A Multi Center, Peri-Cataract Evaluation of TearCare with Expression on Ocular Biometry and Surgical Measurements (PRECISE)

Protocol Number: TC-2026-TearCare

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Study Design: IIT, Prospective, multicenter, interventional study (2 centers) and 72 eyes (approximately 36 subjects depending on laterality)

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1. Background and Rationale

Dry eye disease (DED), particularly meibomian gland dysfunction (MGD)-driven DED, is highly prevalent in the cataract-age population and significantly impacts the accuracy and repeatability of pre-operative corneal measurements. Instability of the tear film may result in variability in keratometry, corneal topography, higher order aberrations (HOA), and intraocular lens (IOL) power calculations.

The TearCare System is an in-office therapeutic system designed to treat MGD through localized thermal eyelid therapy followed by gland expression cleared. Improving tear film stability may enhance corneal measurement reliability and help determine the appropriate timing for cataract surgery planning.

This study evaluates whether TearCare treatment stabilizes corneal measurements sufficiently to determine when cataract biometry can be considered reliable.

2. TearCare Device

2.1 Device Description

The Sight Sciences' TearCare System being studied in this study is FDA 510 cleared and comprised of the following components:

- SmartLid™ devices
- SmartHub™ Kit, including SmartHub, SmartHub Nest, and Charging Adapter
- Clearance Assistant Plus™ devices with debridement edge

The SmartLid devices are custom designed to conform to the tarsal plate of each respective eyelid allowing subjects to blink normally throughout the procedure and naturally express melted meibum with every blink. Immediately following the thermal procedure, the physician uses the Clearance Assistant device to further express the meibomian glands manually to maximize the evacuation of melted meibum. The Clearance Assistant also provides a tool for debridement to thoroughly remove any blockages at the meibomian gland orifices to facilitate and enhance natural and manual meibum evacuation.

The SmartLid Devices, shown below in Figure 1, are single-use, flexible, sensor-controlled devices that adhere to each of the 4 eyelids. They contain flexible circuits, sensors and a microprocessor which provide accurate and precise thermal energy to the eyelids to melt oil in the meibomian glands. Medical grade adhesive on the skin-facing surface of the SmartLid devices allow them to be affixed to the external surface

of the eyelids during the procedure and easily removed at the end of the procedure. The flexibility of the SmartLid devices permit them to remain attached to the eyelids throughout the procedure while subject blinks normally.

The SmartLid devices are connected to the SmartHub via a cable. The SmartHub, shown in figure 2, delivers electrical energy to the SmartLids, and this energy is subsequently converted into thermal energy. Embedded software and a closed loop sensor system ensures that the temperature delivered at the eyelids is maintained within a precise range. A control button on the center of the SmartHub is used to turn the system on and off and to initiate or discontinue the TearCare session. Two buttons, "+" and "-", on the left side of the face of the SmartHub allow the user to adjust the temperature to a level that is comfortable for the patient. The current warmth setting is indicated by the warmth level indicators between the two adjustment buttons. The SmartHub also has a display on the right side of its face that indicates how much time is left in the session. The SmartHub is battery operated, with a built-in battery, and is recharged by placing it on the charging nest.

The clearance assistance device, shown in figure 3, is a single use, sterile device that is designed to facilitate manual expression of the meibomian glands after the application of heat by the TearCare SmartLid devices.

Figure 1: SmartLid Devices applied to the Eyelids



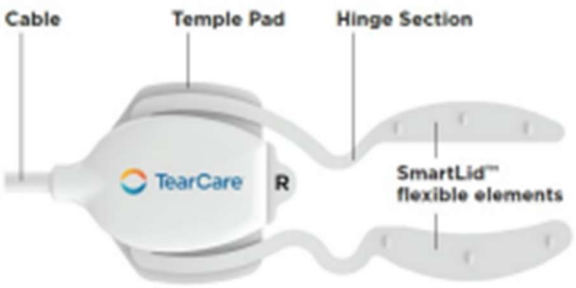


Figure 2: TearCare SmartHub



1. Power Button
2. Warmth Setting Increase Button
3. Warmth Setting Indication #4 (of 5)
4. Active Therapy Indicator
5. Warmth Setting Decrease Button
6a. SmartLid Port- Left
6b. SmartLid Port – Right
7. Charging Port
8a. SmartLid Error Indicator – Left
8b. SmartLid Error Indicator - Right
9. Remaining Procedures
10. Timer Complete Indicator
11. Timer Indicator

Figure 3: Clearance Assistant Plus Device



2.2 Instructions for Use

Instructions for use of the device are listed in Appendix A.

