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

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ABSTRACT

Dermal acellular 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 and rotator cuff repair), pelvic organ prolapse repair, among others.[1,2,3,4,5,6]

Introduction

AlloMend™ ADM *(figure 1)*, acellular human dermal matrix tissue (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. 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 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 process of manufacture results in a three-dimensional, collagen-rich, biocompatible, non-cytotoxic matrix that retains its biomechanical properties. This processing helps ensure AlloMend ADM will be readily accepted by the recipient with subsequent revascularization and cell 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. AlloMend ADM Tissue

Materials and Methods

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. Tensile strength is ideally measured in the SI (International System of Units) unit megapascals (MPa). One MPa is the equivalent of one Newton (the SI-derived unit of force) per square millimeter (N/mm^2). Using MPa unit of measure allows researchers to take into account the thickness of the tissues, thereby "normalizing" them for intrasample tissue comparison.

Process

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)" [7] and ASTM's "Standard Test Method for Tensile Properties of Plastics." [8]

A tensile load was applied to each specimen using an electro-mechanical test machine at a rate of 10mm per 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.

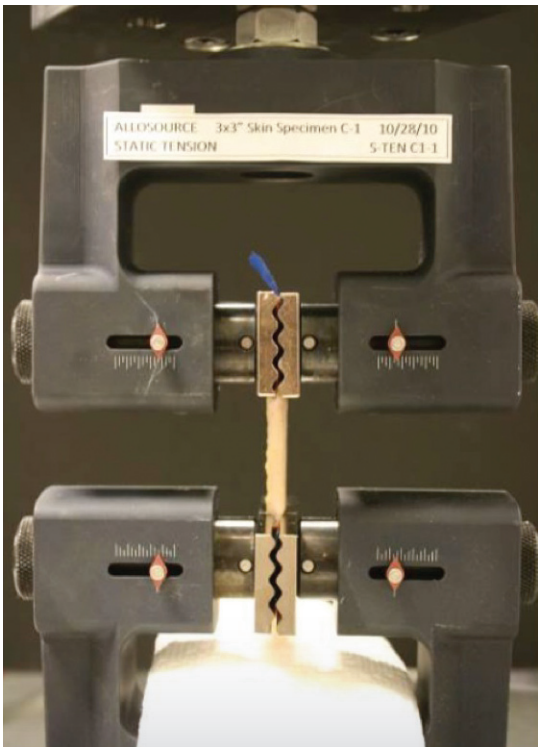

Figure 2. Static Tension Grip Fixture

Results

An acellular 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 is often 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.[9,10]

In the course of biomechanical stretch testing, AlloMend exhibited UTS of 20.7 MPa ± 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)*.

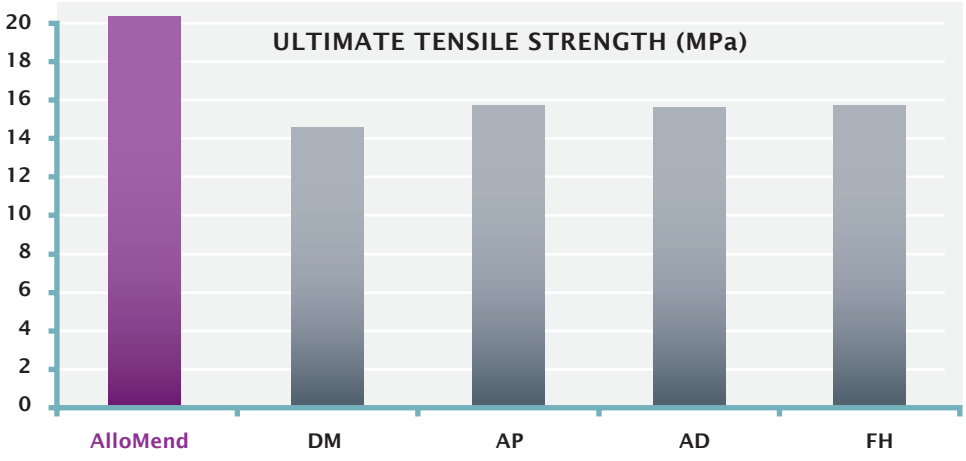

Figure 3. Ultimate Tensile Strength (MPa) Comparison of Dermal Matrix Products*

Process

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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