Analysis of DNA Residuals in DermACELL® Tissue

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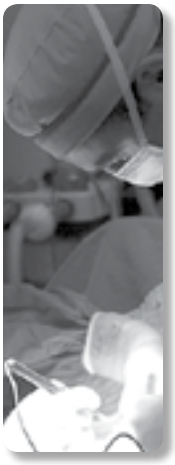

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Introduction

Decellularized skin is used for an array of procedures, such as repairing non-healing diabetic wounds, breast reconstruction, and treatment of burn injuries. In theory, decellularization results in a material devoid of immunogenic components, improved graft incorporation, healing, and biocompatibility. A novel acellular dermal matrix (ADM), called DermACELL®, goes through a validated and patented process called MATRACELL®[1], which renders the grafts acellular (Fig. 1), without compromising the biomechanical or desired biological properties of the graft. A key measure of the effectiveness of decellularization is removal of DNA. Here, quantitative DNA analysis of DermACELL is reported and compared to other available ADMs.

DNA Analysis

The DNA content of DermACELL was assessed using a highly sensitive fluorometric dye, PicoGreen (Invitrogen) that intercalates the DNA minor groove. The dye has a lower limit of detection of 0.7g ng DNA/ml and lower limit of quantitation of 2.7 ng DNA/ml. The validated assay found the DNA content of tissue decellularized using the MatrACELL process (resulting in DermACELL) is reduced by ›97%2, to approximately 16 ng/mg dry weight.

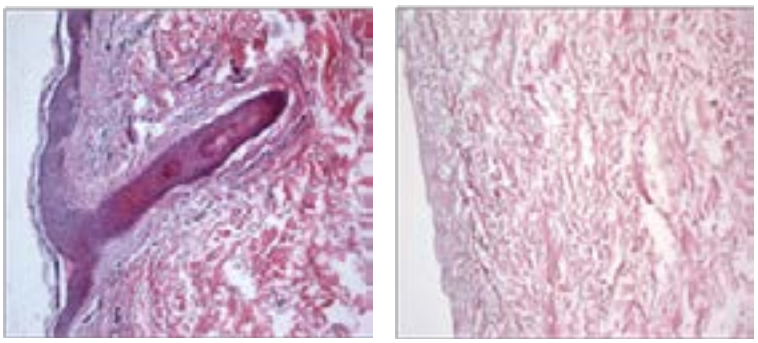

Figure 1 Histological analysis of tissue prior to decellularization (left) and after treatment with the MatrACELL process to yield DermACELL (right). The staining methodology is Hemotoxylin and Eosin (H&E) to show general nuclei remnants (blue dots). Note the presence of stained cellular material prior to decellularization in contrast to the absence of nuclear staining in DermACELL.

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Comparative Results

In addition, a comparison of the DNA content of two other commercially available decellularized human tissues, Alloderm and GraftJacket, which are both produced by the same manufacturer, was undertaken. Please note this is not a side-by-side experiment, rather a comparison to the literature. However, all values are represented as ng/mg dry weight of tissue, and the method of detection was identical.

In the respective publications for Alloderm and GraftJacket, the DNA analyses are quoted as follows; GraftJacket: "DNA content was determined with use of the PicoGreen dsDNA Assay (Molecular Probes) according to the manufacturer's instructions...DNA content of GraftJacket averaged 134.6 ffl 44.0 ng/mg dry weight."[3] And for Alloderm: "Mean DNA concentration plus or minus standard error was...272.8 +/- 168.8 [ng/mg] tissue for...cadaveric dermis"[4] (see fig. 2).

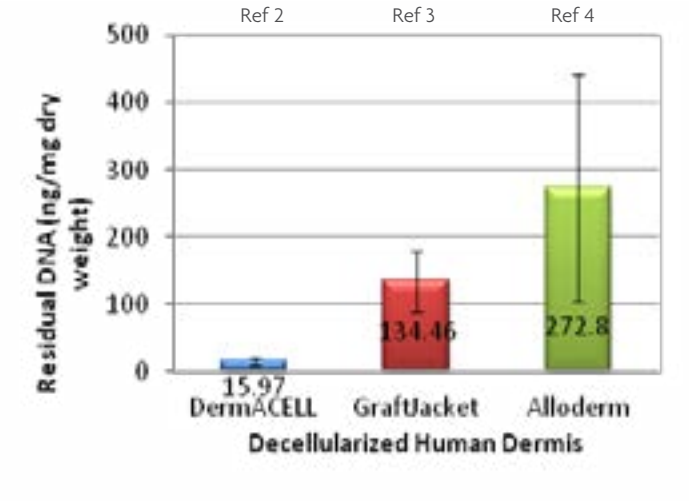

Figure 2 Comparison of Residual DNA values for DermACELL[2] (Data on file) and values reported in the literature for GraftJacket[3] and Alloderm[4], respectively.

Conclusion

As demonstrated, MatrACELL processing used to produce DermACELL effectively removes DNA and cellular content from human dermis, potentially improving graft incorporation, healing, and biocompatibility by decreasing or eliminating cellular immune responses.

References:

1. US Patents 6,734,018; 6,743,574; 6,837,907; 7,338,757
2. Data on File, LifeNet Health
3. Derwin KA, Baker AR, Spragg RK, Leigh DR, Ianotti JP. Commercial extracellular matrix scaffolds for rotator cuff tendon repair. Biomechanical, biochemical, and cellular properties. J Bone Joint Surg Am. 2006; 88: 2655-2672
4. Choe JM, Bell T. Genetic material is present in cadaveric dermis and cadaveric fascia lata. J Urol. 2001; 166:122-4

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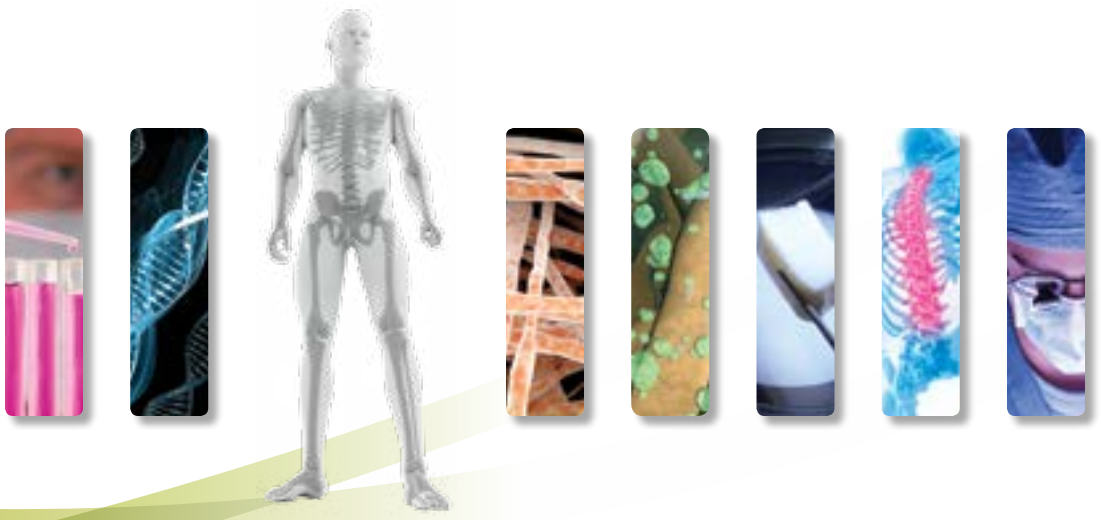

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