3. Study Hypothesis

TearCare treatment will improve ocular surface stability in MGD-driven DED patients, resulting in improved repeatability and stability of corneal measurements and IOL power calculations, thereby helping determine the appropriate timing for cataract surgery.

4. Risk-Benefit Analysis

4.1 Anticipated Clinical Benefits

The TearCare® procedure will be performed with the aim of reducing the signs and symptoms of dry eye.

4.2 Anticipated Adverse Device Effects

Anticipated adverse effects associated with the TearCare System have been described in Section 14.

4.3 Risk Associated with being in this Clinical Trial

All anticipated study risks are listed in Section 14.

4.4 Possible Interaction with Concomitant Medical Treatment

It is anticipated that there will be no interactions with concomitant medical treatments.

5. Study Objectives

5.1 Primary Objectives

1. To determine the mean change and stability in IOL predicted power calculation using:
    - Barrett Universal II
    - Kane formula

- Hill-RBF

2. Stability is defined as ≤0.25 D difference between post-TearCare visits at 2, 4, or 6 weeks

5.2 Secondary Objectives

1. Mean change/stability in Keratometry (Tmax) from baseline and at 2, 4, 6, and 8 weeks
    - Stability defined as ≤0.25 D between visits
2. Mean change/stability in Total Corneal Refractive Power (Pentacam)
3. Mean change in:
    - SPEED score
    - OSDI score
    - Corneal staining (Oxford scale)
    - TBUT
    - HOA (central 4mm zone)
4. Percentage of patients demonstrating improvement in SPEED and OSDI
5. Determination of earliest timepoint at which corneal and IOL calculations stabilize

6. Endpoints

6.1 Primary Endpoints

1. Mean change/stability in Keratometry (Tmax) from baseline and at 2, 4, 6, and 8 weeks
    - Stability defined as ≤0.25 D between visits
2. Mean change/stability in Total Corneal Refractive Power (Pentacam)

6.2 Secondary Endpoints

1. Mean change in:
    - SPEED Score
    - OSDI Score
    - Corneal Staining (Oxford Scale)
    - TBUT
    - HOA (central 4mm zone)
2. Percentage of patients demonstrating improvement in SPEED and OSDI
3. Determination of earliest timepoint at which corneal and IOL calculations stabilze

7. Statistical Considerations

- Descriptive statistics for all continuous variables
- Repeated measures ANOVA or mixed-effects modeling
- Stability analysis via absolute inter-visit difference
- Significance level $\alpha = 0.05$
- Analysis per eye
- Exploratory subgroup analysis may evaluate early stabilization (Week 2 vs Week 4 vs Week 6 vs Week 8).

8. Study Design and Timeline

36 patients (72 eyes) between two sites. Max of 20 patients per site. Prospective, interventional, multicenter study over approximately 3 months.

Visit Schedule:

- Visit 1 (Day 0): Baseline + TearCare Treatment
- Visit 2 (Day 10–17)
- Visit 3 (Day 25–35)
- Visit 4 (Day 37–47)
- Visit 5 (Day 49–62)

Follow-up visits correspond approximately to Weeks 2, 4, 6, and 8.

9. Enrollment Criteria

9.1 Inclusion Criteria

1. Age 50–75 years
2. Diagnosis of MGD and DED
3. OSDI score 23–79
4. TBUT > 1 second and ≤ 7 seconds
5. MGSS <12 in both eyes
6. ≥15 expressible meibomian glands
7. Candidate for cataract surgery planning (ie. Phakic)

