Study Title: Efficacy and safety of loteprednol 0.5% gel for routine prophylaxis after photorefractive keratectomy compared to prednisolone acetate 1% suspension and fluorometholone 0.1% suspension

NCT #: NCT03123614

Document Date: 27 July 2018

INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH
75 South 2000 East Salt Lake City, UT 84112 | 801.581.3655 | IRB@utah.edu

IRB: IRB_00075978

PI: Mark Mifflin

Title: Efficacy and safety of loteprednol 0.5% gel for routine prophylaxis after photorefractive keratectomy compared to prednisolone acetate 1% suspension and fluorometholone 0.1% suspension

Date: 7/27/2018

Thank you for submitting the Final Project Report for the above referenced research study. This report has been administratively reviewed by the IRB and is acknowledged as submitted on 7/27/2018.

Please accept this correspondence as official notice from the University of Utah Institutional Review Board office that this research study and the corresponding IRB number are closed and archived.

You can access this Final Project Report at CR_00029335 .

Electronic
RESEARCH INTEGRITY AND COMPLIANCE
THE UNIVERSITY OF UTAH

Date: Monday, June 15, 2020 11:58:05 AM

Print Close

IRB_00075978 **Created:** 8/9/2014 9:53 AM

PI: Mark Mifflin M.D. **Submitted:** 8/20/2014

Title: Efficacy and safety of loteprednol 0.5% gel for routine prophylaxis after photorefractive keratectomy compared to prednisolone acetate 1% suspension and fluorometholone 0.1% suspension

IRB_00075978
View: 1. Study Introduction

1. Study Introduction

1. **Responsible Investigator:**
Mark Mifflin

Email	Training	CoI Date
mark.mifflin@hsc.utah.edu	6/12/2020 MCG	2/27/2020

a. **Position of the Investigator:**

- (●) **Faculty or** Non-Academic Equivalent
- ( ) Student
- ( ) Staff
- ( ) Resident/Fellow
- ( ) Other

2. **Contact Persons for the Responsible Investigator:**

Name	Email	Training
Brent Betts	brent.betts@hsc.utah.edu	6/28/2017 G
Deborah Harrison	deborah.harrison@hsc.utah.edu	2/24/2020 MCG
Barbara Hart	barbara.hart@hsc.utah.edu	2/24/2020 MCG
Elizabeth Nuttall	Elizabeth.Nuttall@hsc.utah.edu	2/4/2020 MCG
Severin Pouly	severin.pouly@hsc.utah.edu	6/24/2017 G
Brian Zaugg	brian.zaugg@hsc.utah.edu	1/26/2018 MCG

3. **Guests of the Responsible Investigator:**

Last Name	First Name	E-Mail
church-livingston	myrna	myrna.church@hsc.utah.edu

4. **What type of application is being submitted?**
New Study Application (or Amendment/Continuing Review)

5. **Title Of Study:**
Efficacy and safety of loteprednol 0.5% gel for routine prophylaxis after photorefractive keratectomy compared to prednisolone acetate 1% suspension and fluorometholone 0.1% suspension

6. **Study Purposes and Objectives:**

Hypothesis: Loteprednol 0.5% gel will perform similarly or better than a regimen of prednisolone acetate 1% and fluorometholone 0.1% in the prevention of visually significant postoperative corneal haze after photorefractive keratectomy (PRK) with a lower incidence of intraocular pressure elevation.

Objectives: We aim to conduct a prospective, randomized trial to compare the incidence of intraocular pressure rise and visually significant postoperative corneal haze after PRK with the use of loteprednol 0.5% gel compared to the use of earlier generation steroids, prednisolone acetate 1% suspension and fluorometholone 0.1% suspension. Patients undergoing PRK will be assigned to 1 of 2 postoperative steroid regimens. Group 1 will use only loteprednol 0.5% gel, tapered off slowly based on clinical evaluations of the corneal healing response. Group 2 will use prednisolone acetate 1% suspension tapered down to a regimen of fluorometholone 0.1% which will then be tapered off based on clinical evaluations of the corneal healing response. If no difference in efficacy or safety is detected between these two regimens, this study will support the use of either steroid regimen in patients after PRK. If there is a major difference in the efficacy or safety of these two regimens, this could influence post-refractive surgery treatment practices.

