FlexHD Acellular Dermal Matrix

BIOMECHANICAL PROPERTIES

Currently, numerous materials are available for surgeons requiring allograft dermis, each material having its own set of advantages and disadvantages. Allograft dermis has been demonstrated to be an effective biomaterial for the use in the repair of abdominal wall defects[1], dental applications[2], full-thickness burns[3] and breast reconstructions post-mastectomy[4]. Among the materials that have been available, the biologic prosthetics have shown distinct biomechanical advantages, with the distinct disadvantage of requiring time-consuming step of rehydrating the freeze-dried graft material.

FlexHD acellular dermal matrix was created to answer the need for a dermal graft that does not require rehydration, yet provides all the biomechanical advantages of a biologic prosthetic.

FlexHD acellular dermal matrix is derived from allograft human skin that is processed using proprietary procedures developed by MTF[†]. Allograft skin is decellularized, removing the epidermal layer and cells, leaving an acellular dermis that is disinfected and packaged. Acellular dermal matrix is packaged hydrated in 70% ethanol solution. It does not require rehydration or rinsing prior to use.

BIOMECHANICAL PROPERTIES

FlexHD acellular dermal matrix has been subjected to biomechanical testing to characterize its physical properties. Testing is conducted in accordance with MTF-established procedures and ASTM International standards[‡] for mechanical strength and ability to hold suture. Test results were compared to the properties of a leading competitor's dermal matrix material.

Acellular dermal matrix demonstrates superior biomechanical properties in comparison with the leading competitor's dermal matrix material. Acellular dermal matrix exhibits an average tensile strength, an intrinsic property, of 16.5 N/mm^2 and can withstand an average maximum load of 69.5 N prior to yielding. The competitor material, when subjected to the same testing, exhibited an average tensile strength of 8.0 N/mm^2 and a maximum load before yield of 44.2 N. The average tensile modulus, or ability of the dermal matrix to resist deformation, is 20.6 MPa, compared to 5.8 MPa for the competitor matrix. Suture retention testing showed that acellular dermal matrix was equivalent to the competitor material in testing.

These biomechanical properties are significant when considering applications such as abdominal wall repair, where material strength is required to promote healing and prevent additional failures at the wound repair site.

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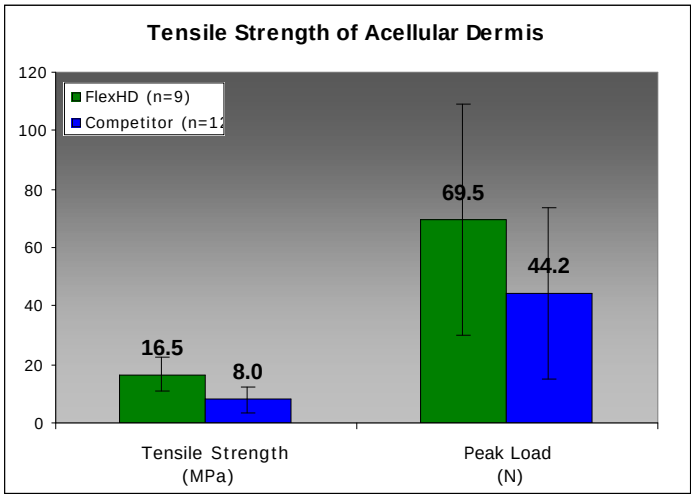
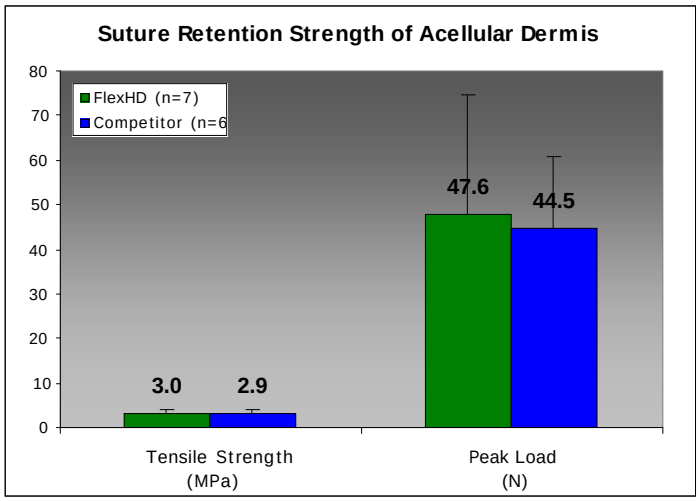
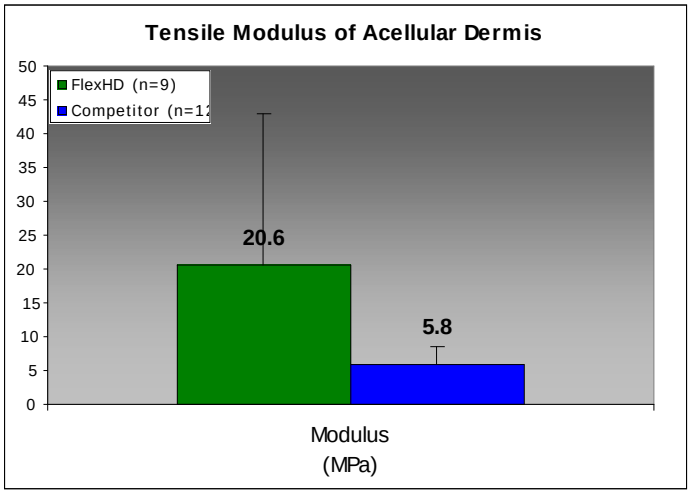
[†] U.S. and international patents pending.
[‡] ASTM D638





