

**AWARD NUMBER:** W81XWH-21-1-0959

**TITLE:** A Dual Antibiotic-Steroid Drug-Eluting Contact Lens for Treatment of Eye Injuries That Can Be Used in an Austere Environment or Prolonged Field Care Setting

**PRINCIPAL INVESTIGATOR:** Joseph B. Ciolino, M.D.

**CONTRACTING ORGANIZATION:** Schepens Eye Research Institute, Boston, MA

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# REPORT DOCUMENTATION PAGE

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<b>13. SUPPLEMENTARY NOTES</b>						
<b>14. ABSTRACT</b> We have developed a therapeutic contact lens that releases BOTH a broad spectrum antibiotic (moxifloxacin [MXF]) and a steroid (dexamethasone [DEX]). The drug-eluting contact lens consists of a thin drug-polymer film encapsulated within the periphery of a standard contact lens. Importantly, the MXF-DEX TCL is available for immediate On-Demand use. We achieved this significant advantage over the prior approach by using a non-degradable polymer to help modulate the drug release. The non-degradable polymer allows the lenses to be stored for 1-2 years at room temperature in a hydrated state within a blister pack or bottle. This application will test MXF-DEX TCLs in both infectious and inflammatory animal model						
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## 1. INTRODUCTION:

Both steroid and antibiotic eye drops are typically frequently given after ocular surgery or injury to prevent infection and excessive inflammation. In our previous work, we developed a DEX-TCL for inflammatory ocular conditions. In this project, we have developed a combined steroid and antibiotic TCL to further simplify treatment regimens after surgery or injury.

## 2. KEYWORDS:

Inflammation, contact lens, sustained release, dexamethasone, keratitis

## 3. ACCOMPLISHMENTS:

**What were the major goals of the project?**

**Aim 1. *In vitro* assessment of the MXF-DEX TCL**

**Aim 2. *In vivo* evaluation of drug flux and biocompatibility**

**Aim 3. *In vivo* evaluation of efficacy**

**What was accomplished under these goals?**

Aim 1: Perform *in vivo* efficacy testing for of the steroid eluting therapeutic contact lens (TCL) in back of the eye animal models

1. Aim 1. Characterization of the TCL

In performing additional optimization, we found using besifloxacin in lieu of moxifloxacin resulted in a more sustained antibiotic release profile for the TCL. Like moxifloxacin, besifloxacin is a fluoroquinolone antibiotic, commonly used in ocular infections (Besivance® eye drops) and was listed in the initial grant as an alternative. The addition of triethyl acetate as a plasticizer also improved the TCL lens shape while maintaining sustained release.

Aim 2. *In vivo* evaluation of drug flux and biocompatibility

The animal protocol for the evaluation of drug flux was approved by both IACUC and ACURO. To measure tear concentrations, New Zealand White rabbits (NZWs) were given 0.6% besifloxacin drops for four hours, concurrently with hourly dexamethasone eye drops for three hours, Eye drops were given five minutes apart to maximize absorption and mimic real-wold instructions. After eye drop administration, tears were collected by Schirmer strip at 1, 2, 4, 8 and 24h.

For a test fitting, TCLs were fitted on the eyes of NZWs and worn for two days without sample collection. No adverse effects were observed.

Aim 3. *In vivo* evaluation of efficacy

The animal protocol for the efficacy bacterial keratitis treatment was approved by both IACUC and ACURO. Other protocols are in progress.

**What opportunities for training and professional development has the project provided?**

**How were the results disseminated to communities of interest?**

Nothing to report.

**What do you plan to do during the next reporting period to accomplish the goals?**

Complete drug flux, corneal neovascularization, and bacterial keratitis studies. Begin storage studies.

#### 4. IMPACT:

**What was the impact on the development of the principal discipline(s) of the project?**

Nothing to report

**What was the impact on other disciplines?**

Nothing to report.

**What was the impact on technology transfer?**

The drug eluting contact lens patent has been licensed to a company, TherOptix, which was founded to commercialize the technology.

**What was the impact on society beyond science and technology?**

Nothing to report

**5. CHANGES/PROBLEMS:**

Nothing to report

**Actual or anticipated problems or delays and actions or plans to resolve them**

Nothing to report

**Changes that had a significant impact on expenditures**

**Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

**Significant changes in use or care of human subjects**

Not applicable

**Significant changes in use or care of vertebrate animals**

**Significant changes in use of biohazards and/or select agents**

Not applicable

**6. PRODUCTS:**

- **Publications, conference papers, and presentations**

**Journal publications.**

**Books or other non-periodical, one-time publications.**

**Other publications, conference papers and presentations.**

- **Website(s) or other Internet site(s)**

Nothing to report

- **Technologies or techniques**

Nothing to report

- **Inventions, patent applications, and/or licenses**

- **Other Products**

Nothing to report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

Name: Joseph B Ciolino

Project Role: PI

Nearest person month worked: 3.00

Contribution: Oversight, experimental design

Name: Amy Ross

Project Role: Technician

Nearest person month worked: 12.0

Contribution: fabrication of TCLs, writing and submission of protocols, animal studies

### Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

### What other organizations were involved as partners?

## 8. SPECIAL REPORTING REQUIREMENTS

**COLLABORATIVE AWARDS:**

**QUAD CHARTS:**

## 9. APPENDICES: