FULL PROTOCOL TITLE: The Impact of Contact Lens Coefficient of Friction (CoF) on the Development of Lid Wiper Epitheliopathy (LWE)

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PRINCIPAL INVESTIGATORS:

Eric Ritchey, OD, PhD
Clinical Assistant Professor
University of Houston College of Optometry
ERRitche@central.UH.edu
713-743-1933

Rachel Redfern, OD, PhD
Assistant Professor
University of Houston College of Optometry
Rredfern@central.uh.edu
713-743-1943

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1.0 Objectives

The primary study objectives are to determine the amount of Lid Wiper Epitheliopathy (LWE) induced in subjects after contact lens fitting that do not have LWE at study enrollment. Subjects in the trial will be fit in 2 contact lenses with different coefficients of friction (CoF). One eye will be fit in a contact lens with a low coefficient of friction (Acuvue Oasys®, Johnson & Johnson Vision, Jacksonville FL) while the contralateral eye will be fit in a contact lens with a high CoF (Air Optix® Night & Day® Aqua, Ft. Worth, TX), as reported in the scientific literature. The eye receiving each lens will be assigned randomly. The presence of LWE will be assessed at 2 different time points:

- Approximately 2 hours after contact lens fitting and
- After 7(±2) days of contact lens wear

Study Hypotheses: Contact lenses with a greater coefficient of friction will induce a greater amount of LWE than contact lenses with a lower coefficient of friction. The presence of LWE will be assessed at 2 different study time points. As such, the following hypotheses will be tested:

After one week of contact lens wear

- H_{01}: There is no statistically significant difference in the amount of LWE between contact lenses with different coefficients of friction
- H_{a1}: There is a statistically significant difference in the amount of LWE between contact lenses with different coefficients of friction

After 2 hours of contact lens wear

- H_{02}: There is no statistically significant difference in the amount of LWE between contact lenses with different coefficients of friction
- H_{a2}: There is a statistically significant difference in the amount of LWE between contact lenses with different coefficients of friction

2.0 Background

Today in clinical practice, dropout from contact lens wear remains a significant problem, with up to 34% of patients discontinuing lens wear. Contact lens discomfort is one of the main causes of contact lens dropout. There are many factors that may play a role in contact lens comfort, but the primary factor may be the interaction of the eyelid and the contact lens material. It has been proposed that reduced contact lens lubricity, a measure of the friction inherent to a contact lens material, may lead to increased contact lens discomfort. Contact lens lubricity can be described by the coefficient of friction (CoF) of the contact lens material. CoF has been reported to be inversely proportional to reported contact lens comfort; therefore, materials with a higher CoF tend to be less comfortable.

While CoF is a useful laboratory metric, it cannot be measured clinically. Therefore, a clinical corollary for CoF may be useful in determining which contact lens materials will minimize the potential for contact lens dropout. A possible clinical corollary for CoF is Lid Wiper Epitheliopathy (LWE), which has been reported to be related to contact lens discomfort. LWE leads to a loss of superficial epithelial cells in the lid wiper region of the eyelid. If CoF is indeed related to contact lens discomfort, subjects wearing a high CoF lens could potentially develop greater amounts of LWE compared to that observed with a low CoF lens.

While previous studies have determined the amount of LWE present in habitual contact lens wearers and non-contact lens patients, it is currently unknown how quickly LWE may develop in patients after contact lens fitting. Development of LWE in the post-contact lens fitting period may allow clinicians to predict the potential for contact lens discomfort and future dropout. This pilot study will collect data examining the development of LWE in the period immediately following contact lens fitting (2 hours post-fit) and after approximately 1 week of contact lens wear, corresponding to the time for a typical post-contact lens fitting assessment in clinical practice.

