STUDY PROTOCOL

The Efficacy of the Systane iLux System on Preoperative Cataract Patients on Dry Eye Disease Due to Meibomian Gland Dysfunction

Protocol Information

ClinicalTrials.gov Identifier: NCT06483750
Document Date: May 12, 2026
Protocol Number: NCR245538
IRB Number: NCR245538
Principal Investigator: Keith Wroblewski, MD
Institution: George Washington Medical Faculty Associates
Study Site: George Washington Medical Faculty Associates Ophthalmology Clinic
ClinicalTrials.gov Identifier: NCT06483750
Document Date: May 12, 2026
Funding Sources: Gill Fellowship; Sigma Xi GIAR Grant
Study Type: Prospective Interventional Study
IRB Approval: George Washington University IRB

Study Description

Dry eye disease (DED) is a common complication following cataract surgery and is frequently associated with meibomian gland dysfunction (MGD). Cataract surgery can alter tear film stability and ocular surface homeostasis, contributing to postoperative dry eye symptoms. Thermal pulsation therapies, including the Systane iLux system, have demonstrated efficacy in improving meibomian gland function and reducing symptoms associated with evaporative dry eye disease.

The Systane iLux device is an FDA-approved handheld thermal pulsation system designed to heat and evacuate obstructed meibomian glands. While prior studies have evaluated the role of thermal pulsation therapy in MGD management, limited data exist regarding preoperative iLux administration in cataract surgery patients.

This study aims to evaluate whether preoperative Systane iLux treatment improves objective and subjective dry eye outcomes in cataract surgery patients.

Study Objectives

Primary Objective

To evaluate the effect of preoperative Systane iLux treatment on dry eye disease parameters following cataract surgery.

Secondary Objectives

1. To assess changes in Ocular Surface Disease Index (OSDI) scores.
2. To assess changes in Standard Patient Evaluation of Eye Dryness (SPEED) scores.
3. To assess changes in lipid layer thickness.
4. To evaluate changes in meibomian gland morphology and function.

Study Design

This study is a prospective, randomized, open-label, parallel-assignment interventional clinical study.

Participants scheduled for senile cataract surgery were recruited from the George Washington Medical Faculty Associates Ophthalmology Clinic.

Participants were randomized into one of two groups:

1. Control Group: No Systane iLux treatment
2. Treatment Group: Preoperative Systane iLux treatment

The treatment arm received Systane iLux administration at the baseline visit, approximately two weeks prior to cataract surgery in the single eye scheduled for cataract surgery. The control arm received no Systane iLux treatment.

Participants underwent baseline evaluation and returned for follow-up evaluation four weeks after cataract surgery.

Analyses were conducted at the participant level and objective ophthalmic assessments were performed on the eye undergoing cataract surgery.

Study Population

Inclusion Criteria

- Age greater than 18 years at time of informed consent
- Ability and willingness to comply with study procedures, visit schedule, and restrictions
- Upcoming scheduled senile cataract surgery

Exclusion Criteria

- Eyelid abnormalities
- Patients with active ocular infection, active ocular inflammation, or history of chronic recurrent ocular inflammation within prior 3 months
- Ocular surgery within the prior 6 months
- Occlusion therapy with lacrimal or punctum plugs within the prior 3 months
- Ocular surface abnormalities that may compromise corneal integrity

- Ocular injury, trauma, chemical burns, or limbal stem cell deficiency within prior 3 months
- Cicatricial lid margin disease
- Lid surface abnormalities affecting lid function in either eye
- Aphakia
- Permanent makeup or tattoos on the eyelids
- Previous application or administration of Systane iLux or LipiFlow treatment

Sample Size

A total of 30 participants were enrolled and randomized:

- 15 participants assigned to the control arm
- 15 participants assigned to the treatment arm

Study Procedures

Baseline Visit

Outcome measures

- Lipid layer thickness assessment
- OSDI questionnaire
- SPEED questionnaire
- Meibomian gland imaging using LipiView II

Participants randomized to the treatment arm additionally underwent Systane iLux administration while those assigned to the control arm received no interveniton

Follow-Up Visit

Approximately four weeks after cataract surgery, participants returned for repeat assessments, including:

- Lipid layer thickness
- OSDI questionnaire
- SPEED questionnaire
- Meibomian gland imaging using LipiView II

Outcome Measures

Primary Outcome

Change in lipid layer thickness values following cataract surgery.

Secondary Outcomes

- Change in OSDI score
- Change in SPEED score
- Change in meibomian gland imaging findings

Statistical Analysis Plan

Continuous variables were summarized using means and standard deviations. Comparisons between groups were performed using standard statistical testing methods appropriate for continuous and categorical variables. Within-group and between-group analyses were conducted to evaluate changes from baseline to postoperative follow-up. A p-value of less than 0.05 was considered statistically significant. Statistical analyses were performed at the participant level.

Safety Monitoring and Adverse Events

Adverse events were monitored from the baseline visit through four weeks postoperatively. Participants were instructed to report any ocular discomfort or adverse symptoms during the study period. No serious adverse events were reported during the study.

Ethical Considerations

This study was approved by the George Washington University Institutional Review Board.

Written informed consent was obtained from all participants prior to enrollment.

The study was conducted in accordance with institutional and federal human subjects research guidelines.

Study Contacts

Central Contact Person

Arnold Leigh
George Washington University School of Medicine and Health Sciences
arnold.leigh@gwu.edu

Principal Investigator

Keith Wroblewski, MD
George Washington MFA
kwroblewski@mfa.gwu.edu

Funding

This investigator-initiated study was supported through the Gill Fellowship and Sigma Xi GIAR Grant. The study was not industry-sponsored.

Informed Consent to participate in Study Titled: The Efficacy of the Systane iLux System on Preoperative Cataract Patients on Dry Eye Disease due to Meibomian Gland Dysfunction

Investigators: Keith Wroblewski MD

Site: The George Washington Medical Faculty Associates

Study related contact information: Keith Wroblewski MD, kwroblewski@mfa.gwu.edu

IRB#: NCR245538

Key Information (Study Overview)

You are invited to participate in this study. This study will evaluate the effect of the Systane iLux system on the function of meibomian glands, which are glands along your eyelids that help to lubricate the eye. If you agree to participate in this study, you will be randomly placed into one of two groups: the experimental group or the control group. The investigators will not know if the participants have meibomian gland dysfunction (MGD) prior to enrollment in the study and the presence or lack of MGD will not impact enrollment into the study. Thus, participants in the experimental group will be given pre-operative iLux administration prior to cataract surgery, while participants in the control group will be given no treatment. After 4 weeks post-cataract surgery, you will be required to return to the clinic for a follow-up visit. The iLux will be administered only once at the baseline visit only on the eye to undergo cataract surgery.

If you wish to enroll in the study, you will be invited back to the MFA Ophthalmology Clinic for a baseline study visit, and then a final study visit, four weeks after cataract surgery. At the baseline visit and the end-of-study visit, the investigators will carry out several measurements using equipment and ask you some questions as a short survey. The measurements and equipment used are part of standard of care for ophthalmic examinations such as cataract surgery and assessment of dry eye disease (DED). A visual acuity test will also be performed at both visits.

The main expected benefits of participating in this study include potential reduction in DED and DED symptoms. If randomly assigned to the experimental group, patients in this group will receive iLux treatment. There are risks related to the side effects of the Systane iLux treatment,

but in very rare cases potential side effects include eyelid/eye pain requiring stopping the treatment procedure, eyelid/eye irritation or inflammation, temporary reddening of the skin, and other eye symptoms (burning, stinging, tearing, itching, discharge, redness, feeling like there is something in the eye, changes in your vision, sensitivity to light. There is minimal risk of loss of confidentiality and no legal or financial risks associated with participation in this study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please read through the following information. Feel free to ask questions (see research team info above) if something is not clear or if you wish to discuss any information provided to you. Participation in this study is completely voluntary and your treatment/care will not be affected if you decide not to participate in this study.

Introduction

What is the purpose of this study?

The purpose of this study is to investigate the effect of the pre-operative Systane iLux system on the function of meibomian glands in preventing the progression of dry-eye disease (DED) in cataract surgeries. Approximately four million people in the United States undergo cataract surgery each year with DED representing one of the most common complications post-cataract surgery. There is a current lack of research on the iLux system's impact during pre-operative cataract surgery. This study aims to evaluate the effects of iLux as a preventative measure for cataract induced dry eye. In addition, this study wants to better understand the potential of iLux in managing dry eye disease in cataract patients. The results of the research will provide data on the iLux system in helping dry eye symptoms which helps healthcare workers have a better understanding of treatments for dry eye disease in cataract patients. The results of the research will be published in a peer reviewed journal to help inform clinicians and patients on dry eye disease stemming from cataract procedures.

Background Information

Cataract surgery is one of the most prevalent surgical operations in the United States with about four million cataract surgeries performed annually. During cataract surgery, sensation in the eye can be reduced, ultimately affecting tear quality and production. In addition, the usage and

stoppage of medications from cataract surgery can contribute to the development of dry eye disease. Thus, one of the most frequent complications arising from cataract surgery is the onset of dry eye disease ultimately affecting up to 55.7% of patients. In dry eye disease, the oil producing glands in your eye (meibomian glands) can be disrupted and its quality can be reduced. Consequently, one's tear film layer can become disrupted and can cause other eye problems. The disruption in one's meibomian glands is called meibomian gland dysfunction (MGD) and is a common cause of dry eye in cataract patients. Current treatments for MGD include the use of artificial tear drops, antibiotic and steroid drops, omega-3 supplements, use of warm compresses or heated pads, intense pulse light, Lipiflow Thermal pulsation, and the Systane iLux Thermal Pulsation System. This study aims to look at the relationship between dry eye disease from cataract surgery and the potential role of Systane Lux as a preventative measure for reducing dry eye disease. In this study, the iLux system will be used before cataract surgery to treat the meibomian glands to prevent and improve conditions of dry eye disease following cataract surgery.

What are meibomian glands?

Meibomian glands are oil glands along the edge of the eyelids where the eyelashes are found. For each eye, we have about 30 of these glands along our upper eyelid, and about 20 along the lower eyelid. These glands secrete a small amount of an oily substance onto your eye, which strengthens tears so that our eyes do not dry up too quickly. Dry eyes are the most common ocular disease globally, and a common cause of dry eye is the improper functioning of the meibomian glands. Changes in the amount or quality of oil produced from the meibomian glands can lead to a feeling of dryness, itchiness, and inflammation.

What is the Systane iLux System?

The Systane iLux System is a device that utilizes localized heat and therapeutic pressure and has been shown to significantly reduce dry eye disease stemming from Meibomian gland dysfunction. iLux was released in 2019 and offers a promising treatment for MGD through the application of heat and pressure to both eyelids. iLux is a hand-held device that uses disposable tips that are heated through LED excitation to around 38 degrees ℃ (100.4º for ten minutes.

The application of heat and compression melts meibum in the obstructed glands to restore the secretion and production of meibum to the eye. Meibum is a fatty liquid secreted by glands in your eyelid to lubricate and protect the health and duration of one's tears. This device is FDA approved for treatment of patients with meibomian gland dysfunction. The iLux system will be administered by a medical student who has been comprehensively trained on the device usage and application. The iLux will be administered only once at the baseline visit only on the eye to undergo cataract surgery. Prior to application of iLux, a numbing drop of Proparacaine will be administered.

What is the LipiView II?

The LipiView II is an imaging device produced by Johnson & Johnson to provide high quality meibography images of the Meibomian glands to provide healthcare workers with more detailed information on the condition of the Meibomian glands. Through the specialized and precise imaging, the LipiView provides accurate and qualitative measurements of the absolute thickness of the tear film lipid layer in one's tears. The lipid layer is most commonly the layer that is impaired in DED. By measuring the thickness, the investigators will have a better picture of the health of one's tears and DED. In regards to the LipiView II, no known or anticipated adverse effects are associated with the use of the device. This device is FDA approved and will be used in accordance with the according FDA approved utilization and labeling.

What information does this study collect?

This study will collect medical information related to your visual health (medications, diagnoses, and other information in your medical record). We will store that information in a database on RedCap, a commonly used service in clinical trials for the protection and documentation of research data. The data will be password-protected and access to the same data will be available only to investigators of the research team. The information in the database will be used to answer the research question regarding the Systane iLux's impact on dry eye disease in cataract patients. At least 50 subjects from George Washington MFA are expected to participate.

ELIGIBILITY

Inclusion criteria

You must be older than 18 years of age at the time of the study and have a scheduled senile cataract surgery.

Exclusion criteria

You may be excluded from the study if you have any pre-existing eye conditions other than dry eye disease, have had ocular surgery, punctum plugs (small plugs inserted into your eyelid margins to help with dry eyes), previous application of Systane iLux or LipiFlow treatment, or have an active allergy or infection at the front of your eye.

What are participants required to do?

Upon entering this study, you will be randomly assigned into either the Systane iLux treatment group, or the control group of the study which will receive no treatment. Your assignment will be determined at random, like flipping a coin. To participate in this study, you must be willing to attend a follow-up visit four weeks post cataract surgery to assess various functionality tests of the eye.

