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3D Retinal Transplants Derived from Human Induced Pluripotent Stem Cells to Treat Combat Laser-Induced Blindness

Principal Investigator: CANTO-SOLER, MARIA VALERIA

Institution Receiving Award: COLORADO, UNIVERSITY OF, AT DENVER

Program: VRP

Proposal Number: VR190095

Award Number: W81XWH-20-1-0748

Funding Mechanism: Investigator-Initiated Research Award - Funding Level 2

Partnering Awards:

Award Amount: \$777,500.00

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PUBLIC ABSTRACT

Eye injuries currently account for 16% of all battlefield injuries with one-third of affected Warfighters becoming legally blind. Battlefield injuries to the eye mostly occur on the cornea and retina through trauma to the head and laser-related exposures. The incidence of eye injuries sustained by our forces has increased 32-fold since the U.S. Civil War, with the escalating use of laser weapons significantly contributing to this rise. The retina is the tissue most vulnerable to laser-induced trauma, and even small amounts of energy from relatively low-power laser devices can lead to permanent vision loss. Furthermore, the development and deployment of new laser technology and the unfeasibility of providing appropriate eye protection against laser to military combatants poses an ever-raising threat for active military personnel. As such, there is an urgent need for improving standard of care that can effectively reduce long-term permanent vision loss suffered by combat Soldiers affected by laser-induced retinal trauma. The outlined proposal will address the FY19/20 VRP Investigator-Initiated Research Award by establishing the feasibility of a stem cell-based regenerative treatment for retinal trauma caused by directed energy weapons, such as lasers. This approach would utilize a regenerative retinal therapy strategy, with the purpose of regrowing the missing portions of the damaged retina to restore visual function, significantly improving the standard of care of laser-induced retinal injuries.

The goal of this project is to establish evidence in an animal model for a regenerative therapy that has the potential to become the first available treatment for retinal laser injury. This regenerative approach relies on previous research from our group demonstrating the use of human induced pluripotent stem cells (hiPSC) to grow functional human retinal tissue in the lab. hiPSC are generated from cells obtained from an adult person through a routine clinical biopsy, as, for example, skin or blood cells. These cells are then reprogramed to "go back in time" and become stem cells that can be redirected to differentiate into human retinal tissue containing rod and cone photoreceptors with the capacity to respond to light. This lab-grown functional retinal tissue can then be used as a transplant to replace and regrow the cells that have been lost in the retina due to laser injury.

In these studies, we will use stem cell-derived retinal transplants to restore vision in a validated minipig model of retinal laser injury. Similar to humans, pigs have binocular vision, a retina fully developed at birth, and adapted to a diurnal activity. Furthermore, the pig eye is very close to the human eye in size, anatomy, and physiology, including the presence of a cone-enriched visual streak resembling the macula, thus providing a very translatable model for developing eye treatments that could be used in human patients. The minipig retinal injury model uses a laser wavelength within the range of lasers commonly found in the battlefield and produces retinal lesions similar to those observed in laser-injured military personnel. After inducing laser retinal injuries in the minipigs, we will conduct an already established eye surgery to implant the stem cell-derived retinal transplant at the site of the laser injury and evaluate the ability of the transplant to regrow the lost cells and restore visual function over time.

If successful, our stem cell-derived retinal transplant will significantly advance the field of visual system trauma care by providing preclinical evidence for a regenerative therapy that could become the first available treatment for restoring vision in the Warfighter, Veterans, and civilians affected by retinal laser injury. Importantly, we have already developed and validated the surgical instruments and procedures for transplanting the stem cell-derived retinal transplants. Additionally, the composition and size of these retinal transplants are the same as those potentially to be used in humans, supporting a relatively seamless transition from the minipig model to the human patient.

This novel retinal regenerative therapy has the potential to drastically improve standard of care to

treat laser-induced retinal injuries and long-term clinical outcomes to the Warfighter. The preservation of the eyes and eyesight of military personnel is of extremely high importance. Although accepted medical priorities are described as "life, limb, and sight," most casualties would reprioritize the list as "life, SIGHT, and limb." Regretfully, there is currently no available treatment for Soldiers suffering from permanent vision loss due to laser injury. Our regenerative therapy would signify a turning point in the standard of care for these casualties, providing long-term vision restoration to them, significantly impacting their quality of life, and reducing the financial and resource burdens to Soldiers and society.

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