Histological Investigations of Recellularization, Revascularization, Adhesions of DermaSpan™ Acellular Dermal Matrix[1]

DermaSpan Acellular Dermal Matrix, processed by Aziyo Biologics, is a collagen matrix allograft manufactured from donated human skin allograft with no cellular elements present. The allograft has undergone a series of aseptic cleaning steps that remove the cellular components, leaving the collagen matrix intact. The advantage of a collagen scaffold with the cellular components absent is dramatically reduced immunogenicity while making available the scaffold for host-cell remodeling into the graft.2, 3

DermaSpan matrix has a dermal side which supports recellularization and subsequent revascularization and a basement membrane side to which the host tissue adheres at a slower rate. This has been shown to help prevent adhesions in animal studies.4 Unlike the majority of other tissue banks' Acellular Dermal Matrix (ACD), DermaSpan matrix is provided sterile at a validated Sterility Assurance Level (SAL) of 10-6.

DermaSpan matrix can be used in various surgical practices, for the repair or replacement of damaged or inadequate integumental tissue. DermaSpan matrix can also be used for supplemental support, protection, reinforcement or covering of tendon. The DermaSpan matrix acts as a scaffold, into which the host cells can penetrate and remodel the allograft, replacing it with healthy, viable tissue.

Aziyo Biologics' exclusive proprietary methodology for terminal sterilization by precision gamma irradiation limits the possibility of irradiation overdosing. This process achieves a SAL of 10-6, as validated Method VDmax15 (ANSI/AAMI/ISO 11137-1 and 2: 2006, Sterilization of Healthcare Products – Radiation).

Utilizing standard histological staining techniques as well as transmission electron microscopy (TEM), the collagen structure and the elastin fibers were qualitatively assessed between native human skin, non-gamma irradiated human ACD and gamma irradiated human ACD as shown in Figures 1, 2,and 3.

Hematoxylin and eosin stain micrographs of normal human skin, unirradiated ACD & gamma irradiated ACD are shown in Figures 1a, 1b, 1c. Note that the collagen structure is similar in all three specimens. Comparing the normal human skin to the irradiated ACD shows the absence of cellular components, i.e. there are no visible intact cells remaining after the ACD processing.

Similar micrographs for the same three groups are shown in Figures 2a, 2b, 2c except that these are Verhoeff-Van Gieson Staining which shows that the elastin fibers of acellular dermal matrix are similar for normal human skin, unirradiated and irradiated ACD.

TEM, shown in Figures 3a, 3b, 3c, was utilized to qualitatively assess the collagen fibril structure. These images show normal human skin, unirradiated ACD & gamma irradiated ACD. The collagen structure does not exhibit differences between the three.

Summary

In summary, DermaSpan Acellular Dermal Matrix shows a similar histology of the collagen structure and elastic fibers when compared to normal human skin and unirradiated ACD. Furthermore, the DermaSpan matrix shows an absence of intact cells following processing. Maintaining a collagen structure can help support new tissue ingrowth and can assist as a tissue regeneration scaffold.5 Elastin fibers provide elasticity to the allograft allowing it to stretch while supporting tendon or wound coverage.6 Finally, the absence of intact cells discourages an immunogenic response.

Figure 1a, 1b, 1c—H&E Stain Micrographs: Normal human skin, unirradiated ACD & gamma irradiated ACD. Histology of the collagen structure of acellular dermal matrix is similar for normal human skin, unirradiated and irradiated ACD **(H&E - hematoxylin and eosin stain)**. Furthermore, comparing Figure 1a to Figure 1c, the irradiated ACD shows the absence of cellular components, i.e. there are no visible intact cells remaining after the ACD processing.

Figure 2a, 2b, 2c—VVG Stain Micrographs: Normal human skin, unirradiated ACD & gamma irradiated ACD. Histology of the elastin fibers of acellular dermal matrix is similar for normal human skin, unirradiated and irradiated ACD **(VVG - Verhoeff-Van Gieson Staining for elastin fibers)**.