9.2 Exclusion Criteria

1. Use of:
    a. Cyclosporine, Xiidra, or serum tears within 30

    days prior to Screening;

    b. Antihistamines (oral or topical) within 7 days prior to Screening;

    c. Oral tetracyclines or azithromycin within 30 days prior to Screening;

    d. d. Topical ophthalmic antibiotics, anti-glaucoma medications, steroids, non-steroidal anti-inflammatory medications within 30 days prior to Screening

    e. e. Isotretinoin (e.g. Accutane) at any time.
2. Any of the following dry eye treatments:
    a. Office-based dry eye treatment (e.g. IPL, TearCare, thermal pulsation [LipiFlow], iLuxetc.) within 12 months prior to Screening either as part of routine care or clinical investigation;

    b. Planned or recent surgical procedures to the eye or eyelid (90 days prior to Screening);

    c. Meibomian gland expression within 6 months prior to Screening;

    d. Blephex or debridement within 3 months prior

to Screening;

e. Punctal occlusion (including collagen, e.g. Soft Plug, UltraPlug, or crosslinked hyaluronic acid, e.g. Lacrifill) or punctal plugs within 15 days of the Screening visit;

f. Use of tear neurostimulators (i.e., True Tear, iTear100, Tyrvaya) within 2 weeks of the baseline visit. (Subjects must refrain from using tear neurostimulators for the duration of the study)

g. Any history of meibomian gland probing.

3. History of eyelid, conjunctiva, or corneal surgery (including refractive surgery) within 12 months prior to Screening.
4. Any history of chalazion surgery, surgery on the tarsal conjunctiva, radial keratotomy (RK), complicated blepharoplasty, lid reconstruction, or significant complications post-refractive surgery.
5. Contact lens use within 2 weeks of the Procedure visit. Subjects presenting at the Screening visit using contact lenses must agree to discontinue use for a full 2 weeks (14 days) prior to the Procedure Visit.
6. Active hordeolum, stye, or chalazion at the time of the Screening visit
7. History of Herpes Simplex or Herpes Zoster of the eye or eyelid.
8. Any active, clinically significant ocular or peri-ocular infection, inflammation, or irritation based on Investigator's judgement.
9. Recurrent clinically significant eye inflammation, other than dry eye, within 3 months prior to screening based on Investigator's judgement.
10. Clinically significant anterior blepharitis. In addition, collarettes or flakes of more than one quarter of the eyelid are excluded.
11. Clinically significant eyelid abnormalities in either eye (e.g. entropion/ectropion, blepharospasm, aponeurotic ptosis, lagophthalmos, distichiasis, trichiasis).
12. Clinically significant dermatologic or cutaneous disease of the eyelid or periocular area based on Investigator's judgement.
13. In the clinical judgement of the Investigator, meibomian glands have significant capping, atrophy, or are unable to be expressed, digitally or with a cotton swab.

14. Corneal surface abnormalities such as corneal epithelial defects (other than punctate staining), ulcers, corneal epithelial dystrophies, keratoconus, and ectatic disease of the cornea
15. Any active, clinically significant allergic, vernal, or giant papillary conjunctivitis.
16. Ocular trauma within 3 months prior to Screening.
17. Known history of diminished or abnormal facial, periocular, ocular or corneal sensation
18. Systemic diseases, in the Investigator's medical judgement, resulting in dry eye (e.g. autoimmune diseases such as Sjogren's syndrome, rheumatoid arthritis, lupus, Graves' disease, sarcoidosis, etc.)
19. Subject is currently using Retin A /Retin A derivatives.
20. Subject has permanent eyeliner/lid tattoos, eyelash extensions or wears false eyelashes.
21. Subject is currently using Latisse, Lash Boost or any other type of eyelash growth serum. Prostaglandin analog products such as Latisse should not be used within 30 days of the Screening visit.
22. Temporary false eyelashes, lash extensions, or any other type of false eyelash within 15 days of the Screening Visit.
23. Allergies to silicone tissue adhesives, acrylates and/or copper.
24. Subject has a pacemaker or implantable cardiac defibrillators (ICD).
25. Co-existing condition, either ocular or non-ocular that, in the judgement of the Investigator could affect the safety or effectiveness of treatment or the compliance of the subject to the protocol.

10. Study Visits and Procedures

Procedures required by the protocol to be conducted at each study visit are listed in the Study Visit Schedule and Appendix A, Methods of Clinical Evaluations.