7. **Is this a multi-site study, where more than one site needs IRB approval?**

○ Yes ● **No**

8. **Background and Introduction:**

In photo-ablation procedures, an excimer laser is used to sculpt corneal tissue to correct refractive error. During PRK, the surface epithelium is removed and the laser energy is applied to reshape the underlying corneal stroma. This procedure is FDA approved and used widely. Corneal haze is a well known and a potentially vision threatening postoperative complication of PRK. Topical ophthalmic corticosteroids are routinely prescribed by most surgeons postoperatively to help prevent this complication.

Desirable characteristics for prophylactic topical steroids to be used after PRK include effective modulation of the healing response to prevent corneal haze while at the same time minimizing side effects, such as intraocular pressure elevation or cataract formation. Loteprednol etabonate is a corticosteroid that exerts its therapeutic effects and is then quickly changed into inactive metabolites by nonspecific esterases found in the cornea [1]. This relatively fast metabolism of loteprednol gives it a lower side effect profile than other steroids, including a smaller effect on intraocular pressure [2, 3]. In the ophthalmic literature, there is currently no consensus on a standard regimen or which type of corticosteroid should be used after PRK.

A retrospective study done at our institution demonstrated a similar incidence of haze and increased intraocular pressure in patients treated with loteprednol 0.5% suspension or fluorometholone 0.1% suspension after both groups received prednisolone acetate 1% suspension for the first 3-4 weeks postoperatively after PRK [4]. This study was limited by its retrospective nature, but was the first study to report the efficacy and noninferiority of loteprednol compared to other steroids for prophylaxis after photorefractive keratectomy. Our current prospective study could help determine whether loteprednol has true advantages over traditional topical steroids after PRK.

References:

1. Noble S, Goa KL. Loteprednol etabonate: clinical potential in the management of ocular inflammation. Bio Drugs. 1998;10(4):329-339.

2. Holland EJ, Bartlett JD, Paterno MR, Usner DW, Comstock TL. Effects of loteprednol/tobramycin versus dexamethasone/tobramycin on intraocular pressure in healthy volunteers. Cornea. 2008;27(1):50-55.

3. Bartlett JD, Horwitz B, Laibovitz R, et al. Intraocular pressure response to loteprednol etabonate in known steroid responders. J Ocul Pharmacol. 1993;9(2):157-165.

4. Mifflin MD, Leishman LL, Christiansen SM, Sikder S, Hsu M, Moshirfar M. Use of loteprednol for routine prophylaxis after photorefractive keratectomy. Clin Ophthalmol. 2012;6:653-659.

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IRB_00075978
View: 2. Location and Sponsor

2. Study Location and Sponsors

1. **Add all locations applying for approval of research via the University of Utah IRB or Human Research Protection Program (HRPP).**

   Click the appropriate button(s) below to add locations:

	Site Name	Investigators Name	Covered Entity	Sub Sites
View	University of Utah		Yes	

2. **Will a Central IRB (CIRB) or Single IRB (SIRB) model be used for review of this study for the sites listed in this application?**
   ◯ Yes ◯ No

3. **Indicate the source(s) of funding obtained or applied for to support this study.**

Sponsor	Sponsor Type	Sponsor Contact Information	Prime Sponsor	Prime Sponsor Type
There are no items to display				

4. **Does this study have functions assigned to a Contract Research Organization (CRO)?**
   ◯ Yes ● **No**

5. **Does this study involve use of the Utah Resource for Genetic and Epidemiologic Research (RGE)?**
   Examples: Utah Population Database (UPDB), Utah Cancer Registry (UCR), All Payers Claims Database (APCD), etc.
   ◯ Yes ● **No**

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Addition of a Site

1. **Site Name:**
   University of Utah

2. **Site Principal Investigator**
   ☐ **Mark if Same as Responsible Investigator (syncs with investigator on the first page)**
   a. **Position of the Site Principal Investigator**
   b. **Will the Site PI consent participants?** ◯ Yes ◯ No

3. **Site Contact Persons, if different from the Site PI:**
   ☐ **Mark if Same as Contacts for Responsible Investigator (syncs with contacts on the first page)**

Name	Email	Training

There are no items to display

4. **Site Staff and Sub-Investigators**

Name	Email	Training	Obtaining Consent	CoI Date
Amy Lin	amy.lin@hsc.utah.edu	4/9/2018 MCG	☑	12/2/2019
Severin Pouly	severin.pouly@hsc.utah.edu	6/24/2017 G	☑	5/18/2017
Brian Zaugg	brian.zaugg@hsc.utah.edu	1/26/2018 MCG	☑	10/30/2019

5. **Site Guests:**

Name	Email	Training

There are no items to display

6. **Select HIPAA coverage for this study:**
   Study procedures will be conducted within a HIPAA Covered Entity at this site (HIPAA Privacy Rule applies)

7. **Select the study procedures that will be conducted at this site:**
   There are no items to display

8. **Select the University of Utah department responsible for this research:**
   OPHTHALMOLOGY

9. **Add any additional sites that are part of this performance group**
   There are no items to display

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IRB_00075978
View: 3. Participants

3. Participants

1. Ages of Participants:

18 and older (Consent form needed)

2. Specific age range of participants (e.g., 7-12 years old, 60+, etc.):
21+

3. Indicate any vulnerable participant groups (other than children) included:

None

If 'Other', please specify:

If 'None' and no children are involved, answer the following question.
Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?

○ Yes ● **No**

4. Number of participants to be included and/or enrolled in this entire study, across all study locations: 250

At Utah prior to October 2019: 250

5. Characteristics of Participants/Inclusion Criteria:

All subjects who are deemed suitable candidates for PRK after routine refractive surgery screening will be considered eligible for participation in this study. Subjects must be at least 21 years of age and not pregnant or nursing (due to fluctuations in visual parameters during pregnancy).

6. Participant Exclusion Criteria:

Selection will be consistent with the current standard of care for PRK. Any patient that is not a suitable candidate for PRK will not be included.

7. Is a substantial percentage of the participant population anticipated to be non-English speaking?

○ Yes ● **No**

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IRB_00075978
View: 4. Study Information

4. Study Information

1. **Design of Study (select all that apply):**

   ☐ **Non-Experimental and/or Descriptive Research Design:**

   There are no items to display

   ☑ **Experimental and/or Interventional Research Design:**

   Prospective Biomedical Intervention or Experiment
   Randomized Trial

   ☐ **Development of a research resource (repositories, databases, etc.)**

   ☐ **Other**

2. **Does your study involve the use of any placebo?**
   ○ Yes ● **No**

3. **Length of entire study, from initiation through closeout:**
   2 years

4. **How will participants be recruited or identified for inclusion in the study?**

   a. **Select all methods that will be used:**

   In-person contact (e.g., patients, students, etc.)

   Written advertising (flyers, brochures, website postings, newspaper ads, etc.)

   Other

   Information will be included on the Moran Eye Center website, Moran Eye Center Facebook. and Moran Eye Center Twitter account.

   Http://healthcare.utah.edu/moran/patient_care/refractive_surgery_lasik
   Https://www.facebook.com/moraneyecenter
   Https://twitter.com/moraneyecenter

   b. **Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**

   Patients requesting refractive surgery will be informed about the study and asked if they would like to participate. Advertisements will also be included on the Moran Eye Center website, Facebook page, and Twitter account, as well as in newsprint.

5. **How will consent be obtained?**

   Informed Consent Process (with or without a document)

6. **Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.**

Patients who are interested and eligible to participate in this study will be enrolled and will read and sign the study informed consent prior to surgery. As is standard for our PRK cases, they will also be required to watch an informational video, read and sign the "Consent to Have Refractive Surgery" and respond to a brief test concerning its content.

Prior to surgery, patients will be randomly assigned to one of two postoperative steroid regimens. Group 1 will use loteprednol 0.5% gel in both eyes, starting at a frequency of four times per day for the first week and then tapered off based on clinical judgement of the corneal healing response. Group 2 will use prednisolone acetate 1% suspension in both eyes, starting at a frequency of four times per day for the first week, then tapered down to a regimen of fluorometholone 0.1% suspension, which will then be tapered off based on clinical judgement of the corneal healing response.

All surgical procedures will be performed according to the standard of care and the surgeons' standard practices. The study outcome measures are standard of care for pre-operative and post-operative evaluation of refractive surgery patients.

The primary outcome measure will be intraocular pressure at each study time point. Secondary outcomes will be grade of corneal haze, manifest refraction, best corrected visual acuity, and uncorrected visual acuity.

