

Retention Processing Preserves Beneficial Stromal and Molecular Components

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Abstract

Introduction:

It has been researched and well documented that placental tissue has a plethora of growth factors present. Many of these factors are beneficial when it comes to wound treatment as they facilitate an optimal wound environment upon placement of the graft. In the past, processing has been primarily focused on the preservation of cells within a tissue or removal of all non-solid matrix components to provide a substrate for regenerative growth. Since the development of these processes, scientific progress has been made, uncovering the value of factors within the placental tissue for wound treatment. When tissue is being processed, it becomes imperative to retain as much of the natural matrix as possible to preserve the beneficial factors. To provide safe, factor-rich grafts, a retention-based method utilizing gentle processing was developed (BioREtain®). We tested the impact of this processing regime on stromal and molecular content.

Methods:

Histology, scanning electron microscopy (SEM), and cytokine analysis by enzyme-linked immunosorbent assay (ELISA) were utilized to assess five separate lots of terminally sterilized, final product amnion/chorion grafts for structural components and molecular factors. Products were reported as amount of factor per cm².

Results:

Data obtained from this study show the retention of structure as well as the preservation of numerous factors including GAGs, collagen I, collagen III, total collagen, fibronectin, HA, IL-1ra, HGF, PDGF-BB, FGF2, and VEGFR1 in gently processed, dehydrated, terminally sterilized amnion/chorion placental tissue grafts.

Discussion:

This study highlights the hypothesis that retention-based processing demonstrates conservation of structural and molecular components.

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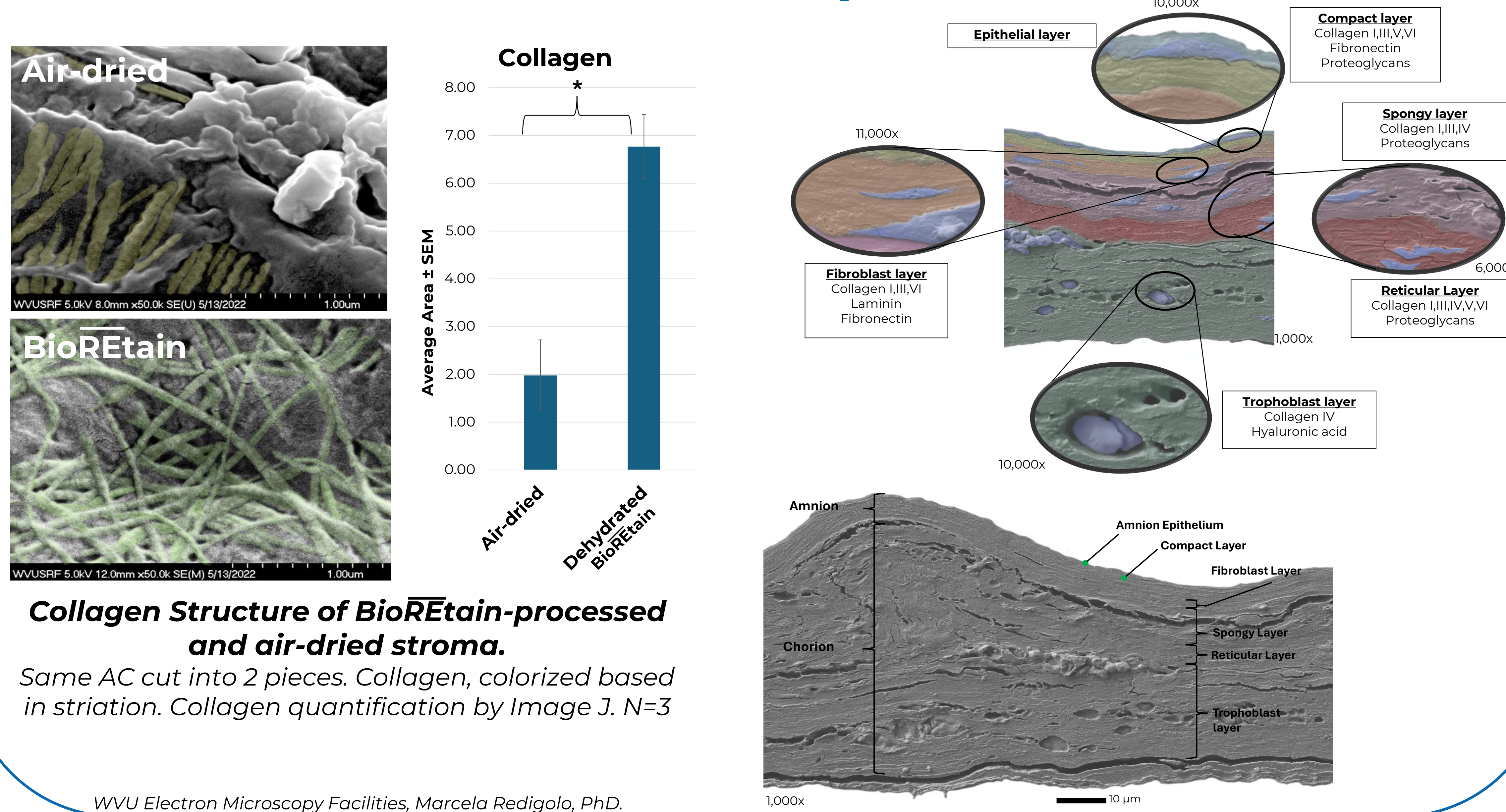
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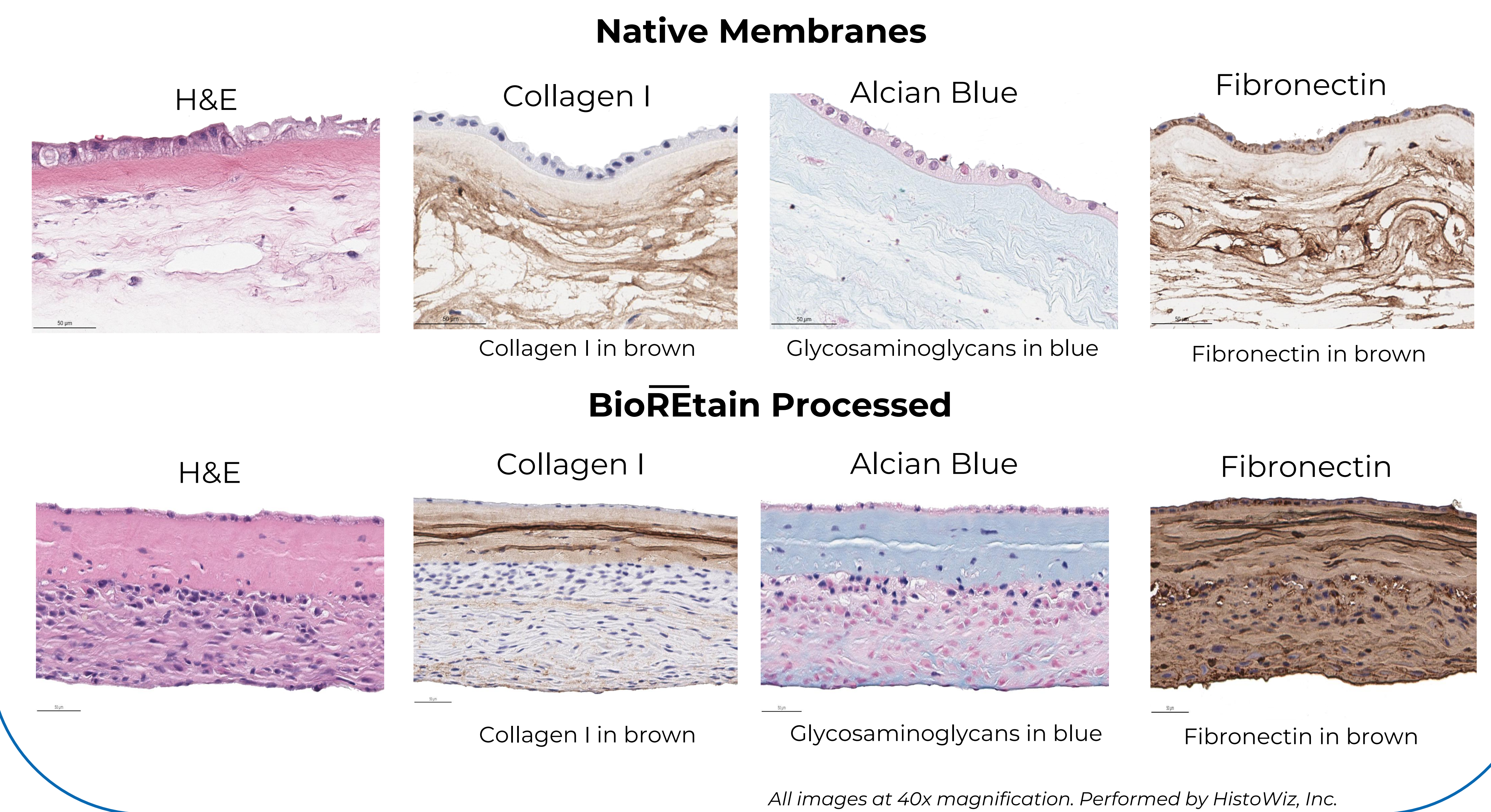
Abstract

