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Centre for Ocular Research & Education

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Protocol

CLINICAL EVALUATION OF PROCLEAR TORIC AND BIOFINITY TORIC (POND)

Sponsor: CooperVision Inc.

Sponsor study number: EX-MKTG-158

CORE protocol number: P/860/24/CVI

Protocol author: Marc-Matthias (Marc) Schulze

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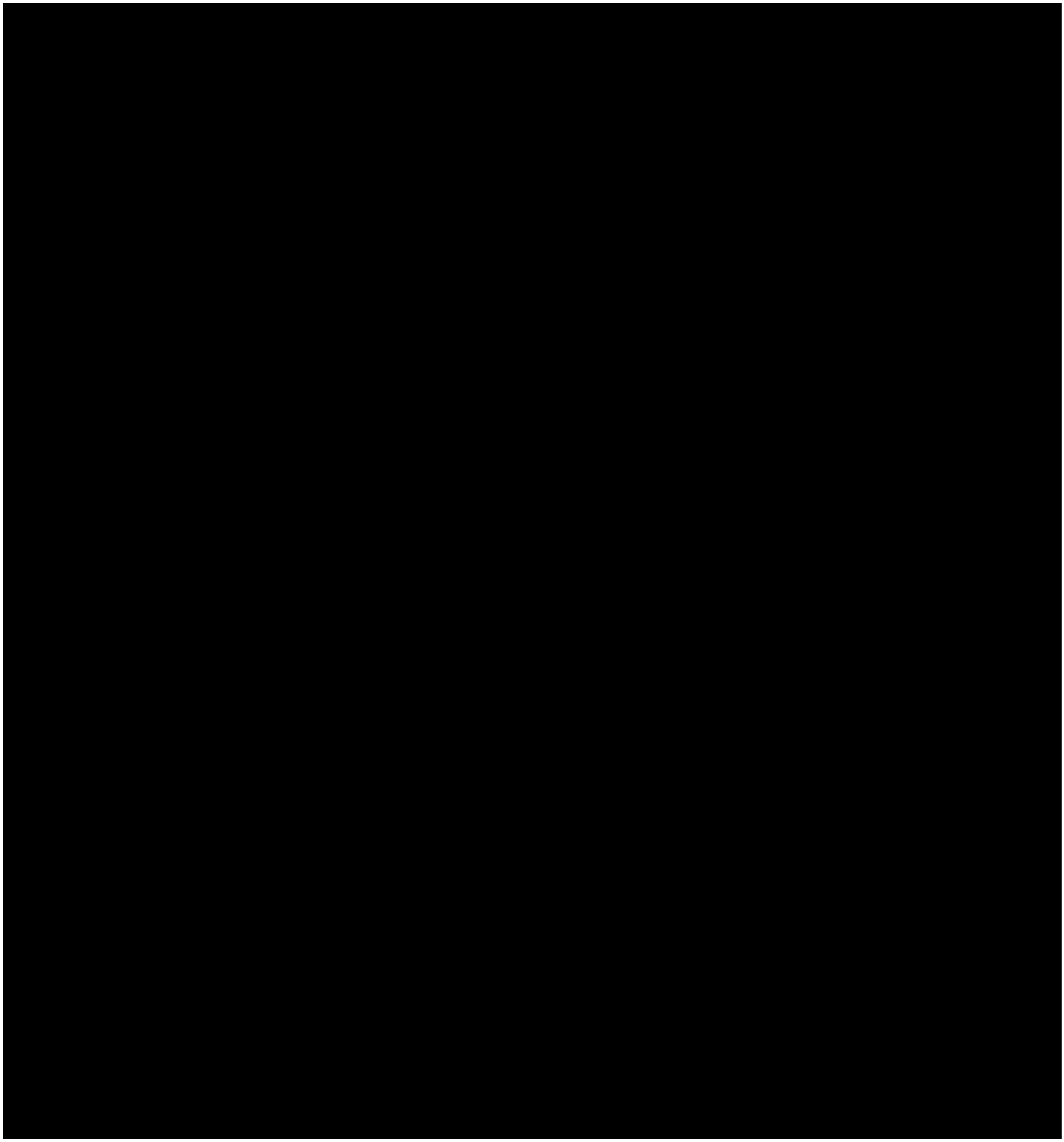
[redacted]



DOCUMENT CHANGE HISTORY

Version date	Author	Description of change(s)
05apr2024	Marc Schulze	Original protocol
1may2024	Marc Schulze	Correction of typos. Added Komal Kumar to study Personnel list (page 2) Section 4.2.5: Increased total number of screenings to 3; Section 4.3.2: Updated process of ordering study lenses; Section 4.4.1: Updated and clarified screening procedures, removed duplicate steps; Section 13.1: Added ISO14155 to Statement of Compliance;

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Confidentiality

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Disclaimer

This study will be conducted for research purposes only.

1 INTRODUCTION

Toric soft contact lenses work best for people with astigmatism and other refractive errors (e.g., nearsightedness, farsightedness). The use of toric soft contact lenses has increased significantly in recent years. Recently released data on prescription habits with soft toric lenses ranged from 13% to 59%. Soft toric contact lens wearers demand two things from their contact lenses, great comfort and excellent vision.

Contact lens manufacturers are continuously innovating in this area, with increased availability of soft toric contact lenses with novel designs in a range of replacement frequencies, from daily disposables to monthly replacement, and different materials, including silicone hydrogels.

Therefore, CooperVision is interested in comparing the short-term clinical performance and subjective acceptance of Proclear toric contact lenses (Lens A; Control) with Biofinity toric (Lens B; Test) silicone hydrogel lenses in a short-term, non-dispensing fitting study.