Study outcome measures will be evaluated for each treated eye of each subject at each study time point. Routine clinical management may be altered if the intraocular pressure is elevated sufficiently to require medical intervention, if there is significant postoperative corneal haze, or if there are other postoperative complications. In these situations, additional IOP lowering drops may be added or the steroid decreased, changed, or increased, based on the clinical picture and physician judgement. Additional examinations between study time points may be performed as necessary according to the surgeon's usual care, but will not be considered part of the study data. Patients have the right to withdraw at any time and future medical care will not be influenced by their lack of participation.

If enhancement surgery is deemed necessary and performed during the one-year post-operative period, study data collection will end for that eye at the time of the enhancement. All prior data collected will still be included in the statistical analysis and if only one eye requires enhancement, data collection will continue on the fellow eye until the last planned study time point.

Eyes will be evaluated with the following procedures:

- Intraocular pressure (by applanation tonometry): Pre-operatively and post-operative week 1 (± 3 days), month 1 (± 10 days), month 2 (± 10 days), month 3 (± 14 days), month 6 (± 1 month), and month 12 (± 1 month)

Note: Intraocular pressure will be measured by a technician or physician who is masked to the treatment regimen of the patient at each visit.

- Grade of corneal haze (Fantes scale): Post-operative month 1 (± 10 days), month 2 (± 10 days), month 3 (± 14 days), month 6 (± 1 month), and month 12 (± 1 month)

Note: Corneal haze will be graded by a study physician who did not perform the original surgery and is masked to the treatment regimen of the patient at each visit.

- Manifest refraction (sphere, cylinder, and axis): Pre-operatively and post-operatively month 1 (± 10 days), month 2 (± 10 days), month 3 (± 14 days), month 6 (± 1 month), and month 12 (± 1 month)

- Best corrected visual acuity: Pre-operatively and post-operatively month 1 (± 10 days), month 2 (± 10 days), month 3 (± 14 days), month 6 (± 1 month), and month 12 (± 1 month)

- Uncorrected visual acuity: Pre-operatively and post-operative day 1 (± 1 day), week 1 (± 3 days), month 1 (± 10 days), month 2 (± 10 days), month 3 (± 14 days), month 6 (± 1 month), and month 12 (± 1 month)

- Pupil size measured in the dark: Pre-operatively only

- Corneal pachymetry: Pre-operatively only

Data and Safety Monitoring:

There is no formal data and safety monitoring board for this study. All treatments, procedures, and testing being performed in the study are within the standard of care and treatment for PRK patients. This study does not put study participants at any known increased risk beyond that normally assumed by patients undergoing PRK outside the study. The investigators feel that the standard processes for identifying and reporting adverse events (AE) are sufficient to safeguard the well-being of study participants.

The investigators have a nomogram from which they work and therefore have expected vision outcomes for patients on an individual basis. It is routine practice to compare actual with expected outcomes as a quality assurance measure. Should any concerns arise prior to completion of the study, a safety analysis will be conducted immediately.

For this protocol, an AE is any "on study" untoward medical occurrence (e.g., sign, symptom, disease, syndrome, intercurrent illness) that is experienced by a study subject, regardless of the suspected cause. Both serious and non-serious AEs will be graded on a three-point scale (mild, moderate, severe), and the investigators will assess whether there is a reasonable possibility that study procedure caused or contributed to the AE.

Adverse events that start on Day 0 (Surgery) through the last study visit will be recorded on the study AE log and described in detail in the patient chart. Subjects discontinued early from the study due to an adverse event will be asked to return for a final evaluation. All study-related adverse events will be followed until resolution (or determined to be irreversible, chronic, or stable).

Adverse events that are determined to be unexpected, possibly related to the study procedure, and place subjects at increased risk, will be reported to the Institutional Review Board (IRB) according to their guidelines.

Standard of Care / Research Costs:

All procedures are considered within the standard of care for PRK surgery and will be billed to patients in the usual manner; however, participants will be eligible for a reduced study fee for their surgery and post-operative care. PRK surgery is considered cosmetic surgery and is never billed to insurance. The refractive surgery charge includes standard post-operative examinations up to one year.

