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## Ocular Safety of Topical Naltrexone

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### PUBLIC ABSTRACT

The cornea of the eye is the clear tissue through which light enters the front of the eye so that it can be focused as an image on the retina in the back of the eye. The cornea is protected by a thin, five cell thick, skin-like tissue called its epithelium. Breaks in this tissue frequently occur from eye injuries, such as may occur in warfighters from blast-related trauma. These injuries expose the cornea to further damage such as from infections or ulcers, which can result in scarring and permanent vision loss. Abnormalities of corneal epithelial wound healing, such as occur in individuals with diabetes mellitus, may further inhibit wound healing and increase the likelihood complications from corneal epithelial injuries.

There are multiple treatments for corneal epithelial injuries. Unfortunately, none are uniformly successful, particularly in individuals such as diabetics. Therefore, there is a need for treatments to enhance corneal epithelial wound healing.

Although we commonly think of opioids as pain medications and consciousness-altering drugs, they perform many other bodily functions unrelated to these stereotypes. For the past 18 years, we have studied the role of a naturally occurring opioid growth regulatory system in controlling cell division and wound healing of the corneal epithelium. We have demonstrated that one component of this system, the naturally occurring opioid growth factor (OGF), metenkephalin, decreases the rate of corneal epithelial cell division and wound healing. Conversely, blocking the effect of OGF by applying eyedrops containing the strong blocking agent, Naltrexone (NTX) significantly increases the rate of corneal epithelial cell division and wound healing in normal and in diabetic animals.

Before we can use NTX as a treatment for corneal wounds, we must demonstrate that it is safe to use in patients. The proposed study has been designed in consultation with the U.S. Food and Drug Administration to determine the safety and tolerability of NTX eyedrops in 16 human volunteers. Multiple tests will be performed to document the side effects of this medication, if any. The medication is approved to be taken by mouth to treat overdose of substances, such as heroin. It is extremely doubtful, therefore, that the medication will have any adverse side effects when taken in eyedrop form.

NTX has the potential to be a significant improvement in the treatment of corneal injuries in warfighters and in their family members, especially those with abnormalities of corneal wound healing, such as diabetics. The proposed study is a major step in achieving this goal.

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