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Early Intervention Stem Cell-Based Therapy (EISCBT) for Corneal Burns and Trauma

Principal Investigator: DU, YIQIN

Institution Receiving Award: PITTSBURGH, UNIVERSITY OF

Program: VRP

Proposal Number: VR180189

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Funding Mechanism: Expansion Award

Partnering Awards:

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PUBLIC ABSTRACT

Corneal trauma and chemical burns lead to corneal scarring, producing a long-term reduction in vision, sometimes blindness. Corneal scarring and decompensation are the second-most common causes of poor vision among ocular injuries in combat, commonly caused by explosions with fragmentary munitions and by chemical and thermal exposure. Although corneal transplantation is effective at restoring vision, it is not an ideal solution for the warrior. The eye must stabilize for weeks or months before surgery, and afterward, corneal strength is compromised and the recipient usually requires long-term ophthalmological care. The half-life of uncomplicated corneal transplants is 10 to 15 years, after which a new transplant is required. There is a high failure rate in corneal re-grafts leading to complex medical solutions, sometimes with unsatisfactory outcomes. Corneal scarring and subsequent transplantation, therefore, compromise the effectiveness of military personnel and represent a considerable human and financial cost to the system.

We found in 2014 that stem cells from cornea (CSSC) can restore transparency to corneal wounds caused by injury or chemical burns. A clinical trial in India using CSSC was successful in treatment of 80 patients with corneal scarring and burns and CSSC therapy is slated to be approved for use in India. This treatment is simple and rapid and a single application of cells to the corneal surface can clear scarring that has blocked vision for years. The goal in this project is to make this gentle and highly successful treatment available to injured US military personnel and eventually to the millions of affected individuals around the globe. We believe two modifications of the Indian approach are required. We propose to compile a "biobank" of CSSC, pooling several cell lines so that thousands of doses of a standardized reagent can be frozen and used. This approach avoids the variability of generating a new culture of stem cells for each patient. To do this, we need a measure of the potency of each cell line so we can use only cells that are highly effective. We have identified several genes expressed by CSSC that we believe are markers for their regenerative potential. The work proposed in this application would confirm the use of these marker genes for identifying highly effective stem cells. This information would represent a novel and important advanced in stem cell treatment.

The second goal of the research was to develop a device to simplify application of stem cells to the eye. We created a Regenerative Corneal Bandage (ReCoBand) in which CSSC cells are embedded in a small disk of collagen. The ReCoBand is applied to the cornea like a contact lens and is held in place with a drop of adhesive. Within 24 hr the collagen disk melts, leaving no trace. The ReCoBand can be frozen for months without loss of activity, it can be stored and shipped and thus will bring stem cell treatment to the clinic, possibly even to battlefield hospitals. In experiments with mice, the ReCoBand improved the potency of stem cells in comparison with direct application of CSSC in a gel. We believe the ReCoBand can move stem cell treatment from large hospitals with stem cell labs allowing treatment anywhere in the world.

The work we have done with ReCoBand at this time has used only mice. Mice have corneas less than 10% the thickness of human corneas. Before testing can advance to clinical trials, we will demonstrate that the device works on corneas of the appropriate size. In this proposal, we will examine the ability of ReCoBand to prevent scarring of rabbit corneas with chemical burns. This animal model has been used in many previous scientific studies and it is known to mimic human responses. We will examine freshly injured eyes and eyes one week after injury, a time that should approximate the delay individuals might experience before treatment.

The final goal of the project is to examine the effectiveness of ReCoBand with a different kind of regenerative agent. Extracellular matrix (ECM) is a biological material with curative properties extracted from porcine tissue. Dr. Badylak, collaborator in the project, has studied this material for decades and demonstrated its usefulness in restoration of a number of damaged tissues including muscle, brain, and

heart. Forms of ECM are already in clinical use. We previously found that ECM works well in suppressing mouse corneal wounds. In the current proposal, a ReCoBand gel with ECM will be used to treat rabbit corneal burns. A ReCoBand gel containing ECM would be more temperature-stable and have an extended shelf life compared to ReCoBand with CSSC cells. Because it does not involve living cells, FDA approval for ECM-ReCoBand might be easier to obtain. The goal of our project is to provide restoration of vision to injured military personnel. Having the chance to compare two highly effective regenerative agents will help us determine the most rapid path to that goal.

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