Loteprednol 0.5% gel is not available in a generic formulation and is therefore significantly more expensive than generic prednisolone acetate 1% suspension and fluorometholone 0.1% suspension. A request for a donation of loteprednol 0.5% gel for this study has been submitted to Bausch and Lomb and is currently under review. If approved, this drug donation will allow us to eliminate the additional expense of a branded drug for patients that are randomized to the loteprednol group.

If enhancement surgery is deemed necessary during the one-year post-operative period, this will be included based on the patient's initial fee, as is standard of care. Any other costs related to management of adverse events, or if additional refractive correction is necessary at some time after the one-year postoperative period, will remain the patient's responsibility and are not included in the study surgery fee.

7. **Are all procedures for research purposes only (non-standard or non-standard of care procedures)?**
   ○ Yes ● **No**

   If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

   Only data collection and analysis are for research purposes only. All other procedures are within the standard of care.

8. **Is there a safety monitoring plan for this study?**
   ○ Yes ● **No**

9. **Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.**

   Standard statistics will be calculated and used to describe the two treatment groups in terms of all study variables: intraocular pressure, grade of corneal haze, manifest refraction, best corrected visual acuity, and uncorrected visual acuity. Statistics will be compiled for each variable at the study time points listed in the data collection protocol. Patients withdrawn from the study prior to surgery will not be included in the data analysis and will be replaced in the enrollment group. For eyes that require enhancement surgery, only data collected prior to the enhancement surgery will be included in the statistical analysis.

   Prior studies have considered intraocular pressure elevation of greater than or equal to 10 mm Hg above baseline clinically significant. A prior study of healthy volunteers demonstrated an incidence of IOP elevation > 10 mm Hg of 1.95% in patients using loteprednol eye drops versus 7.48% in patients using dexamethasone eye drops [1]. Using these expected proportions, an alpha of 0.05, and a power of 80%, we would need a sample size of 230 patients (460 eyes). In order to account for about 10% dropout, we intend to enroll 250 patients in the study, 125 in the loteprednol arm and 125 in the prednisolone and fluorometholone arm.

   1. Holland EJ, Bartlett JD, Paterno MR, Usner DW, Comstock TL. Effects of loteprednol/tobramycin versus dexamethasone/tobramycin on intraocular pressure in healthy volunteers. Cornea. 2008;27(1):50-55.

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IRB_00075978
View: 4.2 Consent Process

Consent Process

1. **The following investigators and internal staff will obtain consent (as indicated on the Study Location and Sponsors Page):**

Amy Lin	University of Utah
Mark Mifflin	
Severin Pouly	University of Utah
Brian Zaugg	University of Utah

List by name, role, and affiliation any others who will obtain consent (e.g. Dr. John Smith, Co-Investigator, etc.).

2. **Describe the location(s) where consent will be obtained.**
Moran Eye Center Clinics

3. **Describe the consent process(es), including the timing of consent. Describe whether there is a waiting period between the consent process and obtaining consent from the participant (i.e., any time between informing participants and actually obtaining consent).**
All of our standard evaluation and consent processes for refractive surgery will be followed. Patients who are interested in refractive surgery undergo a standard refractive surgery screening examination with the surgeon, during which their candidacy for refractive surgery is determined and the risks and benefits of all potential refractive procedures for which they medically qualify, which may or may not include PRK, are discussed. Patients who are not already aware of the study are also informed about the possibility of participating in the study during or prior to this first clinic visit. Patients who are good candidates medically and motivated to undergo surgery are then scheduled for a repeat examination to ensure refractive and keratometric stability, as well as to further discuss and finalize the surgical plan based on the patient's goals and clinical findings, as is our usual standard. If a patient is deemed medically eligible for and chooses to undergo PRK, they may choose to be included in the study. The study risks and benefits will be discussed and patients will be given opportunities to ask questions regarding the study at any of the clinic visits described above. Consent will be signed by the patient prior to undergoing surgery.

4. **Describe what measures will be taken to minimize the possibility of coercion or undue influence.**
Patients interested in refractive surgery are screened and, based on clinical findings, the screening surgeon presents them with the risks and benefits of all procedures for which there are good candidates, which may or may not include PRK. All patients are free to undergo the refractive procedure that is best suited to them, including PRK, without participating in the study.

5. **Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and participant.**
All study participants will meet with their surgeon on at least 3 occasions prior to undergoing surgery. This includes the initial refractive surgery screening, repeat exam, and on the day of surgery prior to the procedure. Patients will have the opportunity to discuss the study and surgical plan at any of these visits.