It has been researched and well documented that placental tissue has a plethora of growth factors present. Many of these factors are beneficial when it comes to wound treatment as they facilitate an optimal wound environment upon placement of the graft. In the past, processing has been primarily focused on removal of all non-solid matrix components to provide a substrate. Since the development of these processes, scientific progress has been made, uncovering the value of factors within the placental tissue for wound treatment. When tissue is being processed, it becomes imperative to retain as much of the natural matrix as possible to preserve the beneficial factors. To provide safe, factor-rich grafts, a retention-based method utilizing gentle processing was developed (BioREtain®). We tested the impact of this processing regime on stromal and molecular content.

SEM and Stromal Components



Histology and Molecular Components



The BioREtain® Process

1. Minimally damaging, yet effective disinfection:

- Gently kills any external contamination.

2. Hand removal of blood/debris:

- It is general practice to scrape and/or scrub all the material from the membrane, damaging the fibers and removing the favorable factors.
- BioREtain focuses on gentle removal, ensuring the membrane integrity is not damaged or weakened thus providing retention of the favorable components within the tissue.

3. Cold isotonic cleansing:

- No harsh chemicals are used.
- It is general practice to use water and room temperature solutions, or chemicals such as NaOH, HCl and/or H₂O₂.
 - Water is hypotonic to the membrane, causing cells to lyse, and valuable factors to move from the membrane to the water, where it is discarded.
 - These chemicals can have a high or low pH which alters the structure of membrane proteins and residual amounts can be left behind in the tissue.

4. Gentle dehydration:

- Slow drying of the membrane preserves tissue structure and natural growth factors.
- It is general practice to use freeze drying, air drying on towels or accelerated drying (heat), which can tear up the crucial stromal support system within the membrane and degrade factors.

5. Low-dose Electron beam sterilization:

- The tissue is packaged and subjected to low-dose E-beam irradiation → terminally sterilized graft.
- It is common practice to use gamma irradiation, which cross-links and sometimes breaks down the factors in the tissue.



Our membranes are intended for homologous use as a barrier membrane or protection over acute and/or chronic wounds.

*Placental Processing for Retention of Factors. Patent pending