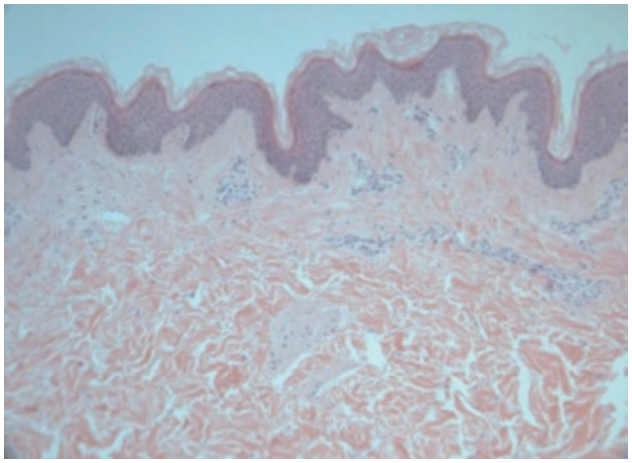

Figure 1a: Normal Human Skin

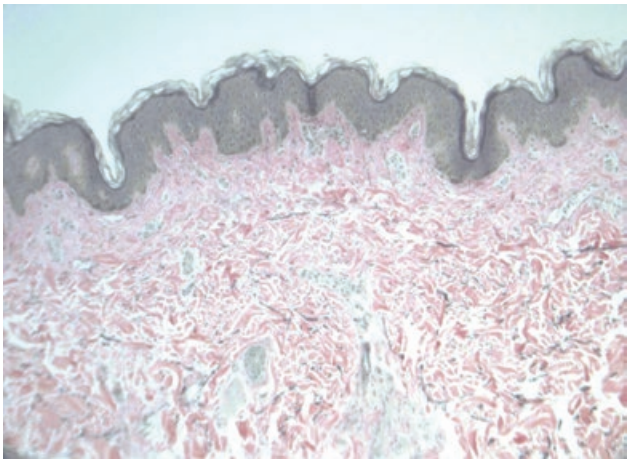

Figure 2a: Normal Human Skin

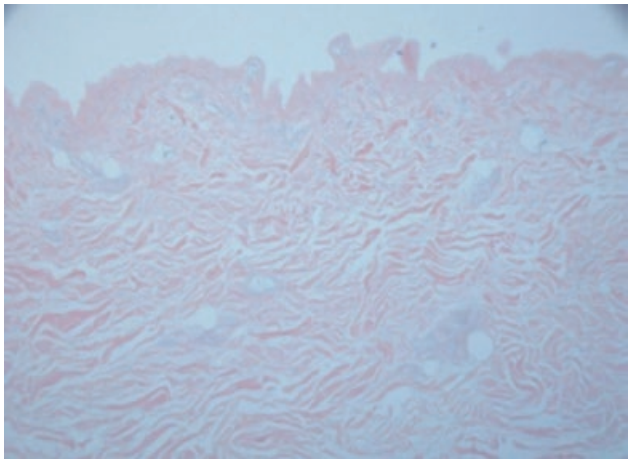

Figure 1b: Acellular Dermis, Unirradiated

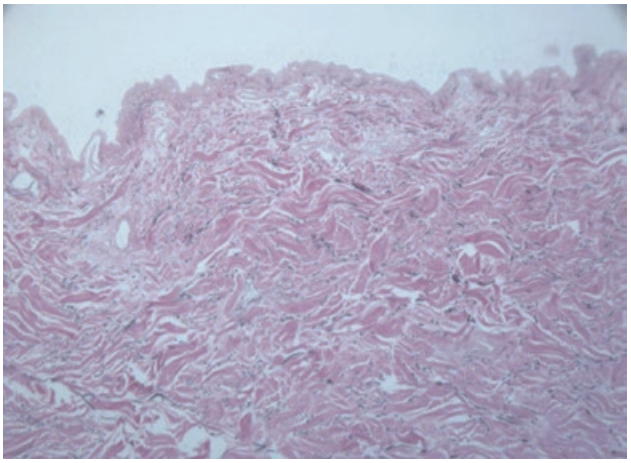

Figure 2b: Acellular Dermis, Unirradiated

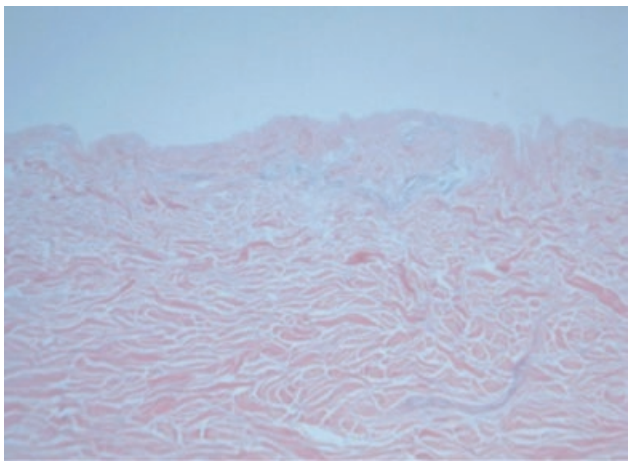

Figure 1c: Gamma Irradiated ACD

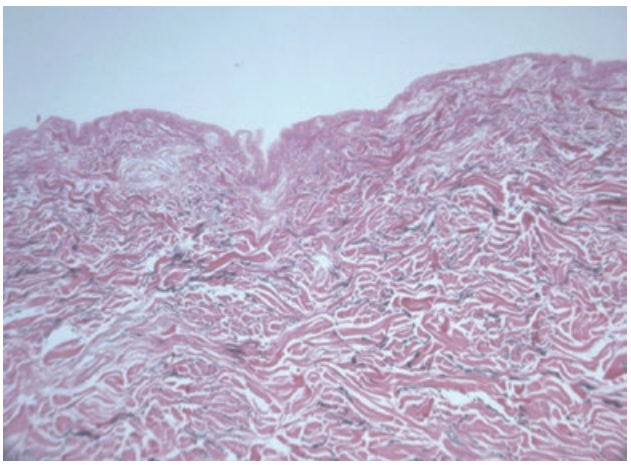

Figure 2c: Gamma Irradiated ACD