3.0 Inclusion and Exclusion Criteria

Potential study subjects must meet the following study inclusion criteria:

1. Must be able to read and understand the study informed consent
2. Must be a minimum of 18 years of age and less than 46 years of age at study enrollment
3. Must be healthy non-soft contact lens wearers (neophytes), or experienced contact lens wearers that have not worn their contact lenses for a minimum of 7 days
4. Have a spherical equivalent refractive error between –0.75 to –6.50DS at the spectacle plane
5. The subject must be able to attend study visits at the prescribed visit times and adhere to the study instructions

Potential study subjects cannot meet any of the following study exclusion criteria:

1. Pregnant and/or lactating females by self-report
2. Presence of current LWE on the upper eyelid (>0.5 in height or width)
3. Has greater than –1.00DC of refractive cylinder
4. Has greater than 1.00D of anisometropia
5. Is aphakic
6. Has clinically significant corneal or conjunctival staining that would prevent contact lens fitting, as assessed with sodium fluorescein dye

7. Has significant ocular surface disease (e.g. Sjögrens Disease, Stevens-Johnson Syndrome, etc.) or significant Dry Eye Syndrome
8. Has clinically significant corneal vascularization or central corneal scaring
9. Has active ocular surface infection (e.g. conjunctivitis)
10. Has a positive history of eyelid surgery or trauma
11. Has a positive history of refractive surgery
12. Takes medications that significantly impact contact lens comfort and/or ocular surface health
13. Has taken part in another contact lens or contact lens solution clinical trial within the last 7 days
14. Is unwilling to have eyes photographed or video recorded

Potential subjects will be initially screened for study eligibility through collection of demographic data and medical history. An upper age limit for study inclusion is set at 46 years of age to 1) prevent the inclusion of presbyopic patients (i.e. those that need bifocal glasses), given that the contact lenses used in the study are single vision contact lenses and 2) reduce the number of individuals who would screen fail due to significant dry eye disease. Subjects will complete a questionnaire, the Ocular Surface Disease Index (OSDI), and subjects with a score ≥23 will be excluded from the study. A slit lamp evaluation will be performed to screen for the presence of LWE of the upper lid and for significant corneal/conjunctival staining that would prevent contact lens fitting. If the subject does not have LWE, the subjects will be refracted to determine eligibility based on their refractive error. If the refractive error is within the study specified inclusion criteria, the subject will be fit into contact lenses.

4.0 Vulnerable Populations

The following vulnerable populations will be excluded from the study:

1. Adults unable to consent
2. Individuals who are not yet adults (infants, children, teenagers under the age of 18)
3. Pregnant/lactating women
4. Prisoners

The following vulnerable population may be included in the study:

1. Students for whom the principal investigators have direct access to/influence on grades.

Study subjects may be students for whom the principal investigators have access to or influence over their grades. For this reason, the principal investigators will not be responsible for recruiting or obtaining consent from students in their own

courses in order to prevent undue influence or coercion. A study team member (e.g. study coordinator) without access to or influence on grades will be responsible for these tasks.

5.0 Number of Subjects

The proposed single-site study will be conducted at The Ocular Surface Institute at the University of Houston College of Optometry. Up to 60 subjects will be screened for study inclusion, with the goal of completing 20 subjects. Subjects that screen fail may be rescreened for study inclusion up to 3 additional times at the discretion of the study investigator.

Currently, there is no information on the time from contact lens fitting to the development of LWE. This pilot study is designed to collect data which can be used to determine the sample size required to conduct a larger-scale clinical trial. It is anticipated that enrolling 20 subjects will approach the requirements of the central limit theorem for statistical analysis. Since the subjects in the study will be wearing FDA-approved contact lenses on a daily wear modality (i.e. not sleeping in contact lenses), the study does not present more than minimal risk to the subject and a power analysis is not required.

6.0 Recruitment Methods

Potential subjects will be recruited from the patients, students and staff of the University Eye Institute/University of Houston College of Optometry, as well as the surrounding community via verbal communication, print media (e.g. study fliers, newspaper adverts), telephone and electronic media (e.g email, The Ocular Surface Institute Website, social media). Additionally, potential subjects will be identified and recruited via The Ocular Surface Institute's research database.

