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Development and Validation of a Smart-Memory Intravitreal Tamponade Stent for Retinal Detachment in Combat Ocular Trauma

Principal Investigator: BRAMBLETT, GREGORY

Institution Receiving Award: METIS FOUNDATION

Program: VRP

Proposal Number: VR150135

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Funding Mechanism: Technology/Therapeutic Development Award

Partnering Awards:

Award Amount: \$1,417,454.00

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PUBLIC ABSTRACT

Problem and Potential: The retina is a highly specialized layer of cells at the back of the eye that is key for vision. The retina has nerve cells that connect to the optic nerve and to the brain. These cells are specialized to see color (cones) or light (rods). The vision is most acute at the center of the retina in an area called the macula. Retinal detachment occurs when the retina separates from the tissues below it, leading to permanent vision impairment or even irreversible loss. There are many reasons why retinal detachment occurs, namely, advancing age, previous cataract surgery, myopia, severe hypertension, cancer, and trauma. The earlier the diagnosis and treatment, the better the chances for preservation of vision. Although retinal detachment is relatively uncommon in civilians, affecting only 1 in 10,000 people per year (or approximately one in 300 patients in the course of a lifetime), it has been much more common in our Soldiers wounded in the war on terrorism in Iraq and Afghanistan. In the 10 years between 2001 and 2011, 10% of our 22,409 Warfighters suffered from these injuries. These combat eye injuries are devastating and have few treatment options on the battlefield or in the remote environment of war zones. Most Soldiers with retinal detachment need immediate temporary treatment to stabilize the retina followed by air evacuation to a specialized hospital for definitive surgical care. However, such temporary treatments are not optimal. For example, they may involve the use of injecting gas into the eye to push the retina back in place and prevent further loss of vision. Since gas floats up, if a patient lies with his face down or to the side (due to other injuries to the face, body, or chest), the gas bubble can press on the retina more than it needs to, causing retinal damage. Also, when a patient is transported in an aircraft, the changes in cabin pressure can cause the gas bubble in the eye to expand and cause damage due to greater compression of the retina. Thus, there is an urgent need for a technology or therapy for retinal detachment that does not expand during flight or changes in position and can serve as a temporary means of protecting the retina from further separation/injury and preserve vision.

Proposed Technology: The technology proposed (OPTISTENT™) is an innovative device for supporting the injured retina. It is composed of a fine wire made of a specialized metallic alloy that is non-irritating to the eye. The device can be inserted via a small needle into the eye. It then opens up inside the eye into a mesh-like structure that can keep the retina in place and preserve the blood flow to the nerve cells critical to vision. When healing is complete, the stent can be retrieved and removed. In some cases the stent may be left in permanently. Since this is a mesh like scaffold, the Optistent device does not “expand” during air transportation of Service members or “shift position” during surgical procedures requiring special posturing of patients with multiple injuries affecting the head, body and limbs. This device can also be used to deliver drugs such as antibiotics to prevent or treat infection within the blast injured-eye. Thus, this technology is a game-changer in treatment of retinal detachment when compared to standard techniques that employ injection of oil or gas into the eye with associated risks of worsening retinal injury or cause other complications such as glaucoma, floaters, or vision impairment. Most importantly the conventional techniques cannot be used safely with air evacuation of patients or in combination with other major procedures in patients (such as reconstructive surgery for other injuries).

Benefit to Service Members, Veterans, and/or their Family Members: Eye injury from blast exposure prevents Service members from returning to duty, compromising years of training and expertise. More importantly, the functional limitations of vision loss result in significant personal, professional, and psychosocial impairments. Many patients with retinal injuries have permanent visual loss. Currently, there is no conventional treatment to recover lost function after retinal separation. The proposed research will address this need. The Optistent device may also be a way to restore visual function in other conditions that result in irreversible losses in vision such as glaucoma, macular degeneration, retinal artery, and vein blockade or other conditions that can cause retinal detachment.

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