Acellular dermal matrix shows greater tensile strength than the leading competitor's material. Tensile strength data (left) and suture retention strength (right) are shown.



Acellular dermal matrix demonstrates higher tensile modulus, or greater resistance to stretching and deformation in laboratory testing.

HISTOLOGY

FlexHD acellular dermal matrix has been processed to remove cells while maintaining histomorphological integrity. Standard histology and immunohistochemical methods have been used to assess dermal matrix structure and its components. Elastin, in conjunction with collagen, contributes to the strength and structure of the dermal matrix scaffold.

Immunochemical evaluation of acellular dermal matrix confirms that the major components of the extracellular matrix, including collagen, elastin, and major matrix components responsible for promoting cell attachment and growth are preserved such that the histomorphological integrity of the dermal matrix is maintained after processing. Cells are effectively removed, leaving the original dermal matrix architecture intact.

For more detailed information on the histological profile of FlexHD acellular dermal matrix, please refer the white paper, "Histology: In Vivo and In Vitro Studies," which offers a more comprehensive evaluation and analysis of the FlexHD allograft's characteristics.

TISSUE SAFETY

From donor screening to tissue testing, FlexHD acellular dermal matrix undergoes a comprehensive process to ensure tissue safety. Every lot of acellular dermal matrix is tested for Sterility per <USP 71>, indicating that there is no microbial growth on a lot-to-lot basis, for release. Its acellular properties and minimized handling (due to its rehydration-free preparation) are among the conditions that help ensure optimum safety. Please refer to the separate white paper on FlexHD Tissue Safety for more information.

CONCLUSION

Flex HD acellular dermal matrix shows great promise, offering the biomechanical advantages of an allograft that maintains a greater percentage of its inherent strength and flexibility, together with the strategic advantage of not requiring time-consuming rehydration.

FlexHD is made available through the Musculoskeletal Transplant Foundation, a non-profit organization that is a national consortium of medical schools, academic institutions and recovery organizations involved in the recovery, processing and distribution of bone and related soft tissue for use in transplant surgery. Our quality and safety standards have been developed by leading physicians, transplant surgeons, and specialists in the fields of science and medicine.

MTF's quality and safety standards consistently meet or exceed the requirements of the American Association of Tissue Banks and the current regulations published by the federal Food and Drug Administration. MTF is also in compliance with established Good Tissue Practices and the International Standards Organization. MTF uses the most complete and technically advanced testing available, including Nucleic Acid Testing (NAT), for detection of transmittable diseases such as HIV, and Hepatitis to assure the safety of every allograft we supply.

Visit our website at mtf.org, or contact MTF at 1-800-433-6576, for further information.

REFERENCES

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