Clinical Study Protocol

A single center randomized controlled, two arm investigator initiated study to assess the efficacy of Kera Sol Tears on surgical temporary ocular discomfort syndrome (STODS) in subjects following LASIK.

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Sponsor:	Vance Thompson Vision
Sponsor Location:	Vance Thompson Vision 3101 West 57th Street Sioux Falls, SD, 57108
Study Name:	**Kera Sol Post-LASIK: A Benefit Study**
Study Phase:	Investigator-Initiated Trial

Clinical Study Protocol Synopsis

Title: A single center randomized controlled, two arm investigator initiated study to assess the efficacy of Kera Sol tears on signs and symptoms of surgical temporary ocular discomfort syndrome (STODS) in subjects following LASIK.

Principal Investigator: Vance Thompson / Vance Thompson Vision

Sponsor Location: Vance Thompson Vision
3101 West 57th Street
Sioux Falls, SD, 57108

Study Name: Kera Sol Post-LASIK: A Benefit Study

Objective: To evaluate the influence of Kera Sol tear usage during the initial two-week postoperative period after LASIK has on the signs and symptoms of STODS.

Background: Laser-Assisted In Situ Keratomileusis (LASIK) is a common and effective refractive surgery that reshapes the cornea to correct vision problems. However, a frequent temporary side effect post-surgery is dry eye. This occurs because the LASIK procedure can disrupt the corneal nerves responsible for signaling tear production and can also affect the goblet cells in the conjunctiva that contribute to the tear film's stability. This neurotrophic effect and potential disruption of the ocular surface lead to reduced tear production, increased tear evaporation, and an unstable tear film. Given the prevalence of post-LASIK dry eye and the established benefits of artificial tears in managing this condition, there is an ongoing need to explore formulations that may offer enhanced or more targeted relief. Kera Sol tears, presumably a specific formulation of artificial tears, may offer unique benefits due to its specific composition.

Study Design: Prospective, single-site, two-arm randomized study evaluating the impact of, Kera Sol tears on the signs and symptoms of STODS in 60 patients who underwent bilateral LASIK. Both groups will be prescribed the standard of care post-operative prescription combination steroid and antibiotic drop. Additionally, subjects will be randomized to administer the study drop (Kera Sol) dosed QID for 14 days.

The primary endpoints, assessed using descriptive analysis, will be the change from baseline corneal staining on the 0-15 NEI scale and the change from baseline discomfort score on the UNC DEMS questionnaire to Day 14. Additional endpoints measured will include uncorrected visual acuity (UCVA), BEDx score and best-corrected visual acuity (BCVA) at 1 week, and residual refractive error at Day 14.

Subject Population: 60 subjects, who have scheduled for LASIK in both eyes, will be enrolled.

Materials and Methods

- Informed consent will be obtained prior to collection of any data.
- Each subjects' demographics, medical history, will be reviewed.
- Inclusion and exclusion criteria will be reviewed for each subject.
- Subjects will be asked to report their daily use of study drop
- Subjects will be asked to report their dry eye symptoms using the developed University North Carolina Dry Eye Management Scale (UNC DEMS) scale
- Each subjects' monocular and binocular uncorrected distance visual acuity (UDVA) will be obtained on an ETDRS chart at a distance of 20 feet
- A manifest refraction will be performed on each subject.
- Monocular and binocular best corrected distance visual acuity (BCDVA) will be obtained on an ETDRS chart at a distance of 20 feet in photopic lighting conditions.
- 25% low contrast sensitivity will be evaluated using a Pelli-Robson chart.
- The subjects' eyes will be thoroughly examined at the slit lamp.
- Corneal fluorescein staining will be evaluated using the BEDx software
- Intraocular pressure will be obtained using clinical standard of care

Inclusion criteria:

1. Be willing and able to sign the informed consent form (ICF)
2. Be at least 18 years of age at the screening visit
3. Be undergoing LASIK treatment in both eyes
4. Be literate and able to complete questionnaires independently
5. Be able and willing to use the study drug and participate in all study assessments and visits
6. Have provided verbal and written informed consent

General Exclusion criteria:

1. Use of topical prescription dry eye medications such as lifitegrast, cyclosporine, loltilaner, etc.

2. Have a break in the integrity of the corneal epithelium such as a persistent corneal epithelial defect, or corneal ulcer.
3. Have presence of corneal pathology that may interfere with LASIK outcomes
4. Active infectious, ocular or systemic disease
5. Have a history of ocular inflammation or macular edema
6. Have had clinically significant active infectious keratitis in the past 3 months
7. Have history of prior refractive surgery
8. Have placement of temporary punctal plugs in the past 1 month or current presence of permanent punctal plugs at time of screening
9. Patients with usual relative and absolute contraindications for LASIK surgery (Patients with severe dry eye, recurrent corneal erosion, uncontrolled Glaucoma, collagen vascular disorders, keratoconus or signs of keratoconus, uncontrolled Diabetes, Herpes)
10. Autoimmune or immunodeficiency diseases
11. Pregnant or nursing women
12. Patients with history of previous ocular surgery

Procedures

Subjects will be recruited from the site's current patient population who have been scheduled and underwent bilateral LASIK procedure. Enrollment and informed consent will be administered by study coordinators. Data will be collected by investigators and study coordinators as follows. Data may be carried from standard of care visits within 90 days of Visit one.

Visit 1 (pre-op):

- Informed consent will be obtained prior to collection of any data
- Each subjects' demographics, medical, and concomitant medications will be reviewed.
- Inclusion and exclusion criteria will be reviewed for each subject.
- University North Carolina Dry Eye Management Scale (UNC DEMS) questionnaire will be administered
- Concomitant medications will be reviewed.

Visit 2 (1 day post-op):

- Randomization will occur
- Daily topical artificial tear and study drop log will be provided

- University North Carolina Dry Eye Management Scale (UNC DEMS) questionnaire will be administered
- Monocular and binocular uncorrected distance visual acuity (UDVA) will be obtained on an ETDRS chart at a distance of 20 feet
- 25% low contrast sensitivity will be measured using the Pelli-Robson chart
- Slit lamp examination will be performed
- Corneal fluorescein staining will be obtained using the BEDx software
- Adverse events will be collected

Visit 3 (7 +/-2 days post-op):

- Daily topical artificial tear and study drop log will be provided
- University North Carolina Dry Eye Management Scale (UNC DEMS) questionnaire will be administered
- Monocular and binocular uncorrected distance visual acuity (UDVA) will be obtained on an ETDRS chart at a distance of 20 feet
- Manifest refraction will be performed
- Monocular and binocular best corrected distance visual acuity (BCDVA) will be obtained on an ETDRS chart at a distance of 20 feet
- 25% low contrast sensitivity will be measured using the Pelli-Robson chart
- Slit lamp examination will be performed
- Corneal fluorescein staining will be obtained using the BEDx software
- Adverse events will be collected

Visit 4 (14 +/-2 days post-op):

- Daily topical artificial tear and study drop log will be provided
- University North Carolina Dry Eye Management Scale (UNC DEMS) questionnaire will be administered
- Monocular and binocular uncorrected distance visual acuity (UDVA) will be obtained on an ETDRS chart at a distance of 20 feet
- Manifest refraction will be performed
- Monocular and binocular best corrected distance visual acuity (BCDVA) will be obtained on an ETDRS chart at a distance of 20 feet
- 25% low contrast sensitivity will be measured using the Pelli-Robson chart
- Slit lamp examination will be performed
- Corneal fluorescein staining will be obtained using the BEDx software
- Intraocular pressure will be measured per standard of clinical care
- Adverse events will be collected

Data Analysis and Data Monitoring

Data will be captured by the principal investigators, sub-investigators and study coordinators. Data will be documented on source documents and subjects will be identified as subject numbers.

Data analysis will occur on an excel spreadsheet or in R statistical software with subjects identified as a subject number. The Excel spreadsheet or R scripts will be on computer(s) that are password protected.

Baseline demographic and ocular characteristics will be quantified using descriptive statistics. Statistical analysis will be completed on all primary and secondary endpoints.

Data Storage and Confidentiality

Private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep all names and other identifying information confidential.

We protect all information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Sources documents will be placed in a binder and stored in locked cabinets.
This trial will be conducted in compliance with the protocol, GCP, and applicable regulatory requirement(s).

The participation for this trial is voluntary and subjects may stop or withdraw during the one-time examination at their discretion.

The principal investigator will report to the IRB any changes in research activity, serious adverse events, and completion of the study.