The total duration of an individual subject's participation in the study will be approximately 1 week (±2 days). The study will consist of 3 visits on 2 days. Visit 1.1 will be a pre-fitting clinical assessment and contact lens fitting. Visit 1.2 will be a post contact lens insertion assessment completed approximately 2 hours after contact lens fitting in Visit 1.1. Visit 2 will be a 7 day (±2 days) post-contact lens fitting assessment for LWE. Expected visit timing is summarized in the table below:

Anticipated Visit Duration	
Study Visit	Duration
Visit 1.1: Baseline and Contact lens fitting	90 minutes
Approximately 2 hour waiting period	
Visit 1.2: 2-hour post contact lens insertion	55 minutes

Visit 2: 1-week post contact lens fitting	55 minutes

The anticipated duration to enroll and complete all study subjects is approximately 3 months. The estimated date for the investigators to complete primary analyses for this study is October, 2017.

7.0 Study Endpoints

The primary study endpoints are as follows:

- Examine the development of LWE post-contact lens fitting at the following time points
    - 1-week post contact lens fitting
    - 2 hours after contact lens fitting

The secondary study endpoints are as follows:

- Examine the level of expression in ocular surface tear MMPs post-contact lens fitting at the following time points
    - Pre-contact lens fitting
    - 1-week post contact lens fitting
    - 2 hours after contact lens fit

8.0 Procedures Involved

The study is a clinical trial. Twenty subjects who are either neophytes or experienced soft contact lens wearers who have not worn contacts for at least the past 7 days will be enrolled. Patients will be seen for 3 visits over a period of approximately 1 week. The pre-contact lens insertion assessment (Visit 1.1) will determine subject eligibility for the study and will take approximately 90 minutes. Subjects will then be released to a waiting room for a 2-hour waiting period. The 2-hour post contact lens fitting assessment (Visit 1.2) will take approximately 55 minutes. The 7 day post-insertion assessment (Visit 2) will take approximately 55 minutes.

Data from subject's routine medical care that is pertinent to the study (e.g. topical ophthalmic medications, oral medications, etc.) will be collected by querying the subject (see Step 1.1.3 below). This data will be considered subject source documentation and will be kept as part of the subject's study binder in a secure room in the Ocular Surface Institute (TOSI).

<u>Sequence of Events</u>

Note: Contact Lens wearing subjects should report to Visit 1 after discontinuing SCL wear for at least 7 days. Subjects should report to the visit wearing their habitual vision correction.

Visit 1.1: Screening, Enrollment and Baseline		
Step	Item	Details
1.1.1	Informed Consent	Review and complete the informed consent form
1.1.2	Subject Demographics	Collect subject demographic data
1.1.3	History	Collect subject history
1.1.4	Concommitant Medications	Collect information on concomitant medications
1.1.5	Habitual Contact Lens Information	For CL subjects, review habitual lens information and verify that they have discontinued lens wear for at least 7 days
1.1.6	Preliminary Review of Inclusion/Exclusion Criteria	Review Inclusion/Exclusion Criteria for subject study eligibility
1.1.7	Distance Visual Acuity	Perform Distance, High Contrast Visual Acuity using Snellen optotype, OD/OS with the patient's habitual correction.
1.1.8	Questionnaires: Ocular Surface Disease Index (OSDI)	All Subjects: Administer the OSDI • If OSDI scores is ≥ 23; skip to 2.9, *Final Evaluation*
1.1.9	Auto-refraction	Perform auto-refraction and record the refractive error and keratometry readings
1.1.10	Oculus Keratograph	Perform the following procedures using Oculus Keratograph, OD/OS • Non-invasive Tear Break Up Time (NITBUT) • Tear Meniscus Height
1.1.11	Phenol Red Thread	Perform Phenol Red Thread test without anesthesia, OD/OS.
1.22	Ocular Surface Tear Collection	Collect 10µL surface tears using a microcapillary tube.
1.1.12	Slit Lamp Exam with vital dye staining/LWE evaluation	Instill 1 drop of NaFL + Lissamine Green Combination Drop, wait 5 minutes, instill an additional drop, wait 1 minute, then evaluate slit lamp findings using the CCLRU grading scale and evaluate LWE

		• If ***no*** LWE is observed in both eyes, skip to *Step 2.9: Final Evaluation* and discontinue the subject from the trial • If LWE ***is observed*** in either eye, continue to *Step 1.1.13: Digital Photography*
1.1.13	Digital Photography	Perform Digital Photography of the Lid Wiper region OD/OS
1.1.14	Subjective Refraction	Perform Manifest Refraction using maximum plus to best visual acuity. • If the subject has > 1.00D refractive cylinder or greater than 1D of anisometropia, skip to *Step 2.9: Final Evaluation* and discontinue the subject from the trial
1.1.15	Subjective Spherical Equivalent Refraction	Perform Subjective Spherical Equivalent using maximum plus to best visual acuity.
1.1.16	Contact Lens Fitting	Fit subject in contact lenses based upon the randomization schedule. Initial base curve should be selected as indicated in the fitting guide for each lens. • If an acceptable contact lens fit cannot be obtained in either eye, skip to *Step 2.9: Final Evaluation* and discontinue the subject from the trial
1.1.17	Contact Lens Over-Refraction	Perform spherical over-refraction using maximum plus to best visual acuity
1.1.18	Contact Lens Power Adjustment (if necessary)	Modify contact lens power, based upon the Contact Lens Over-Refraction, if the subject gains 3 or more letters acuity
1.1.19	2 hour Waiting Period	Subjects released to waiting area for 2 hours

Visit 1.2 Note: Visit should be performed approximately 2 hours after lens insertion		
1.2.1	Visual Performance	Perform logMAR visual acuity
1.2.2	Oculus Keratograph	Perform the following procedures using Oculus Keratograph with the contact lens on eye, OD/OS • Non-invasive Tear Break Up Time (NITBUT) • Tear Meniscus Height • Video Contact Lens Fit
1.2.3	Ocular Surface Tear Collection	Collect 10µL surface tears using a microcapillary tube.
1.2.4	Contact Lens Removal	Remove the contact lenses and store in solution
1.2.5	Slit Lamp Exam with vital dye staining/LWE evaluation	Instill 1 drop of NaFL + Lissamine Green Combination Drop, wait 5 minutes, instill an additional drop, wait 1 minute, then evaluate slit lamp findings using the CCLRU grading scale and evaluate LWE
1.2.6	Contact lens Insertion and Removal Training and Dispense Contact Lens Solution	For Contact Lens Neophytes • Train on Insertion and Removal of contact lenses For all subjects • Educate subject on the proper use of the contact lens care solution
1.2.7	Exit Visual Acuity	Perform Distance, High Contrast Visual Acuity using Snellen optotype with the patient's habitual correction or contact lenses.

Visit 2: 1-Week Follow Up (±2 days) Note: Subjects should report to Visit 2 wearing their study assigned soft contact lenses.		
2.1	History	Collect subject history, compliance and reported wearing time
2.2	Visual Performance	Perform logMAR Visual Acuity
2.3	Questionnaires	Administer the OSDI to the subject
2.4	Oculus Keratograph	Perform the following procedures using Oculus Keratograph (lens on eye for CL patients, bare eye for non-CL patients, OD/OS) • Non-invasive Tear Break Up Time (NITBUT) • Tear Meniscus Height • Video Contact Lens Fit
2.5	Ocular Surface Tear Collection	Collect 10µL surface tears using a microcapillary tube.
2.6	Contact Lens Removal	Remove the contact lenses and store in solution
2.7	Slit Lamp Exam with vital dye staining/LWE evaluation	Instill 1 drop of NaFL + Lissamine Green Combination Drop, wait 5 minutes, instill an additional drop, wait 1 minute, then evaluate slit lamp findings using the CCLRU grading scale and evaluate LWE
2.8	Digital Photography	Perform Digital Photography of the Lid Wiper region OD/OS
Final Evaluation		
2.9	Exit Visual Acuity	Perform Distance, High Contrast Visual Acuity using Snellen optotype with the patient's habitual correction.
2.10	Final Evaluation Form	Complete the final evaluation form and indicate if the subject successfully completed the study
2.11	Protocol Deviations	Ensure any protocol deviations have been recorded

The procedures involved in the study are common clinical procedures found in Optometry/Ophthalmology. LWE assessment will occur following installation of sodium fluorescein and lissamine green ophthalmic drops. The upper and lower lids will be photographed using a slit-lamp biomicroscopy and a camera. Photographs will be de-identified and graded subjectively for LWE using the Korb scale (see below). Photos may also be analyzed for objective LWE grading using custom coding in MATLAB.

Korb LWE Grading				
Grading	Description	Height (%)	Width (mm)	Final score (grade)
0	no LWE	<25	<2	<0.25
1	mild LWE	25-50	2-4	0.25-1.00
2	moderate LWE	50-75	5-9	1.25-2.00
3	severe LWE	>75	>10	2.25-3.00

*Final LWE score is the average of the LWE Height and Width

The tears collected by capillary tubes will be stored at -80°C until luminex multibead analysis. 15 µg of total protein will be analyzed for matrix metalloproteinases (MMP)-1, -2, -7, -9, -10. Pre- and post-contact lens wear concentrations of MMP will be compared for each subject. MMPs are a family of zinc proteases and an increase in MMP expression occurs in response to a wide range of stimuli, including adhesion molecules, growth factors, cytokines and hormones and is associated with ocular surface damage. The correlation coefficient, r, will be determined between LWE and the tear film levels of MMPs.

A $p \leq 0.05$ will be considered statistically significant.

Layman's Description of Procedures	
Patient demographics	The subjects will be asked questions about their age, sex, race and ethnicity.
History	The subjects will be asked questions about their systemic health, ocular disease and surgical history.
Concomitant Medications	The subjects will be asked questions about their current ocular and systemic medications.
Habitual Contact Lens Information	The subjects will be asked questions about how they use their current contact lenses, such as their current contact lens brand and wear time, as performed during a normal eye exam.
Auto-refraction	A machine will shine light into a subject's eye and will estimate their prescription using different powered lenses without making contact with the eye.
Oculus Keratograph	A machine uses a video camera to determine how long it takes for a subject's tear film to

	evaporate and the height of the pooled tears between the lower lid and the ocular surface without making contact with the eye.
Phenol Red Thread	A small thread containing a pH indicator that turns from red to yellow when it contacts tears will be placed at the subject's lower lid margin and left for 15 seconds. The length that the tears have traveled will be measured. This test does not require anesthesia.
Slit Lamp Exam	A specialized microscope is used to shine light on the eye and to examine the health of the eyelids and the front of the eye.
Subjective Refraction/Spherical Equivalent Refraction	The subject's prescription is determined by placing different power lenses in front of the subject's eye, according to the subject's responses.
Contact Lens Fitting	A contact lens is placed on the eye and the fit is assessed (how much is moves, where it sits on the eye, etc.). This is done using a slit lamp biomicroscope.
Contact Lens Over-Refraction and Power Adjustment	Lenses will be placed in front of the subject's eye while wearing the study contact lenses to determine if the prescription needs to be changed according to the subject's responses. The contact lens power will be adjusted if needed.
Questionnaire: Ocular Surface Disease Index (OSDI)	The questionnaire asks the subject's vision during various tasks, eye pain, comfort in various environments, etc.

9.0 Setting

All study visits will be conducted at the University of Houston College of Optometry at The Ocular Surface Institute (TOSI) within the Human and Biological Sciences Building.

10.0 Drugs or Devices

No investigational medical devices or investigational ophthalmic pharmaceuticals will be assessed in this study. The contact lenses fit in the study (Acuvue Oasys, Johnson & Johnson Vision Care; Air Optix Night and Day Aqua, Alcon Laboratories) are commercially available, FDA approved contact lenses that will be fit per the manufacturers recommended fitting guide on a daily wear basis (i.e. subjects will not sleep in lenses). The ophthalmic drops used in the trial to evaluate LWE (sodium fluorescein, lissamine green) are commercially available ocular diagnostic agents commonly used in clinical practice.

11.0 Risks to Subjects

The risks to the subjects in the trial are the same risks found in standard clinical practice. During study procedures, there is the risk of mild ocular discomfort during clinical procedures due to light being shined on the eye (e.g. Slit lamp biomicroscopy), by being asked to not blink for a short period of time during a procedure (e.g. Oculus Keratograph NITBUT), during surface tear collection or through the use of topical ophthalmic diagnostic agents (sodium fluorescein, lissamine green). Potential discomfort from these procedures is transient and self-limiting.

Contact lenses will be fit as part of this study. The US Food and Drug Administration consider daily wear contact lenses Class II medical devices. While most individuals wear contact lenses successfully without incident, problems with contact lenses or lens care products can result in serious injury to the eye. Ulcerative keratitis (infection of the cornea), can develop rapidly and lead to loss of vision. Ulcerative keratitis is estimated to happen to about 4.1 out of 10,000 people who use daily wear contact lenses. The overall risk of ulcerative keratitis may be reduced by carefully following directions for lens care, and subjects in the study will be educated on proper contact lens use and care.

The following problems may also occur when wearing contact lenses:

- Burning, stinging, and/or itching of the eyes
- Less comfort after daily wear than when the lens was first placed on the eye
- A feeling like there is something in the eye (foreign body, scratched area)
- Reduced vision or temporary loss of vision due to peripheral infiltrates (white blood cells), peripheral corneal ulcers (inflammation of the cornea), and/or corneal erosion (defects in the corneal surface)
- Local or generalized edema (swelling)

- Corneal neovascularization (small blood vessels growing into the cornea)
- Corneal staining (defect in the corneal surface)
- Redness
- Tarsal abnormalities (bumps on the inside upper eye lid)
- Iritis (internal inflammation of the eye)
- Conjunctivitis (infection or inflammation of the white part of the eye or under the eyelids)
- Excessive watering, unusual eye secretions, or redness of the eye
- Poor visual acuity
- Blurred vision
- Rainbows or halos around objects
- Sensitivity to light
- Dry eyes may also occur if lenses are worn continuously or for too long a time

Many of the potential problems associated with contact lens wear are self-limiting and can be resolved with discontinuation of lens wear. These problems can be minimized or avoided with proper contact lens fitting and follow-up. Subjects in the study will be examined approximately 7 days after contact lens fitting, which is typical in clinical practice for contact lenses worn in a daily wear modality.

Subject safety will be monitored in the trial through slit lamp evaluation of the ocular surface. Subjects will be educated to potential risk with contact lens wear and instructed to discontinue contact lens wear and contact the study investigators if they experience any eye discomfort, excessive tearing, vision changes, redness of the eye, or other problems.

Subjects will be instructed that in the event they experience signs or symptoms associated with a potential adverse event, they should contact the study personnel immediately for evaluation.

12.0 Potential Benefits to Subjects

There is no direct benefit that the individual subjects may experience from taking part in the research; however, participation in the trial may lead to clinical insights that could potentially predict future contact lens comfort in patients.

13.0 Withdrawal of Subjects

Subjects may withdraw consent to participate in the study at any time. Subjects may be withdrawn from the trial by the study investigators if they are lost to follow up (fail to complete Visit 2 within the allotted time period), become pregnant during the trial, have a study-related adverse event that warrants study withdrawal or they fail to follow the study instructions.

14.0 Costs/Payments to Subjects

There are no expected additional costs to subjects that participate in the study. There is no cost to subjects for contact lens fitting in this study. Subjects will be provided contact lenses and care solution at no cost for the duration of the study. Subjects will be provided with a token for parking at each study visit (if necessary). Subjects that complete contact lens fitting (i.e. that is completes both study Visit 1.1 and 1.2) will be compensated $30. Subjects who complete the 1-week follow up will be compensated $10. If subjects are determined ineligible at screening (screen fail), the subject will be compensated $5, with the opportunity for a total of 3 re-screenings at the investigators discretion. Total subject reimbursement (without rescreening visits) will be $40. Subjects will be compensated using Amazon electronic gift cards in the amounts indicated above, delivered to the subject via an e-mail address provided by the subject, after completion of their last study visit. Subjects who fail to complete a visit will not be compensated for that visit. Subjects will be instructed to contact the study PI in the event that they do not receive the electronic gift card.