10.1 Visit Schedule

Assessments	V1 (Day 0)	V2 (Day 10 – 17)	V3 (Day 25 – 35)	V4 (Day 37 – 47)	V5 (Day 49 – 62)
Informed Consent	X				
Inclusion/Exclusion	X				
Concomitant Medications	X	X	X	X	X
SPEED Score	X	X	X	X	X
OSDI Score	X	X	X	X	X
BCDVA	X	X	X	X	X
Slit Lamp Exam (SLE)	X	X	X	X	X
Hyperemia Grading	X	X	X	X	X
Corneal Staining (Oxford)	X	X	X	X	X
TBUT	X	X	X	X	X
MGSS	X				
MGYSS	X				
Biometry (Axial Length)	X	X	X	X	X
Corneal Topography (HOA – 4mm)	X	X	X	X	X
TearCare Procedure	X				
AE Assessments	X	X	X	X	X

11. Subject Recruitment and Screening Procedures

Potential subjects will be recruited from Investigator's clinic, walk-ins and referrals from other physicians. They will be given a copy of the informed consent and ample time to read it over to decide if they want to participate. If they decide to proceed, the informed consent will be signed prior to any study procedures.

12. Subject Disposition

12.1 Enrolled Subjects

An enrolled subject is defined as a subject who agreed to participate in this clinical trial following completion of the informed consent process during a Screening Visit.

12.2 Subject Withdrawal

All subjects have the right to withdraw consent at any time without prejudice. This includes, but is not limited to:

- AEs
- Protocol Violations
- Withdrawal of consent
- Termination of study by Sponsor
- Termination of study by Site

Notification of a subject's withdrawal and the reason for withdrawal will be documented on the subject's End of Study case report form.

12.3 Lost to Follow Up Subjects

All efforts should be made by the Investigator to retain the subject in the study. At least three attempts should be made to reach the subject and documented prior to being considered lost to follow up.

12.4 Completed Subjects

A subject is considered completed when they successfully complete all study visits. Completion date will be documented on End of Study case report form.

13. Study Discontinuation and Early Withdrawal of Subjects

Investigator has the right to terminate the study at any time with appropriate notification. Reasons for early termination include but are not limited to:

- Subject safety
- Failure to comply with the protocol, the requirements of the IRB/IEC or local health authorities, the sponsor's procedures, or GCP guidelines
- Inadequate or no recruitment (evaluated after a reasonable amount of time) of subjects by the investigator

If the study is terminated, every effort should be made to obtain an early termination visit from all subjects. All final follow up visits are to be completed prior to site closure and End of Study form are to be completed for every subject.

14. Safety Definitions and Adverse Event Management

All ocular adverse events will be documented in the subject's records. Non-ocular events do not need to be recorded unless they are considered a serious adverse event (SAE) or are believed to be related to the study device or study procedure. Both ocular and non-ocular serious adverse events (SAE) will be collected. Medical conditions present at the time of enrollment will be considered pre-existing conditions and will not be recorded as adverse events unless a clinically significant worsening occurs during the study and fit criteria.

14.1 Definitions of AE, SAE, ADE and UADE

Adverse Event: Any untoward medical occurrence in a subject who has been treated with the device that does not necessarily have causal relationship with the treatment.

Serious Adverse Event: Any untoward medical occurrence that:

- Results in death
- Is life-threatening
- *Requires in-patient hospitalization or prolongs existing hospitalization*
- *Neces*sitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure
- Sight threatening

Adverse Device Effect: Any unfavorable and unintended sign (including an abnormal laboratory finding), symptoms, or disease that is possibly related to the study device

Unanticipated Adverse Device Effect: Any serious adverse effect on health or safety, any life threatening problem or death caused by, or associated with a device if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the clinical investigational plan; or any other serious problem associated with a device that relates to the rights, safety, or welfare of subjects (21 CFR 812.3(s)). Any sight-threatening event, whether listed in the protocol or not, is considered to be reportable as a UADE

14.2 List of Anticipated Potential Ocular Adverse Events

Anticipated ocular adverse events are those reasonably expected to occur due to dry eye disease, use of the TearCare System, or study testing methods.

- Eyelid/eye pain requiring discontinuation of the study procedure
- Eyelid/eye pain requiring treatment ≥1 day after the study procedure
- Eyelid irritation, or inflammation

- Discomfort or pain of eyelids or orbit
- Ocular symptoms (such as burning, redness, tearing, visual disturbance, redness)
- Burn, erythema, or swelling of the eyelids
- Thermal injury to the eye, including conjunctiva, cornea or lens
- Allergic or inflammatory reaction to medical adhesive on the SmartLid device
- Physical pressure-induced injury to the eyelid
- Corneal deformation
- Foreign body sensation
- Formation of a chalazion or stye
- Infection of the eyelid or ocular surface
- Ocular surface irritation or inflammation (e.g., Conjunctival injection, conjunctival or corneal abrasion, chemosis)
- Allergic or inflammatory reaction to the SmartLid
- Worsening of dry eye symptoms
- Loss in BCVA (ETDRS) of ≥10 letters

