Composition and Cellular Effects of AmnioRepair® and EpiFix®

PURPOSE

This research report summarizes in vitro assays that compared the composition and cellular effects of AmnioRepair® versus a competitive allograft product.

BACKGROUND

AmnioRepair is a lyophilized placental allograft product that is indicated as a wound cover and biological barrier. AmnioRepair is processed at proprietary methods and solutions to maximize the retention and preservation of growth factors and other ECM components with important clinical benefits. Aziyo takes several steps to avoid tissue degradation during processing. Aziyo also uses a proprietary freeze-drying solution to preserve protein structures and maintain bioactive capabilities of all the important wound healing elements in the placental tissue, while maintaining superior handling characteristics that allow for ease of application and maneuverability.

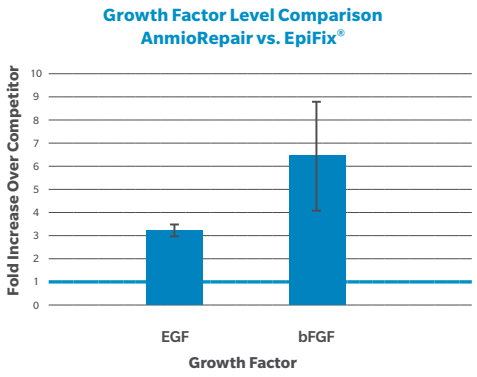
All AmnioRepair samples in these comparison studies were prepared by Aziyo R&D personnel by strictly following the AmnioRepair manufacturing process. We analyzed these samples versus donor-matched samples that were oven dried to compare effects of processing. We also compared these samples with the oven dried competitor product, EpiFix, of equal size. Cell assays and ELISAs were used to quantitate these differences.

RESULTS AND DISCUSSION

Lyophilization Methods Maintain Vast Array of Placental Growth Factors and Cytokines: Quantification showed maintenance of a full spectrum of placental proteins in Aziyo-processed lyophilized tissue that matched those proteins seen in Aziyo-processed cryopreserved tissue. To test the presence of a wide variety of important wound healing elements, protein lysates from two Aziyo's lyophilized donors were compared to three donors of cryopreserved, homogenized sample product. All proteins found in the cryopreserved placental product were also detected in at least one donor of the lyophilized product. Lyophilization and AmnioRepair processing did not eliminate any types of growth factors or cytokines.

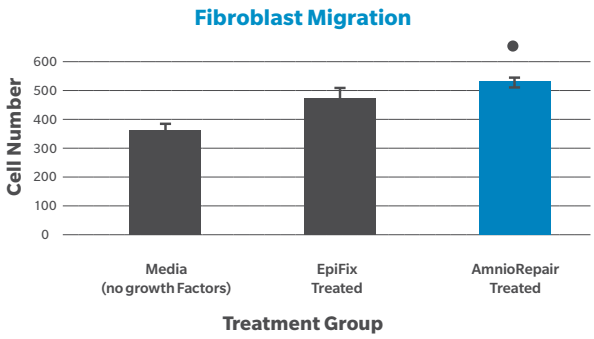
Better Preserved Matrix: AmnioRepair preserves greater quantities of structural ECM components like hyaluronic acid (HA) compared to the competitor's allograft EpiFix. To compare the composition of AmnioRepair versus EpiFix, HA levels were quantified using an ELISA and showed AmnioRepair had HA levels 5-fold higher than EpiFix per square centimeter. HA is a type of GAG that modulates inflammation and can improve cell migration (Jiang et al., 2011). These results indicate AmnioRepair processing creates a product with greater levels of structural ECM components like HA to affect cell function.

Greater growth factor preservation: AmnioRepair preserves more epithelial growth factor (EGF) and basic fibroblast growth factor (bFGF) compared to EpiFix. Growth factors are the most sensitive proteins to removal or degradation during processing and storage. To demonstrate the ability of AmnioRepair's proprietary methods to preserve important growth factors of the placenta membranes, levels of EGF and bFGF were quantified using ELISAs. EGF levels were over 3-fold greater in AmnioRepair, and bFGF was almost 6.5-fold more in AmnioRepair compared to EpiFix. These results show AmnioRepair better preserves quantities of thermal sensitive growth factors than oven dried EpiFix.



AmnioRepair contains 3 times more Epidermal growth factor (EGF) and 6 times more basic fibroblast growth factor (bFGF) than a competitive allograft.[1]

Increased Human Dermal Fibroblast Migration: Cells migrated in greater numbers when exposed to AmnioRepair-treated media versus EpiFix-treated media and no treatment controls. AmnioRepair-treated human dermal fibroblasts showed superior migration over EpiFix treated cells and negative controls. The difference between cell migration in AmnioRepair-treated wells versus no treatment control wells was statistically significant ($p<0.05$) (Figure 2).



AmnioRepair treated cells migrated in significantly greater numbers than the control group.[1]

Increased Fibroblast Growth Factor Production: Cells produced greater amounts of bFGF when seeded on lyophilized placental tissue biopsies versus donor matched oven dried biopsies. An almost 10-fold increase in production of bFGF was seen in fibroblasts seeded on Aziyo's lyophilized tissue compared to the oven-dried samples.

CONCLUSION

The results of these studies demonstrate that Aziyo processes and AmnioRepair better preserve ECM structural components and growth factors than the competitor methods and product. In turn, these optimal processes lead to significant advantages in cell migration and function, facilitating clinical outcomes of wound closure and healthy tissue remodeling.

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