The study period will begin at the baseline study visit and will involve doing several in-office assessments with you. These assessments will include measuring the time it takes for your tears to evaporate (tear film breakup time) using an eyedrop containing a dye called fluorescein. The investigators will also look at your meibomian glands under the microscope and use a device called the LipiView II to provide high quality imaging on the status of the meibomian glands and assess key metrics. The investigator will ask you some questions in the form of two short surveys. Lastly, the Systane iLux will be applied and only once at the baseline visit. When the Systane iLux is administered, a numbing drop called Proparacaine will also be administered. The assessments and Systane iLux will only be administered on the eye undergoing cataract surgery. These assessments will take approximately 40 minutes in total. All of these assessments performed are standard of care for diagnosing and examining dry eye disease.

After the baseline study visit which occurs two weeks prior to cataract surgery, the study period will begin. After 4 weeks following cataract surgery, we request you to return to the clinic for an

end-of-study follow-up visit. During this visit, the investigator will collect the same assessments as the baseline visit.

What are the risks of participating in this study?

There are risks related to the side effects of the Systane iLux treatment, but in rare cases Potential side effects include eyelid/eye pain requiring stopping the treatment procedure, eyelid/eye irritation or inflammation, temporary reddening of the skin, and other eye symptoms (burning, stinging, tearing, itching, discharge, redness, feeling like there is something in the eye, changes in your vision, sensitivity to light. There is minimal risk of loss of confidentiality and no legal or financial risks associated with participation in this study. In regards to the LipiView II, no known or anticipated adverse effects are associated with the use of the device

What measures are being taken to minimize these risks?

- Only authorized persons will be granted access
- Only authorized persons may enter and view study data
- Passwords and system IDs will not be shared
- Physical security of the workstations/files will be maintained
- An adequate backup plan is in effect
- Staff trained on data entry system and the importance of security procedures
- Workstations with databases will not be left unattended
- Hard copies (if applicable) will be kept in a lock filing cabinet behind a locked door and destroyed when no longer in use
- We will minimize risks to protect your confidentiality by removing identifiable information such as your name and date of birth from study records, and storing sensitive study documents in secure, password-protected files with limited access. Thus, no personal identifiers will be used to store your data.
- Proper training from certified ophthalmologists for investigators performing ocular assessments
- Completing of the training course on Systane iLux through the Alcon Academy
- Training from a LipiView agent on optimal practices

What are the benefits for you in participating in this study?

You may experience several health-related benefits. These include a potential improvement in the functioning of your eyelid glands which work to lubricate your eye. You may experience reduced symptoms of dry eyes, reduced redness in your eyes, or reduced inflammation. These benefits may also contribute improved comfort of vision and reduced dry eye symptoms that can often result from cataract surgery. In addition, patients can learn more about the condition of their tear film through high resolution imaging and testing of key dry eye metrics that will be

assessed throughout the study.

Will it cost you anything to participate in this study?

The entire iLux treatment and eye function tests will be provided to you free of charge. However, you will still be responsible for all of the costs related to your medical care outside of this study, which will be billed to you or your insurance company. You will also be responsible for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be for any costs billed to your health insurance outside of this study. You will also be financially responsible for any costs of your medical care not covered by your health insurance.

Payment for participation

You will not be compensated for your participation in this study.

Alternatives to study participation/What else can you do if you do not want to be in this study?

You do not have to participate in the study to receive your regular care.

Who will have access to my records and know that you are in this study?

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to see your information and why they will be able to see it. Your physician must get your authorization (permission) to use or give out any health information that might identify you. Regulatory agencies, such as the FDA, members of the research team, study sponsor, and the GWU IRB committee will have access to the study records and know the patients involved.

What information may be used or given to others?

If you choose to be in this study, your physician or a member of the research team working on the study with your physician will get health information about you. This information might identify you, and may include:

- Medical and research records
- Name

- Date of birth/Age
- Phone Number
- Email
- Date of medical procedures
- Visit dates
- Race/ Ethnicity
- Gender
- Disease Status
- Zip Code
- Medical history
- Records about your visits and physical exams
- Laboratory and other test results
- Medications
- Hospitalization/Clinically significant events

Generally, no one other than your physician and other members of the research team working on the study with your physician will get health information about you, and research studies conducted using your information will not identify you.