14.3 Identification, Documentation and Reporting

Identification, documentation and reporting of an AE begins after informed consent has been obtained and documented. Standard sources of identifying AEs include:

- direct observation by Investigator
- asking the subject a non-specific question (e.g., “Have you had any problems since the last visit?”)
- volunteering of information by the subject (e.g., “I have had red eyes since my last visit.”)
- test results that meet the protocol requirements for classification as an AE

All adverse event information will be documented on the “Adverse Event” form and filed in the subject’s records. Information to be collected:

- Adverse Event Term
- Location
- Severity
- Relationship to study procedure
- Seriousness
- Anticipated or unanticipated
- Treatment
- Outcome

All Adverse Events, Serious Adverse Events and Adverse Device Effects are to be reported to the Principal Investigator and delegated personnel within 24 hours of the site learning of the event. Record all required information on the "Adverse Event" form and email it to Principal Investigator and delegated personnel.

Any unanticipated adverse device effects (UADE) must be reported to the following two entities:

1. The Principal Investigator – Within 24 hours of the Investigator first learning of the event, record all applicable information in the source document and email it over to the Principal Investigator and delegated personnel.
2. The reviewing IRB – As soon as possible, but no later than 10 working days after the investigator first learns of the event, report per the IRB's instructions.

15. Study Oversight Plan

All data and safety monitoring will be conducted remotely by the Investigator and designated research member from his team.

15.1 Site Initiation Visit

Prior to subject enrollment, the Principal Investigator and Study Lead will conduct a remote training session with the clinical study staff once the site is prepared to begin recruitment. The training will cover proper subject selection, execution of study procedures, and accurate documentation of study data. The session will include, but not be limited to, a review of the following:

- Detailed review of the protocol
- Informed consent procedures
- Instructions on how to use the TearCare System
- Instructions on how to perform study procedures
- Guidance in how to administer questionnaires to subjects
- Records and reports

15.2 Interim Visits

Case Report Forms for all study visits will be sent to the Study Lead after each visit to be reviewed with the Principal Investigator, queried if necessary, and then entered in the database once completed.

15.3 Close Out Visit

At the conclusion of the trial there will be a study closure remote visit during which several actions, including but not limited to the following, will be performed:

- A final review of the study binder
- Accountability and return of all devices and study materials to the sponsor
- Discussion of record retention requirements with the Investigator
- Close-out Report/Notification to IRB

15.4 Audits and Inspections

Audits and inspections may be conducted to verify that the clinical trial is performed ethically, safely, and in accordance with Good Clinical Practice (GCP) guidelines and applicable regulatory requirements. If an audit or inspection is requested, the Principal Investigator and Study Lead must be notified immediately.

16. Medical Monitor Plan

The Medical Monitor for this study is Thomas Chester, OD. Throughout the study, his role will be to ensure patient safety, data integrity and regulatory compliance of this study. The Medical Monitor will review study data to ensure accuracy safety and give his expertise when required. Some of the data to be reviewed:

- Protocol Deviations
- Adverse Events and SAEs
- Case Report Forms

17. Data and Safety Monitoring

All data and safety monitoring will be conducted by the Investigator and designated research member from his team.

- Continuous adverse event monitoring
- Documentation of device-related complications
- Reporting per institutional IRB requirements

The investigator will take all appropriate measures to ensure that the anonymity of each study patient will be maintained. The patient's and investigator's personal data will be treated in compliance with all applicable laws and regulations. Subject data recorded on case report forms during the clinical investigation will be documented in a coded fashion. The subject will only be identified by the unique subject number

18. Data Management

The study database will be created using Microsoft Excel. Data will be entered directly from case report forms or copies of the case report forms. The database will be maintained by the Principal Investigator or delegated staff and entered data will be validated prior to database lock.

19. Records Retention

Clinical sites are to retain all clinical trial material (documentation, photographs, etc.) for a period of two years from the date a marketing application is approved or two years after the investigation has been discontinued, or as directed by their institutional document retention requirements, whichever is the longest. Unused medical devices are to be returned to the sponsor at the conclusion of the enrollment period.

