Next-Generation Regenerative Therapy for Wound Healing

A cost-effective, sustainable, and customizable alternative to primary amniotic membranes for wound healing and regeneration.

Technology

The NYU innovators have developed a novel platform technology to produce human amniotic membrane-like cultures (hAMCs) for regenerative medicine applications, such as wound, burn, and ulcer treatment. The hAMCs are generated from human pluripotent stem cells (hPSC) or other starting material (e.g., embryonic stem cell lines) using an optimized, proprietary, multi-step protocol. The hAMCs recapitulate the architecture and functionality of human placenta-derived amniotic membranes (AMs), which are currently standard-of-care for regenerative wound healing applications. In unpublished work characterizing hAMCs, RNA sequencing analysis revealed the hAMCs to have similar gene expression profiles to AMs, implying similar regenerative functionality in wound treatment. The analysis showed similar expression profiles for: (i) AM marker genes (KRT8, KRT18, EPCAM and ACTA2); (ii) essential extracellular matrix components (COL4A1 and FN1) to provide scaffolding for cell adhesion, migration, and survival; and (iii) anti-fibrotic proteins (MMPs) and growth factors (TGFB1 and EGF) for facilitating tissue repair and preventing fibrosis and scarring. Additionally, hAMCs were found to express other factors crucial for wound healing (VEGFA, VEGFB, PDGFA) that are not expressed in AMs, suggesting hAMCs could have differentiated applicability and/or superior efficacy to AMs. Unlike AMs, hAMCs can also be readily genetically engineered to express wound-specific factors, which maximize their regenerative efficacy in a context-dependent manner. Altogether, hAMCs are a relatively low-cost, sustainable, and scalable alternative to AMs that are expected to provide superior performance due to their tailorability for different use cases.

Background

Hard-to-heal wounds affect more than 8 million patients annually in the U.S. alone, with global demand for effective therapies continuing to rise. Anti-inflammatory, anti-fibrotic, and pro-regenerative properties of the AM make it a valuable biocompatible material for various regenerative wound applications. The market for regenerative therapies, particularly those involving AMs, is substantial and growing, driven by the increasing prevalence of conditions like diabetes and vascular disease that often result in chronic wounds. For example, the global market for allografts and human tissue-derived products is estimated to grow to $1.4 billion by 2026, at a CAGR of 9.4%. However, the current gold standard for AM production relies on donated human placentas, which limits availability, scalability, and widespread clinical application. Moreover, long-term storage methods of AMs, such as cryopreservation, dehydration, or decellularization, often result in the loss of important bioactive properties. Other issues include a lack of standardization, due to variability in tissue compositions and growth factor levels, and contamination risk. The novel hPSC-based approach described here addresses these challenges by providing a sustainable, scalable, and standardized alternative to patient-derived AMs, which is cost-effective and customizable.

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Category

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Development Stage

The hAMCs have been molecularly validated to have similar expression profiles to human AMs. Research is ongoing to test the efficacy of hAMCs in mouse models of wound epithelization.

Applications

This innovation could be used as a regenerative therapy for:

- Wounds
- Ulceration
- Burns
- Ocular injury
- Other superficial injuries requiring regenerative therapies

Advantages

- **Cost-effective and scalable:** Inexpensive method with potential for production on a commercial scale
- **Sustainable:** Not reliant upon the limited supply of donated human placentas
- **Sterile**: Avoids risk of microbial contamination from using human tissues
- **Reproducible:** Ensures consistent quality through standardized production protocols
- **Customizable:** Can integrate wound-specific factor expression via genetic engineering

Intellectual Property

NYU has filed a provisional U.S. patent application covering the composition of the hAMCs, their method of generation, and their method of use.