Sustained Corticosteroid Release From a Novel Therapeutic Contact Lens Drug Delivery System for the Treatment of Ocular Inflammation and Corneal Neovascularization

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TECHNICAL ABSTRACT

Background: We aim to develop a corticosteroid-releasing therapeutic contact lens (TCL) that can be used to treat ocular inflammation, corneal neovascularization, and many more ocular indications. Topical steroids are an integral part of ophthalmic therapy and the mainstay of treatment for intraocular inflammation that can be caused by uveitis, trauma, or surgery. Drug-eluting therapeutic contact lenses can greatly expand treatment options by allowing improved topical medication efficacy, non-invasive delivery, simplified treatment regimens, and better patient compliance. The concept of drug-eluting CLs dates back to the 1960s; however, sustained and controlled delivery has historically been a significant challenge. We have developed an innovative TCL that, in contrast to other TCL designs, introduced a thin drug-polymer film within the periphery of a standard contact lens. This allowed the release of large amounts of drug over weeks to months, with relatively zero-order (constant) release kinetics, while allowing unimpeded vision through the lens. We demonstrated the capability of this lens to release a range of small-molecule drugs (ciprofloxacin, econazole, and latanoprost). In rabbit eyes, the TCL achieved sustained delivery of latanoprost to the eye for 1 month.

This application addresses the Vision Research Program Translational Research Award Focus Area that aims to improve treatment for traumatic injuries, war-related injuries, and diseases to ocular structures and the visual system by developing a novel drug delivery system for the eye.

Objectives: The goal of this proposal is to develop a novel corticosteroid-eluting TCL for the treatment of ocular inflammation and corneal neovascularization.

Specific Aims:

Aim 1: Development and in vitro testing of a steroid-eluting TCL. We will develop steroid-eluting TCL formulations, characterize the release kinetics, identify the formulation that exhibits the greatest basal delivery for 1 week, and perform cytotoxicity studies.

Aim 2: In vivo evaluation of drug flux and biocompatibility. We will assess biocompatibility and quantify the drug flux into the aqueous humor and compare the results with topically applied commercial steroid eye drops.

Aim 3: In vivo evaluation of efficacy. We will compare the efficacy of a TCL, no treatment, and an intensive topical steroid drop regimen for the treatment of uveitis and the prevention of corneal neovascularization.

Study Design: This application includes the design, development, and preclinical testing of an antibiotic-eluting TCL. We will compare the
TCL drug flux and efficacy to that of the current standard of care, which is topical antibiotic solution (drops).

Military Benefit: Eye surgery is commonplace among active military personnel and Veterans. From 2000 to 2012, the US military performed over 470,000 kerato-refractive procedures and the Department of Veterans Affairs (VA) performs approximately 50,000 cataract procedures each year. All of these eyes require the use of post-operative steroids and about half also used a bandage contact lens post-operatively. Steroids can also be used to limit scarring following ocular trauma. According to VA data, eye trauma accounted for 15% of all battlefield injuries during Operation Iraqi Freedom and Operation Enduring Freedom, resulting in over 186,000 eye injuries American Soldiers between 2000 and 2010. For Soldiers and Veterans, a TCL could be used post-operatively and to treat ocular pathology that requires topical steroids. If successful, Soldiers, Veterans, and civilians will have a completely new treatment option for treating blinding eye diseases.