20. Study Funding

All funding for this study is provided by Sight Sciences.

Appendix A: Methods of Clinical Evaluations

1. **Informed Consent:** The IRB-approved informed consent form must be signed before any study-related assessments or procedures are conducted. Participants should be provided with sufficient time to carefully read and review the consent form so they can make an informed decision about participation. Before signatures are obtained, the Investigator or authorized study personnel will review the consent form with the participant to confirm understanding and answer any questions. A signed copy of the consent form will be provided to the participant, while the original signed document will be maintained in the participant's study file.

2. **Questionnaires:** Questionnaires are to be completed at the beginning of each visit prior to any other assessments. They are to be completed in blue or black pen and by the subject. The subject is to initial and date at the end of each questionnaire. Prior to the subject leaving the office, check the questionnaire for completion and accuracy.
   - **SPEED -** "SPEED" stands for "**S**tandard **P**atient **E**valuation of **E**ye **D**ryness." Scores range from 0-28 (0-4: mild, 5-7: moderate, 8+ severe)
   - **OSDI** - "**O**cular **S**urface **D**isease **I**ndex" has 12 questions. Based on the answers provided by the subject, study staff will calculate the overall OSDI Total score and scores for the three subscales according to the OSDI instructions. Based on the recommended cutoffs for OSDI Total score, the severity of the subject's dry eye symptoms will be categorized as follows: Normal 0-12, Mild 13-22, Moderate 23-32 and Severe 33 or higher

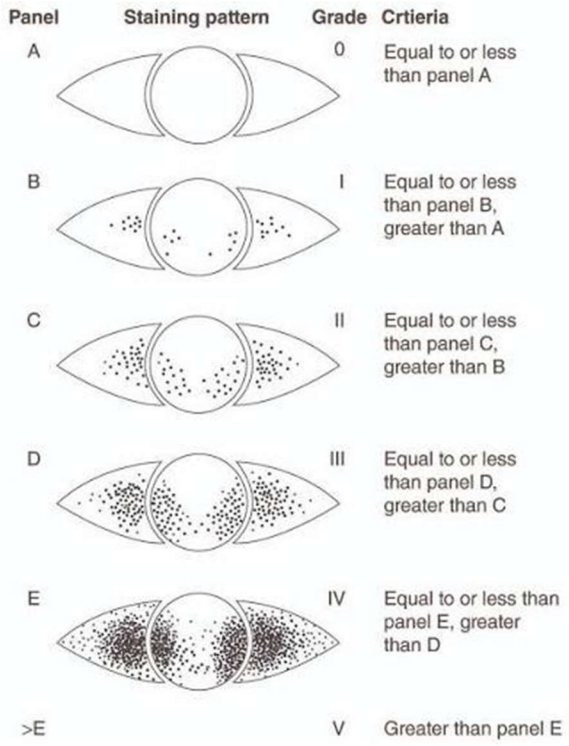
3. **Best Corrected Visual Acuity (BCDVA)** – To be recorded in Snellen for each eye separately using current glasses or most recent historical manifest refraction. Ensure the room is well-lit and the patient is 20 feet away from the chart (a projector, mirror or electronic chart can be used to create a 20-foot distance in a shorter room) Record the line number the subject can read with no more than two errors as their visual acuity (ex: if they can read the 20/40 line but miss two letters, the result is documented as 20/40 - 2.)

4. **Tear Break-Up Time (TBUT)**
   - Using a fluorescein strip with saline solution or a Fluress strip, install a drop into each eye
   - Ask the subject to blink several times and to move the eyes to mix the fluorescein in the tears

- Use the cobalt blue illumination of the slit lamp and a Wratten filter. Use a beam width of approximately 4 mm, and full height. Move the beam slowly from side to side to cover the entire cornea
- Ask the subject to blink 3 times and then hold their eye open
- Record the time when the tear film breaks-up. The time from upstroke of the last blink to the first tear film break or dry spot formation is recorded as the TBUT measurement.

5. **Corneal Staining (Oxford Scale)** - The Oxford Scheme will be used to assess ocular surface staining. Staining will be represented by punctate dots on a series of panels (A – E). Assess each eye in the same order as fluorescein was instilled.

