Retention Processing Preserves Beneficial Stromal and Molecular Components

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Background: To date, processing has been primarily focused on the preservation of cells within a tissue or removal of all non-solid matrix components for the purpose of delivering stem cells and/or providing 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 to wound healing. These factors do not rely on cellular content, and removal of everything down to solid matrix essentially depletes the graft of these valuable factors. The clinical effect of specific endogenous factors within placental tissue grafts is well documented, hence retention of these factors in dehydrated, sterile grafts provides a safe and effective alternative to grafts that are merely structural or non-sterile. To provide safe, factor-rich grafts, we tested the stromal and molecular impact of a processing regime that prepares placental tissues in a gentle manner to minimize loss of beneficial components (BioRetain®).

Hypothesis: This process was hypothesized to demonstrate retention of structural and molecular components.

Methods: Five separate lots of terminally sterilized, final product amnion/chorion grafts were tested for structural components and molecular factors by histology, scanning electron microscopy and cytokine analysis. Molecular analyses were reported as factor per cm2 of product.

Results: Our data demonstrates the retention of structure, GAGs, collagen I, collagen III, total collagen, fibronectin and HA, anti-inflammatory IL-1ra, regenerative HGF, PDGF-BB, and FGF2 and angiogenic VEGFR1 in gently processed, dehydrated, terminally sterilized amnion/chorion placental tissue grafts.

Conclusion: This study highlights the hypothesis that gentle (BioRetain®) processing demonstrates retention of structural and molecular components.