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THE BIOMECHANICS OF ALLOMEND® ACELLULAR DERMAL MATRIX: ULTIMATE TENSILE STRENGTH

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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 abdominal wall reconstruction/hernia repair, breast reconstruction, maxillofacial and dental procedures, sports medicine applications (such as tendon augmentation, rotator cuff repair, and superior capsular reconstruction), pelvic organ prolapse repair and others.[1, 2, 3, 4, 5, 6, 7]

Introduction

AlloMend ADM (figure 1), human acellular dermal matrix (AlloSource®, Centennial, CO) product, 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. The process does not require the use of detergents or enzymes, thereby mitigating the possibility of harmful residuals in the tissue. Further, the tissue 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 its terminal sterilization, AlloMend 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, as well as its availability in various thickness ranges, AlloMend ADM can be easily placed in a variety of anatomical areas.

The AlloMend process of manufacture results in a three-dimensional, collagen-rich, biocompatible, non-cytotoxic matrix that retains its biomechanical properties. This processing helps ensure that AlloMend ADM will be readily accepted by the recipient with subsequent revascularization and cellular repopulation.

Given the variety of possible applications, it is critical that an acellular dermal matrix tissue is strong enough to stand up to internal bodily forces and surgical fixation. AlloMend ADM meets these criteria as supported by test data.

Figure 1. *AlloSource AlloMend ADM Tissue.*

Materials and Methods

The ultimate tensile strength (UTS) of a biomaterial is the maximum stress it can withstand while being stretched or pulled to the point of breaking or failing. Tensile strength is ideally measured in the SI (International System of Units) unit megapascals (MPa). One MPa is equivalent to one Newton (the SI-derived unit of force) per square millimeter of cross-sectional area (N/mm^2). Using this unit of measure allows researchers to evaluate the strength of the tissue independently from thickness and width, thereby "normalizing" them for intrasample tissue comparison. The tensile strength may also be presented as the load to failure in Newtons. This is simply the force at which the material failed during tensile testing and is not independent of thickness or width.

Process

The AlloMend ADM samples were tested in an electro-mechanical device designed for measuring and recording the stress-strain characteristics of biomaterials *(figure 2)*. Samples were cut and tested by a protocol outlining acceptable methodologies for UTS similar to those laid out in USP's "Bovine Dermal Matrix (tensile test)" [8] and ASTM's "Standard Test Method for Tensile Properties of Plastics." [9]

A tensile load was applied to each specimen using an electro-mechanical test machine at a rate of 10mm/minute under displacement control until failure was achieved. Failure was designated as a rapid loss in tensile force with compromised tissue. The force required to cause failure was recorded as UTS.

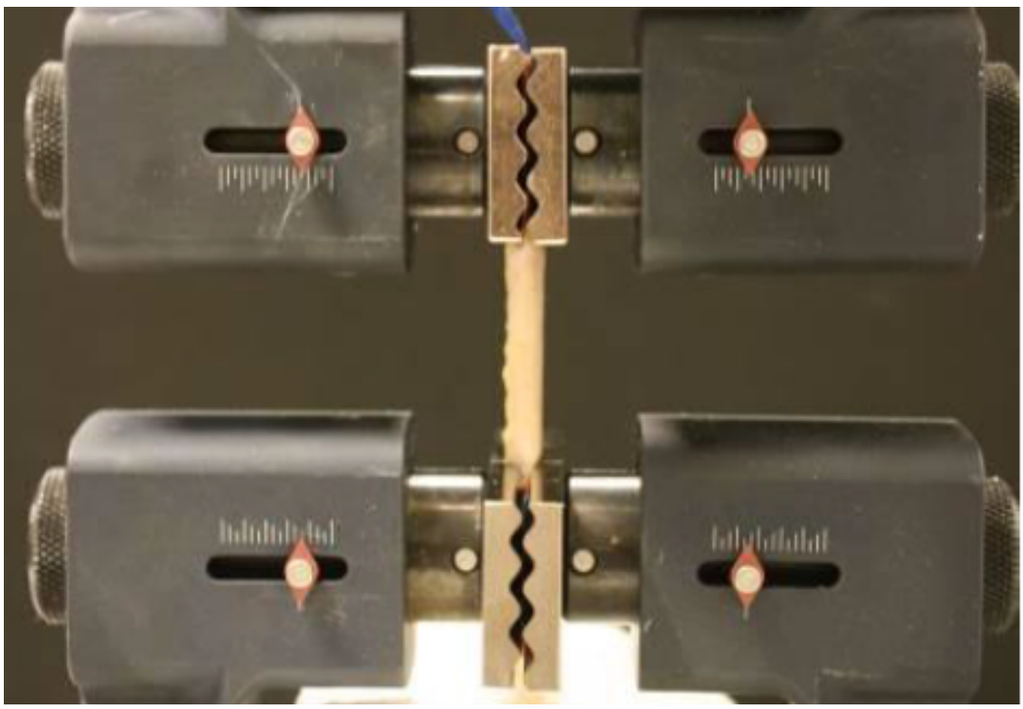

Figure 2. *Static Tension Grip Fixture.*

Results

An accelular dermal matrix must maintain structural competency in the face of biomechanical pressures in all applications. One of the most demanding environments is in the abdominal region, where the tissue often is used to assist with hernia repair and abdominal wall reconstruction, and must withstand the forces exerted by the muscular wall in the herniated region, the highest of which occur with coughing and jumping.[10,11]

