Steroid-Eluting Therapeutic Contact Lens to Treat and Prevent Inflammation and Scarring Following Ocular Trauma

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View Technical Abstract
Objective: The goals of this proposal are to complete safety and efficacy studies that would support a first-in-human clinical study trial using steroid-eluting therapeutic contact lenses (TCLs).

Background: A major unmet need in ophthalmology is a method of sustained ocular drug delivery to the front of the eye and topical drug delivery to the back of the eye. Contact lens drug delivery, conceptualized in the 1960s, could achieve both goals by facilitating topical administration, drug penetration into the eye, and reducing dosing frequency. However, controlling drug release from a contact lens and maintaining optical clarity have proven challenging. The underlying hypothesis of this application is that a drug-eluting therapeutic contact lens (TCL) can be designed to treat ocular inflammation in the front and back of the eye.

We developed TCLs that demonstrated the capability to treat inflammatory conditions in the front of the eye and to delivery steroid to the back of the eye that far exceeds that of intensive drop therapy.

Research Impact: A TCL could be used to release steroids to the front and back of the eye. Topical steroids are an important part of ophthalmic therapy and are used to control ocular inflammation, prevent vision loss, speed recovery, and limit lost productivity following ocular surgery or trauma.

TCLs could be used to treat or prevent ocular inflammation following eye surgery, which may be required following combat-related trauma or to improve Soldier combat-readiness. Currently, bandage contact lenses and steroids drops are often used after corneal refractive procedures. A TCL would combine these treatment modalities. TCL may eliminate the need for intraocular steroid injections, which are used to treat inflammation in the back of the eye, diabetic macular edema, proliferative vitreoretinopathy (PVR), and post-operative macular edema.

This application proposes to complete proof-of-concept preclinical studies to support the use of TCL for inflammation in the back of the eye and human clinical studies needed for regulatory approval and patient use.

Military Benefit: A TCL could help to prevent the loss of vision after eye trauma. From 2000 to 2010 there were over 186,000 eye injuries to members of the U.S. Armed Forces. According to Department of Veterans Affairs (VA) data, eye trauma accounted for 15% of all battlefield injury and was the fourth most common injury during Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF). PVR limits the recovery following retinal detachments and ocular trauma. For example, PVR occurred in 40%-60% of patients with open globe injuries during OIF. In this application, we will directly test the efficacy of TCLs in models of PVR.

A TCL could also help speed recovery after eye surgery. Each year approximately 40,000 corneal refractive procedures (e.g., LASIK) are performed on active military personnel and 50,000 cataract procedures are performed on Veterans. If this project is successful, Soldiers, Veterans, and civilians will have a completely new treatment option for treating blinding eye diseases.
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