Figure 3a, 3b, 3c—Transmission Electron Micrographs: Normal human skin, unirradiated ACD & gamma irradiated ACD. The collagen structure does not exhibit differences between the normal human skin, unirradiated and irradiated ACD.

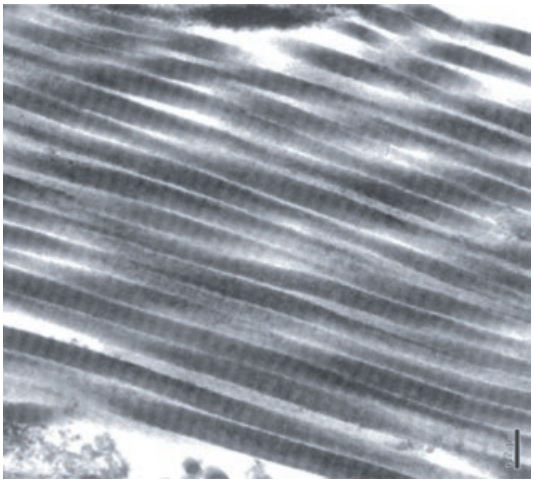

Figure 3a: Normal Human Skin

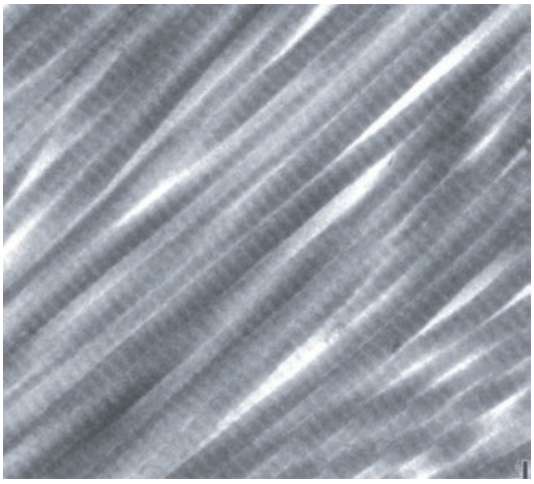

Figure 3b: Unirradiated ACD

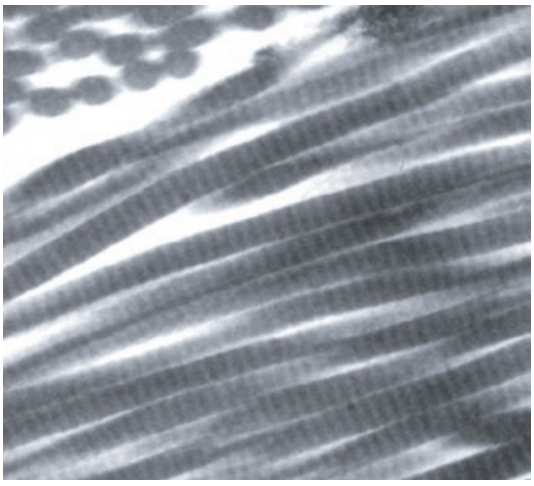

Figure 3c: Gamma irradiated ACD

References

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