Wound Infection

Biologically Active Advanced Antimicrobial Human Skin Substitute for the Treatment of Combat Wounds

Combat-related trauma and blast injuries frequently result in skin loss and infection caused by contaminating foreign material in exposed wounds. Current skin substitutes on the market are designed to replace or compensate for nonfunctioning skin; however, none have been optimized to address the other major challenges in the management of traumatic wounds: direct reduction of microbial infection and enhancement of the immune response to combat the infection. Researchers from Stratatech Corporation (Madison, Wisconsin) have been conducting preclinical studies that are focused on testing the ability of a novel antimicrobial skin tissue, ExpressGraft-C9T1, to promote wound healing and tissue restoration by the patient's own skin and to prevent infection in combat-related wounds. ExpressGraft-C9T1 tissue is composed of a biodegradable matrix and human skin cells expressing the antimicrobial host defense peptide cathelicidin. The research team at Stratatech Corporation used animal models to show that their anti-infective skin replacement product was effective in the reduction of bacterial infection in wounds and remained non-toxic to the host animal. Data generated from this project supported an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) in April 2015, which enabled the May 2016 initiation of a Phase 2 clinical safety trial of the antimicrobial tissue in the treatment of skin wounds in humans (ClinicalTrials.gov Identifier: NCT02657876). In 2016, the project has focused on optimizing the anti-infective skin substitute for increased production and optimal shelf life for use in the aforementioned clinical trial and, potentially, for future commercialization. Armed Forces Institute of Regenerative Medicine (AFIRM) has also funded further development of Stratatech Corporation's first skin replacement product, called StrataGraft® tissue, with a now successfully completed Phase 2 clinical trial of StrataGraft® supporting use of this product to treat deep partial-thickness skin wounds. StrataGraft® has been determined to be Phase 3 ready by the FDA. If proven safe and effective, StrataGraft® skin tissue and ExpressGraft-C9T1 tissue could have a transformational effect on combat casualty care by advancing treatment of Service Members and Veterans recovering from combat-related wounds.