6. **Will a legally authorized representative (LAR) be used?**
○ Yes ● **No**

7. **Will a language other than English be used to obtain consent?**
○ Yes ● **No**

8. **Are you requesting that documentation of informed consent be waived by the IRB (a consent process in place, but no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.)?**

○ Yes ● **No**

If yes, complete the following:

a. **Explain why the waiver of consent documentation is being requested.**

b. **Justification for the waiver is one of the following:**
There are no items to display

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View: 5. Data Monitoring Plan

5. Data Monitoring Plan

1. **Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

   Select all that apply:

   - The research intervention is conducted in a private place
   - Discussing the study with participants individually instead of in front of a group
   - The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected
   - Other or additional details (specify):

   Other or additional details (specify):
   Precautions will be taken to maintain confidentiality of patient records and personal information. Raw data (pre-operative and post-operative measurements and operative report) will be maintained as part of the patient's confidential medical record, in accordance with University, state and federal guidelines. Study data will be compiled into an electronic file by the investigators and maintained on a password-protected network. Data entries will be coded by patient identification number. Any reports of the results of this study that are published or presented will not disclose the subject's identity.

2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

   Select all that apply:

   - Storing research data on password protected computers or in locked cabinets or offices
   - Participant identifiers will be stored separately from the coded, participant data

   Other or additional details (specify):

3. **Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**

   ○ Yes ● **No**

   If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):

4. **How will study data and documentation be monitored throughout the study?**

   Select all that apply:

   - Periodic review and confirmation of participant eligibility
   - Periodic review of informed consent documentation
   - Periodic review of the transfer/transcription of data from the original source to the research record

Confirmation that all appropriate information has been reported to the sponsor, oversight agencies (such as the FDA), and/or IRB

Other additional details (specify):

5. Who will be the primary monitor of the study data and documentation?

Select all that apply:

Principal Investigator

Study Coordinator or Research Nurse

Other or additional details (specify):

Other or additional details (specify):
Sub-investigators

6. How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?
Annually

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View: 6. Risks and Benefits

6. Risks and Benefits

1. Describe the reasonable foreseeable risks or discomforts to the participants:

This study does not put study participants at any known increased risk beyond that normally assumed by patients undergoing photorefractive keratectomy outside the study, including but not limited to decreased vision, over-correction, under-correction, pain, glare, halos, dry eyes, infection, and corneal haze. The risk of topical steroid-related complications following photorefractive keratectomy, including elevated intraocular pressure, infection, and cataract formation, is assumed by all patients undergoing the procedure at our institution, as it is our routine standard practice to put patients on a tapering regimen of topical steroids post-operatively to decrease the risk of corneal haze.

2. Describe the potential benefits to society AND to participants (do not include compensation):

There may be no direct benefits to participants from their participation in this study. If no difference in efficacy or safety is detected between the two post-operative treatment regimens, this study will support the use of either steroid regimen in patients after PRK. If there is a major difference in the efficacy or safety of these two regimens, this could influence post-refractive surgery treatment practices.

3. Are there any costs to the participants from participation in research?

● **Yes** ○ No

If yes, specify:
All subjects will be charged the research-discounted price for PRK ($1200 per eye) and will be responsible for the cost of all necessary medications. Loteprednol is significantly more expensive than prednisolone and fluorometholone. Bausch and Lomb has unconditionally donated loteprednol 0.5% gel for this study, thus patients randomized to the loteprednol arm will be provided this medication without charge. Patients randomized to the prednisolone/fluorometholone arm will be responsible for paying for this medication, just as they would be were they not enrolled in the study.

4. Is there any compensation to the participants?

○ Yes ● **No**

a. **If yes, answer the following:**
Specify overall amount:

b. **Specify when participants will be paid (e.g. at each visit, at end of study, etc.):**

c. **If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):**

d. **If applicable, explain plan for prorating payments if participant does not complete the study:**

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Title: Efficacy and safety of loteprednol 0.5% gel for routine prophylaxis after photorefractive keratectomy compared to prednisolone acetate 1% suspension and fluorometholone 0.1% suspension

