

Processing of Human Amnion and Chorion Matrices Using a Lyoprotectant Improves Retention of the Structural Integrity and Enhances Barrier Properties

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Title: Processing of human amnion and chorion matrices using a lyoprotectant improves retention of the structural integrity and enhances barrier properties

Authors: Praathibha Sripadhan, Hanna Kaliada, Dr. Renaud Sicard, Dr. Timothy Ganey.

Institution: VIVEX Biologics, Miami, FL, USA

Background: Historically, human birth tissue products have demonstrated the ability to function as a tissue barrier for wounds and have shown potential to improve the complex process of wound healing due to their anti-scarring, low immunogenicity, antibacterial and anti-inflammatory properties¹. Additionally, recent advances in preservation of the tissue using freeze-drying process allowed for increased shelf life at ambient temperatures providing better accessibility for clinical use.

Hypothesis: Use of a lyoprotectant aids in preserving the biophysical properties and biological features of amnion and chorion (AM/CM) during the freeze-drying process.

Methods: AM/CM derived from the amniotic sac of the placenta, acquired from a healthy mother during childbirth were cleaned, lyophilized with or without the addition of a lyoprotectant, and terminally sterilized. Histology was performed on 4µm sections using the Masson Trichrome (MT) stain. MT staining is composed of three stains that can help identify and assess the integrity of the amnion and chorion layers. Thickness of the tissue was measured using a Vernier Caliper. Total protein concentration was determined using BCA Assay (ThermoFisher Cat: 23227) following protein extraction.

Results: Histology with the MT stain showed improved structure integrity, particularly in the chorionic membrane when freeze-dried with a lyoprotectant. Additionally, in the absence of a lyoprotectant, results demonstrated a decrease in thickness of the tissue (Figure 2 and 3). Total protein content was about 1.5 times higher in the lyoprotectant group when compared to the control group (Figure 1).

Conclusion: These data support the hypothesis that adding a lyoprotectant aids in preserving the structural integrity and the extracellular matrix content of the AM/CM membrane during the freeze-drying process, which in turn may improve the main characteristic of the product to act as a wound barrier.

1. Kogan S. et al. Amniotic Membrane Adjuncts and Clinical Applications in Wound Healing: A Review of the Literature, *Index Wounds* (2018), 30(6), 168-173

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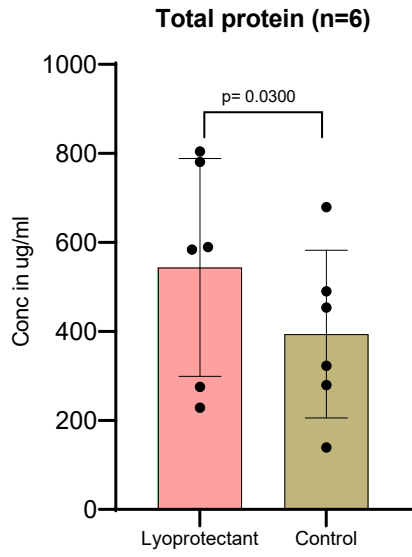


Figure 1 Total Extracted Protein concentration

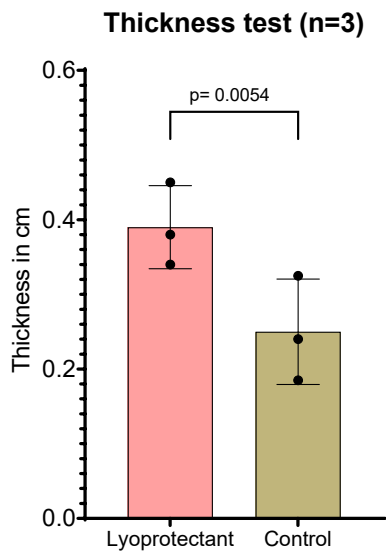


Figure 2 Average Thickness of AM/CM

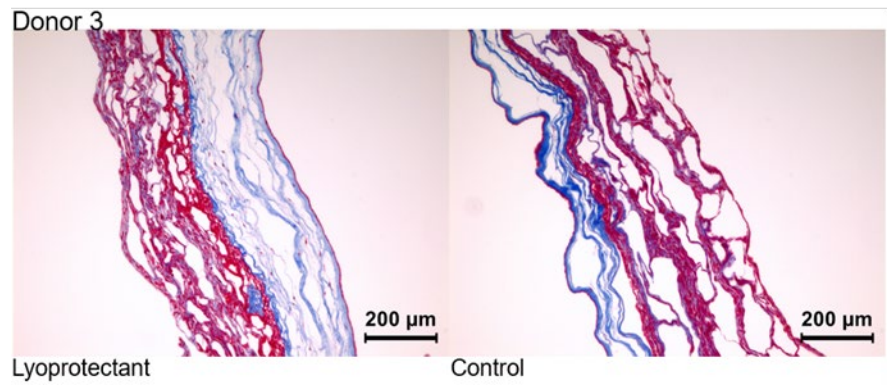
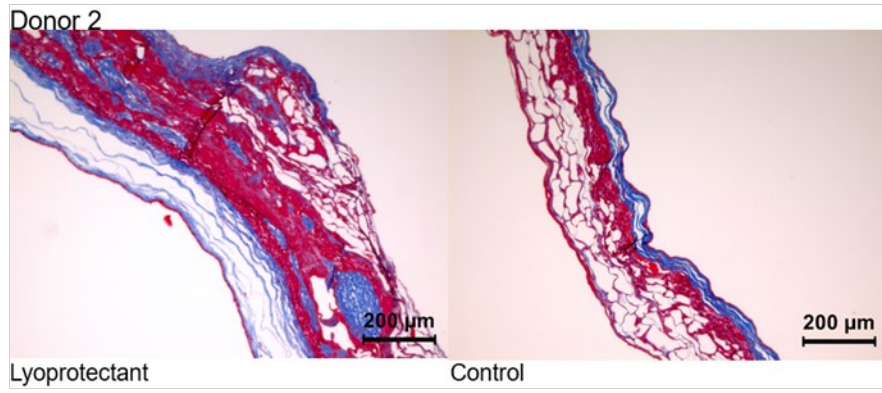
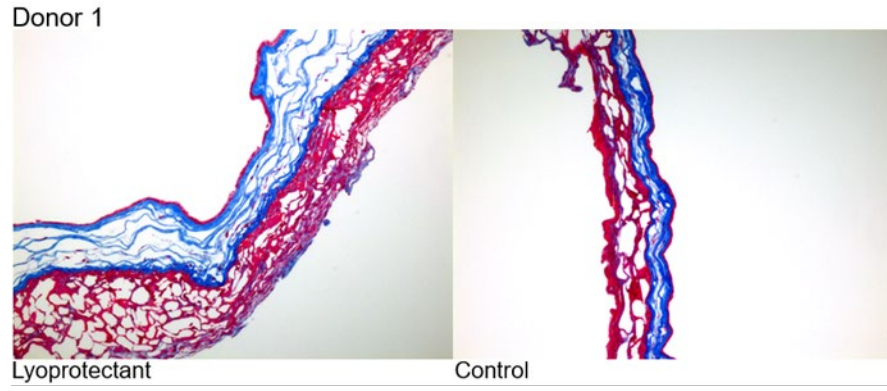


Figure 3 Representative Histology Images