During biomechanical tensile testing, AlloMend exhibited a UTS of 20.7MPa ± 2.2, many times stronger than intra-abdominal pressure maximums. Furthermore, in biomechanical tests AlloMend ADM surpassed published UTS data for other leading acellular dermal matrix products *(figure 3)*.

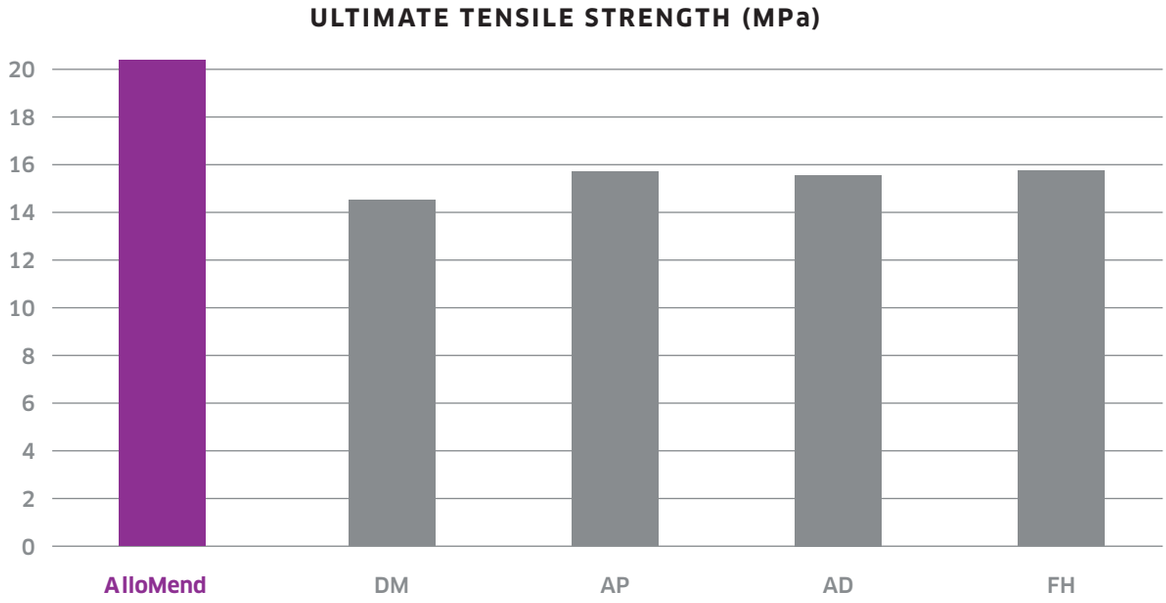

Figure 3. *Ultimate Tensile Strength (MPa) Comparison of Acellular Dermal Matrix Products*.*

As indicated earlier, the tensile strength may also be presented as the average load to failure in Newtons. Evaluating data from the AlloMend UT (Ultra-Thick) thickness range (3.0-4.0mm), the average load to failure is 720.9 +/- 76.7N. In order to make comparisons to other products, the width and thickness of the samples would need to be the same as the samples that were used in this test, which had a width that was approximately 1.0cm.

Conclusion

AlloMend ADM provides optimal tensile strength while retaining essential flexibility and pliability characteristics allowing for precision 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.

*Data on file: AlloMend versus published competitive product specifications

DM is DermaMatrix Acellular Dermis (Synthes): 14.6 MPa. Data from: Synthes/MTF marketing brochure 2006.

AP is AlloPatch HD Acellular Human Dermis (MTF): 15.7 MPa. Data from: MTF marketing brochure 2007.

AD is AlloDerm Freeze-Dried Acellular Dermal Matrix Graft (LifeCell): 15.6 MPa. Data from: Bottino MC, Jose MV, Thomas V, Dean DR, Janowski GM. Freeze-dried acellular dermal matrix graft: effects of rehydration on physical, chemical, and mechanical properties. Dent Mater. 2009 Sep;25(9):1109-15. doi: 10.1016/j.dental.2009.03.007. Epub 2009 Apr 24.

FH is FlexHD Acellular Hydrated Dermis (Ethicon): 15.7 MPa. Data from: Ngo MD, Aberman HM, Hawes ML, Choi B, Gertzman AA. Evaluation of human acellular dermis versus porcine acellular dermis in an in vivo model for incisional hernia repair. Cell Tissue Bank. 2011 May;12(2):135-45. doi: 10.1007/s10561-011-9245-5. Epub 2011 Mar 6.

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