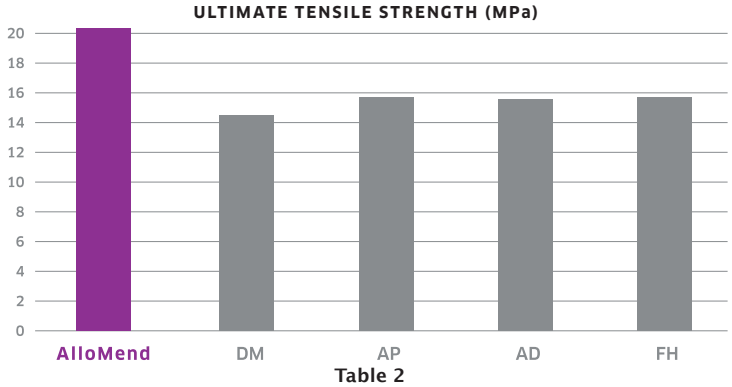


Table 1

The Biomechanics of AlloMend Acellular Dermal Matrix: Ultimate Tensile Strength

The ultimate tensile strength (UTS) of a biomaterial is the maximum stress or strain it can withstand while being stretched or pulled to the point of breaking or failing (biomechanical stretch).[7] Tensile strength is measured in the International System of Units (SI), which is defined as the unit megapascals (MPa). One MPa is the equivalent of one Newton per square millimeter (N/mm2) of tissue.

In the course of biomechanical stretch testing, AlloMend exhibited a UTS of 20.7 MPa ± 2.2. AlloMend surpassed published UTS data for other leading acellular dermal matrix products as shown in Table 2.



DM- DermaMatrix; Synthes
AP- AlloPatch; MTF Biologics
AD- AlloDerm; LifeCell
FH- FlexHD; Ethicon

Table 2

The Biomechanics of AlloMend Acellular Dermal Matrix: Growth Factor Study

The presence of growth factors in an implanted AlloMend Acellular Dermal Matrix (ADM) allograft can help stimulate healing and revascularization.[8] Collectively, these growth factors coordinate cellular incorporation, proper bone attachment and proper differentiation of cells. At the same time, they prevent untoward inflammation and necrosis at the implantation site.[8,10]

In this study an enzyme-linked immunosorbent assay (ELISA) was used to test ADM for the presence of four primary growth factors as shown in Table 3. The specifics of each growth factor are outlined in Table 4.[8,11]

- Fibroblast Growth Factor (bFGF)
- Platelet Derived Growth Factor (PDGFbb)
- Transforming Growth Factor (TGFb)
- Bone Morphogenic Protein 2 (BMP2)

Table 3

	Tendon Reconstruction Procedures	Soft Tissue Reconstruction	Total Surgical Site Benefits
bFGF	Prevents necrosis Assists in angiogenesis Increases attachment strength	Assists in angiogenesis basal membrane formation Prevents necrosis	Prevents necrosis Promotes scar-free healing Promotes surgical wound closure
PDGFbb	Reduces inflammation Serves as a chemotactic guide to graft for host cells Improves tendon strength	Reduces inflammation Serves as a chemotactic guide to graft for host cells	Promotes scar-free healing
TGFb	Assists in the production of new matrix in graft Promotes allograft acceptance Increases tendon-to-bone incorporation	Assists in the production of new matrix in graft Promotes allograft acceptance	Prevents inflammation Coordinates the wound healing process
BMP2	Serves as a chemotactic guide to graft for host cells Improve tendon-to-bone healing Signals tenocytes to form new tissue	Serves as a chemotactic guide to graft for host cells Induces adipogenesis in soft tissue spaces	Promotes stem cell differentiation

Table 4

The Biomechanics of AlloMend Acellular Dermal Matrix: Biocompatibility Study

The AlloMend proprietary decellularization process results in a three-dimensional, collagen-rich, biocompatible, non-cytotoxic matrix that retains its biomechanical properties.[9] This process ensures the tissue will be biocompatible and will be readily accepted by the recipient through healing. The purpose of this study was to evaluate the biocompatibility of AlloMend through an animal model.

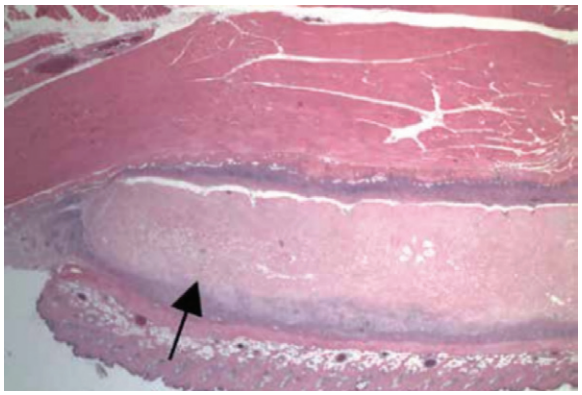


Figure 1. *Graft Implantation (arrow) at Two Weeks.*

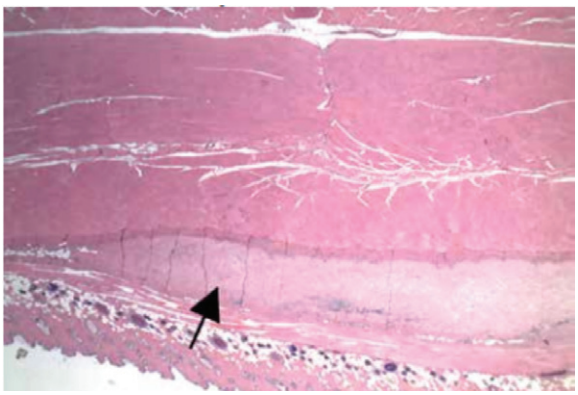


Figure 2. *Graft Implantation (arrow) at 12 Weeks.*

This animal study demonstrated the biocompatibility of AlloMend. No tissue rejection was found. There was strong evidence of tissue incorporation and blood vessel infiltration. No infections were noted and no discernible impact on metabolism; animal growth and development subsequent to implantation were normal.[9]

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