15.0 Compensation for Research-Related Injury

The risks to subjects from participation in the study are minimal. The clinical procedures used in the study (slit lamp biomicroscopy, non-invasive tear break up time) are commonly used clinical procedure in optometry and ophthalmology and may cause some discomfort due to light shining on the surface of the eye, during ocular surface tear collection or during contact lens wear. In the rare case that a subject is injured as part of their participation in the study, the subject will be responsible for any associated medical bills.

16.0 Confidentiality

Subjects will be assigned a unique subject ID. Subjects IDs are two digits and should start at 01 and continue in the order of enrollment. No one outside of the research team will have access to the subject identifiers. A key to the study code will be maintained for 3 years at the time of study completion (i.e. Last Subject, Last Visit).

Any source documents with patient identifiable information will be kept only at the local site (informed consent form, linking log). Individual documents will be kept in a secure room in the Ocular Surface Institute (TOSI).

17.0 Provisions to Protect the Privacy Interests of Subjects.

Those who are potentially eligible and interested in the study will be referred to a study investigator or coordinator who will discuss the study with the patient. This discussion will take place in a quiet, private area and as much time as necessary will be spent discussing the details of the study.

18.0 Informed Consent Process

The participant will be provided an opportunity to read the informed consent and to have any questions answered before agreeing to participate. Prior to any testing, the investigator or study coordinator will obtain written informed consent from all participants. The consent form will be signed and dated by both the participant and a member of the study personnel who has been approved to obtain consent. The participant will receive a copy of the signed consent documents and the originals will be filed in the subject binder on site in a secure location.

19.0 HIPAA

We will be collecting demographic information along with general medical and eye health information. Since protected health information will be collected, the Health Insurance Portability and Accountability Act (HIPAA) authorization form will be included as part of the Informed Consent process.

The linked PHI will be destroyed upon completion of the study. PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

20.0 Data Management

Paper source documents (i.e. case report forms) will only be associated with a subject ID number and will not contain direct subject identifiers.

21.0 Specimen Use and Banking

The tear specimens will be stored in a -80°C freezer until luminex multibead analysis. The specimens will be stored for up to 3 months. The principal investigators and other members of the research team will have access to the specimens.

22.0 Sharing of Results with Subjects

There are no plans to share study results with subjects as it will not directly benefit their eye/vision health. If findings are discovered during the trial that potentially have an impact on the subject's health or wellbeing, the subject will be educated to these findings.

23.0 Resources

The study team completed all necessary ethics training requirements. The co-PIs (Eric Ritchey, OD, PhD and Rachel Redfern, OD, PhD) have over a decade of clinical research experience conducting clinical studies and will oversee the other study personnel.

The number of subjects to be recruited is based on the typical number of subjects needed to approach the central limit theorem. With an abundance of contact lens wearers in the surrounding community, we believe that we should be able to complete enrollment within 3 months.

This study utilizes the clinics of The Ocular Surface Institute to see study subjects on the campus of the University of Houston.

Addendum: Statistical Analyses

Statistical analyses were performed in SPSS v26 (IBM) and GraphPad. When data were not significantly different from a normal distribution (non-invasive tear break up time, tear meniscus height), statistical analyses were conducted using paired t-tests and repeated-measures analyses of variance (RM-ANOVA), with adjusted post-hoc t-tests, when appropriate. For NITBUT and TMH, the RM-ANOVA included two repeated factors—lens type (Acuvue Oasys and Air Optix Night and Day) and time (baseline, 2 hours post-fitting and 7 days after lens fitting). For data that was not normally distributed (LWE staining), Friedman and Mann-Whitney non-parametric statistics were performed. MMP concentrations were adjusted by multiplying raw values by the dilution factor. Tear film MMP concentrations under the level of detection (LOD) were divided by $\sqrt{2}$ (Croghan et al. 2003). Outliers in MMP data sets were analyzed using the ROUT function in Graphpad Prism 8.4.1 and were removed prior to analysis.