What happens to my information collected for the research?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect and copy your information. Others include;

1. Research staff conducting the study.
2. Your physician, staff members of The George Washington Medical Faculty Associates who are responsible for administering clinical trials and other research activities and the study coordinator of the research team working on the study with your physician.
3. Laboratories and other individuals that analyze your health information for this study.
4. The Federal Office for Human Research Protection (OHRP) and Federal agency that oversees studies using the information in the study.

Why will this health information be used and/or given to others?

Results of this research study may be published in a scientific research journal but your identification will not be disclosed

What if you decide not to give permission to use and give out your health information?

By signing this informed consent form, you are giving permission to use and give out your health information as described above. If you refuse to give permission to participate, you cannot participate in the study.

How will my privacy and health information be protected?

The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form.

The use and release of protected health information is for the purpose of collecting data for this study. Protected Health Information to be shared includes: name, medical record #, date of birth, age, phone #, email, race/ethnicity, gender, disease status, zip code. The researcher and The other members of the research team may obtain your individual health information for data collection from Hospital and Clinic records during the study. By signing this form, you are allowing the use, sharing, copying, and release of your protected health information in connection with this study by:

- The members of the research team;
- Institutional officials who are responsible for compliance;

Once your health information (as mentioned above) is disclosed to others outside of the hospitals and medical practices, the information may no longer be covered by the federal regulation that protects privacy of health information. Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for healthcare from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct this study. This Authorization does not have an expiration date.

VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to take part in the study is completely voluntary. You are free to choose not to take part in the study and may change your mind and withdraw at any time. Any coded and de-identified medical information already submitted to the study will not be removed from the

study even if you withdraw. Your relationship with physicians at The George Washington Medical Faculty Associates and your medical care, now or in the future, will not be affected in any way if you withdraw or refuse to participate. You will not lose any benefits to which you are otherwise entitled. Your physician may terminate your participation in this study at any time without your consent if, in his/her judgment, it is inadvisable for you to continue.

To revoke this Authorization, you must write to:

Keith Wroblewski, MD
Division of Ophthalmology 1st Floor
The GW Medical Faculty Associates Washington, DC 20037

If you revoke this Authorization, The GW MFA may still use or disclose de-identified health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research.

COMPENSATION FOR INJURY

You may have medical problems from taking part in this research study. If you have any injury during the study, tell your study doctor right away. Once you tell your study doctor, he will either provide you with or refer you to proper medical treatment.

If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away. This can be done through:

- GWU Hospital and/or the GWU MFA or
- Your physician or
- Treatment center of your choice.

You should contact the study doctor as soon as possible about any illness or injury. There are no plans for GWU Hospital and/or the GWU MFA to pay you for any injuries or illnesses. There are no plans to pay you for lost pay or other losses, but you do not give up any legal rights by signing this form and may have other legal options. If you have medical insurance, please check with your insurance company that taking part in this study will not affect your policy.

SOURCE OF FUNDING

This study is funded by the Gill Fellowship

QUESTIONS

If you have any additional questions later on, or if you wish to report a medical problem that may be related to the study, Keith Wroblewski can be reached at (202) 741-2800 during office hours, or by email at kwroblewski@mfa.gwu.edu.

If you have any questions about your rights as a research subject and/or your participation in the study and would like to talk with an institutional representative who is not part of the study, you can call the George Washington University Institutional Review Board at (202) 994-2715.

Do not sign this informed consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Agreement to Participate: Witnessing and Signature

To be in this study, you or your legal representative must sign this page. Before signing, you should be sure of the following:

- I have had time to read this information and think about the study and my questions have been answered properly.
- I agree to take part in this research study.
- I have been informed on the way my coded personal information and samples may be collected, used and shared as described in this document

	Yes	No
I have read all the information in this form. I have been given the chance to discuss it and ask questions. All my questions have been answered to my satisfaction. I understand I will receive a copy of this form.	☐	☐

By signing this information and consent form, I have not given up any of the legal rights, which I otherwise would have as a subject in a research study. I authorize the collection, use and disclosure of my health information in accordance with this form, including transfer to countries outside of the United States.

You must be given a signed copy of this informed consent form to keep for yourself.

Print Name of Participant Signature of Participant Date

Print Name of Person Obtaining Consent Signature of Person Obtaining Consent Date

By signing above, the person obtaining informed consent confirms that: (i) he/she has discussed the study with the participant named above (including explaining the study and reviewing this informed consent form with, the participant); (ii) this informed consent form was left with the participant and he/she was given time to consider whether or not to be in the study; (iii) the participant was provided with an opportunity to ask questions about the study and have them