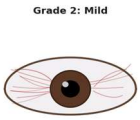
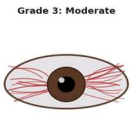
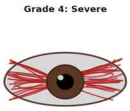
Diagram 1



- Instill one drop of fluorescein solution into each eye
- Have the patient blink a few times to allow the fluorescein to mix with their tears
- Using the cobalt blue illumination filter, the Investigator will asses the cornea by matching the density and distribution of the stained, punctate spots to the Oxford Panels (Diagram 1)

6. **Hyperemia Grading** – Conjunctival hyperemia will be assessed by a trained, masked evaluator at each study visit using a standardized 5-point grading scale (Grade 0–4), adapted from validated reference scales such as the Efron and CCLRU grading systems. Grading will be performed via slit-lamp biomicroscopy under

standardized illumination, with the evaluator comparing the participant's bulbar conjunctiva to the reference images below prior to assigning a score. To minimize inter-rater variability, all evaluators will complete training and calibration against the reference scale prior to study initiation, and a subset of assessments may be photographed for quality assurance and inter-rater reliability review. Any adverse increase in hyperemia grade (e.g., a shift of ≥2 grades from baseline) will be documented and reported in accordance with the study's adverse event reporting procedures

Grade	Image	Category	Clinical Description
0		None	No clinically visible redness; sclera appears white and healthy with no detectable vessel dilation.
1		Trace	Trace redness with minimal, barely perceptible vessel dilation in a localized area.
2		Mild	Mild but definite redness involving a limited area of the bulbar conjunctiva.
3		Moderate	Moderate redness with noticeable vascular engorgement across a broader area.
4		Severe	Severe, diffuse redness with marked vessel dilation across the conjunctival surface.

7. **Slit Lamp Exam (SLE)** - A standard slit-lamp examination shall be performed including inspection of the cornea at a magnification of 10X and/or 16X

8. **Biometry** – Biometry measurements will be performed with the IOL Master or the Argos for this study. Sites will redact the printout from any PHI, write the subject

number on it and send it over to the Study Lead. The Study Lead will run all formula calculations through their corresponding website calculators:

a. Barrett Universal II IOL Calculation: https://www.ascrs.org/en/tools/barrett-toric-calculator
b. Kane Formula Calculation: https://www.iolformula.com/
c. Hill-RBF Calculation: https://rbfcalculator.com/online/index.html

Data from the calculations will then be entered into an excel spreadsheet.

9. **Corneal Topography -** Measurements will be performed with the Pentacam for this study. Once acquired, run displays for HOA-4mm (high order aberrations), Tmax and Total Corneal Refractive Power (Corneal Power Distribution, 4 Map Refractive and Cataract Pre-Op)

10. **Meibomian Gland Yielding Liquid Secretion (MGYLS) Test** - The MGYLS test assesses the number of meibomian glands expressing liquid (clear or non-cloudy) secretion upon manual expression. With the patient seated at the slit lamp, gentle digital pressure is applied along the lower eyelid margin over the central 15 glands of the lower lid, using a cotton swab or standardized meibomian gland evaluator (e.g., Korb meibomian gland evaluator) to apply consistent, firm but non-traumatic pressure for approximately 10–15 seconds per gland or region. Each gland orifice is examined under slit-lamp magnification, and glands are scored as positive if they yield a liquid secretion upon expression. The total number of glands yielding liquid secretion is recorded per eye, providing a quantitative measure of meibomian gland function and patency.

11. **Meibomian Gland Yielding Secretion Score (MGYSS) -** The MGYSS assessment evaluates the *quality* of secretion expressed from each gland. With the patient seated at the slit lamp, gentle digital pressure is applied along the lower eyelid margin over the central 15 glands of the lower lid, using a cotton swab or standardized meibomian gland evaluator (e.g., Korb meibomian gland evaluator) to apply consistent, firm but non-traumatic pressure for approximately 10–15 seconds per gland or region. Each gland is scored on a scale (0–3) reflecting secretion characteristics. A score of 0 indicates clear, liquid meibum; a score of 1 indicates cloudy liquid, a score of 2 indicates turbid, granular, toothpaste-like secretions and a score of 3 indicates absent (no expressible) secretion. Scores from each gland assessed are summed or averaged across the examined region to generate a composite MGYSS for each

11. **TearCare Procedure:**

Standardized Meibomian Gland Expression Procedure

The following standardized expression procedure shall be performed immediately upon completion of the 15-minute thermal cycle, while the eyelid tissue remains thermally conditioned. All personnel performing expression must complete site initiation training and demonstrate procedural competency prior to enrolling subjects.