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View: 7. HIPAA

7. HIPAA and the Covered Entity

1. **Does this study involve Protected Health Information (PHI) or de-identified health information?**
   ● **Yes** ○ No

   a. **Select the method(s) of authorization that will be used:**

   (Consent and) Authorization Document

   b. **Will PHI be disclosed outside the Covered Entity?**
   ○ Yes ● **No**

Does this study involve any of the following:

2. **The investigational use of a drug?**
   ○ Yes ● **No**
3. **The investigational use of a medical device?**
   ○ Yes ● **No**
4. **Is this an investigator-initiated drug or device trial lead by the Principal Investigator?**
   ○ Yes ● **No**
5. **Exposure to radioisotopes or ionizing radiation?**
   ○ Yes ● **No**
6. **A Humanitarian Device Exemption (HDE)?**
   ○ Yes ● **No**
7. **Genetic testing and/or analysis of genetic data?**
   ○ Yes ● **No**
8. **Creating or sending data and/or samples to a repository to be saved for future research uses?**
   ○ Yes ● **No**
9. **Are you:**
   - **Collecting samples of blood, organs or tissues from participants for research purposes;**
   - **Introducing Recombinant or Synthetic Nucleic Acids (e.g. viral vectors, oligonucleotides) or cells containing recombinant nucleic acids (e.g. CAR-T) into participants; OR**
   - **Introducing other biological materials (e.g. bacteria, viruses) into participants.**

◯ Yes ● **No**

10. **Does this study involve any of the following?**
    - **Cancer Patients**
    - **Cancer Hypothesis**
    - **Cancer risk reduction**
    - **Cancer prevention**

    ◯ Yes ● **No**

11. **Any component of the Center for Clinical and Translational Science (CCTS)?**

    ◯ Yes ● **No**

    The Clinical Services Core (CSC)?

    ◯ Yes ● **No**

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View: 8. Resources & Responsibilites

8. Resources and Responsibilities

1. * **State and justify the qualifications of the study staff:**

   Dr. Mark Mifflin specializes in the medical and surgical treatment of corneal and anterior segment eye diseases. His expertise includes corneal transplantation, cataract surgery, and vision correction using lasers, intraocular lenses, and conductive keratoplasty.

   Dr. Amy Lin is a board certified Ophthalmologist specializing in the medical and surgical treatment of corneal and anterior segment diseases at the Moran Eye Center.

   Dr. Brian Zaugg is a fellow in cornea and refractive surgery at the Moran Eye Center and works under the supervision of Dr. Mifflin.

2. * **Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:**

   All investigators have completed the CITI human subjects training. The PI will train the sub-investigators on the protocol.

3. * **Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.).**
   All resources required to implement the study protocol are available at the Moran Eye Center clinics. Clinical care services at the Moran Eye Center include three fully equipped operating rooms, minor procedure rooms, 25 examination rooms, a laser suite, an optical shop, and a pharmacy.

4. * **Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**
   The investigators will be available to answer any questions or discuss any concerns the participants have. Dr. Mifflin has the expertise and medical resources to appropriately handle any medical consequences of the research study.

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View: 9. Documents and Attachments

Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

Naming Documents: Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:
Consent Document Control Group 04/14/05
Consent Document Treatment Group 4/14/05
Sponsor Protocol 04/14/05 Version 2
Assent Document(Highlighted Changes)

Apple/Macintosh Users:MS Word documents must have a .doc file extension. See ERICA home page for instructions.

Print View: IRB Draft Protocol Summary

eProtocol Summary:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Parental Permission Documents:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Assent Documents:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

VA Consent Documents:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Surveys, Questionnaires, Interview Scripts, etc.:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Literature Cited/References:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Principal Investigator's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved
Mifflin CV 04.09.2014.pdf(0.01)	0.01	7/14/2015 3:23 PM	7/14/2015 3:23 PM	
MifflinCV11-04-2016.doc(0.01)	0.01	2/21/2017 7:55 PM	2/21/2017 7:55 PM	

Faculty Sponsor's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Other Stamped Documents:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

Other Documents:

Name	Version	Date Created	Date Modified	Date Approved

There are no items to display

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View: 12. Finish Instructions

Finish Instructions

Finish Instructions

1. **To view errors, select the "Hide/Show Errors" option at the top or bottom of the page. If you have errors on your application, you won't be able to submit it to the IRB.**
2. **Selecting the Finish button will NOT submit the application to the IRB.**
   You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.
3. **If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.**