Instrument

Expression shall be performed using the **Rhein Medical Meibomian Gland Expressor Forceps (paddle-style, stainless steel, single use)** Cotton-tipped applicators or digital (finger) pressure alone are not permitted, as they do not provide the standardized, planar compression required for inter-site reproducibility

Anatomical Locations:

Lower eyelid: Expression shall be performed across the full horizontal extent of the lower tarsus, from the medial to lateral canthus, targeting the meibomian gland orifices along the posterior lid margin. The instrument shall be applied at a position approximately 1–2 mm posterior to the mucocutaneous junction (grey line), over the inferior tarsal plate.

Upper eyelid: Expression shall be performed symmetrically along the superior tarsal plate, from the medial to lateral canthus, targeting the meibomian gland orifices along the posterior lid margin. The instrument shall be applied at a position approximately 1–2 mm posterior to the mucocutaneous junction (grey line), over the superior tarsal plate.

Technique

1. Obtain a new set of SmartLid devices and a TearCare SmartHub with enough battery left for at least one procedure.
2. Position the subject at the slit lamp to perform debridement of the eyelid margin followed by expression of the meibomian glands such that expression takes place within 3 minutes of completion of the thermal portion of the procedure.
3. Apply 1 drop of proparacaine or tetracaine into each eye.

4. Visualize the lid margin and line of Marx's (LOM) and debride eyelid margins by sweeping (very gently scraping) the debridement edge across the LOM back and forth going over meibomian gland orifices. Start nasally and work laterally multiple times using gentle pressure until the eyelid margins appear free of debris, keratin, and gland capping. Often the gland orifices become visible at this point.

5. Wipe the subject's eyelids and temple with the TearCare wipes. Allow the skin to dry or pat dry with a tissue. Use care not to allow any of the wipe to get into the eye.

6. Place a pair of SmartLid devices on the subject's eyelids and affix the temple housing to the subject's temple. Use the clip to secure the cables behind the subject's head.

7. Connect the SmartLid devices to the SmartHub.

8. Inform the subject that the SmartLid devices will heat up very quickly once the TearCare procedure is started.

9. Start TearCare procedure. Subjects should be encouraged to keep their eyes open and blink naturally during the TearCare procedure.

10. If the subject indicates the temperature is too hot, decrease the temperature set point to a setting that is comfortable for the subject.

11. Following completion of the thermal cycle and removal of the SmartLids, instill one drop of topical anesthetic (proparacaine 0.5% or equivalent) in the study eye(s) per site standard of care.

12. Position the subject at the slit lamp or in a reclined exam chair with adequate fixation.

13. Place the flat plate of the expressor forceps against the anterior surface of the eyelid (skin side) and the opposing paddle against the posterior (conjunctival) surface at the medial-most gland location.

14. Apply firm, steady, compressive pressure perpendicular to the lid margin for **2 seconds per gland location**, then release fully before advancing to the adjacent location.

15. Advance the expressor in approximately **2 mm increments** laterally, repeating the 2-second compression at each location until the full tarsal width has been expressed.

16. A single pass (medial-to-lateral) constitutes one expression sweep. The protocol mandates **two complete expression sweeps per eyelid** per treatment session.

Extent and Endpoints: Expression shall cover 100% of the accessible tarsal width. The endpoint of expression at each location is defined as the visible egress of meibum from the gland orifice or, in glands producing no secretion despite adequate compression, completion of the 2-second dwell time. The examiner shall not apply prolonged or repeated compression to a single gland orifice in an attempt to force secretion; this is documented as a non-expressive (obstructed or atrophic) gland.

Grading and Documentation: Immediately following expression, the examiner shall grade meibum quality and expressibility using the **Meibomian Gland Yielding Liquid Secretion (MGYLS)** scale or the protocol-specified grading instrument at the pre-defined gland evaluation zones (nasal 5 glands, central 5 glands, temporal 5 glands of the lower lid), consistent with the TFOS DEWS II standardized assessment framework.

Safety Constraints: The procedure shall be terminated and an adverse event report initiated if visible conjunctival or tarsal hemorrhage occurs, or if the examiner notes eyelid margin abnormality inconsistent with baseline findings.