2 OBJECTIVES

To evaluate and compare the performance of Proclear toric (control) and Biofinity toric (test) contact lenses in existing soft toric lens (CL) wearers in a short term (15 minutes wear) study.

The primary outcome variable for this study is:

- Overall fit acceptance

[redacted]

3 HYPOTHESIS

Null Hypothesis (H_0) There is no difference in overall fit acceptance between the study lenses.

Alternative Hypothesis (H_1) There is a difference in overall fit acceptance between the study lenses.

4 MATERIALS AND METHODS

4.1 STUDY DESIGN

4.1.1 OVERALL DESIGN

This is a prospective, participant masked, bilateral eye, non-dispensing cross-over study with 3 study visits that will be conducted on 2 separate days. The consent, screening and lens fitting assessments will be done on study day 1 (Visit 1) to determine eligibility and confirm optimal contact lens powers. The performance of both lens types during bilateral wear will be assessed on study day 2, with a cross-over from Lens A (Visit 2) to Lens B (Visit 3). Participants will exit the study at the end of V3.

4.1.2 RANDOMIZATION

There is no randomization in this study. Each participant will wear each of the two lens types for approximately 15 minutes during the assessment visits. Each participant will wear the Proclear toric lens first (Visit 2) and the Biofinity toric lens (Visit 3) second.

4.1.3 MASKING

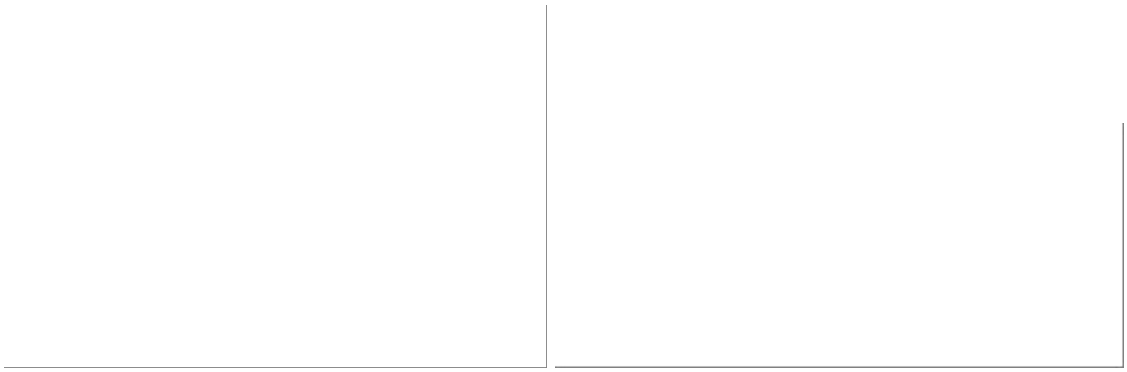
The order of contact lens wear will be masked to the study participants only. The lenses will be removed from their blister pack by an assistant and transferred to an unmarked lens case to maintain participant masking of the study lenses. Participants will then be instructed to remove the lenses from the lens case and insert them onto their eyes. It is not possible for the study investigators to be masked because of the plan for a fixed lens order.

4.2 STUDY POPULATION

4.2.1 SAMPLE SIZE CALCULATION

Figure 1 shows the sample size determination for a paired t-test, with alpha=0.05 and a power of 84%. In order to detect a difference of 0.42 points between lenses on the 0 to 4 fit acceptance rating scale, a sample size of 37 completed participants is needed.

Figure 1: Sample size calculation (Minitab 20.2. Statistics software)



4.2.2 NUMBER OF PARTICIPANTS

Participants will be recruited using CORE records and advertising approved by the UW Office of Research Ethics. To account for potential dropouts, up to 40 participants may be dispensed with the study lenses on visit day 2, with the goal to have 37 participants complete the study. Informed consent will be obtained for all participants prior to their enrolment in the study.

4.2.3 INCLUSION AND EXCLUSION CRITERIA

A person is eligible for inclusion in the study if they:

1. Are at least 17 years of age and has full legal capacity to volunteer;
2. Have understood and signed an information consent letter;
3. Are willing and able to follow instructions and maintain the appointment schedule;
4. Are an adapted soft toric contact lens wearer;
5. Do not habitually wear either of the two study lens types;
6. Have a vertex-corrected contact lens prescription with a spherical component of +4.00D to -9.00D in combination with astigmatism of no less than -0.75D and no more than -2.25D in each eye;
7. Can achieve best corrected distance visual acuity of +0.10 logMAR (subjective refraction) or better in each eye;
8. Can be fitted with and achieve a distance visual acuity of +0.18 logMAR or better in each eye with the study contact lenses;

A person will be excluded from the study if they:

1. Are participating in any concurrent clinical or research study;

2. Have any known active* ocular disease and/or infection or slit lamp findings that would contraindicate contact lens use;
3. Have a systemic condition that in the opinion of the investigator may affect a study outcome variable;
4. Are using any systemic or topical medications that in the opinion of the investigator may affect a study outcome variable;
5. Have known sensitivity to the diagnostic pharmaceuticals to be used in the study;
6. Have a history of not achieving comfortable CL use (5 days per week; > 8 hours/day)
7. Are an employee of the Centre for Ocular Research & Education directly involved in the study (i.e. on the delegation log).

* For the purposes of this study, active ocular disease is defined as infection or inflammation which requires therapeutic treatment. Mild (i.e. not considered clinically relevant) lid abnormalities (blepharitis, meibomian gland dysfunction, papillae), corneal and conjunctival staining and mild dry eye are not considered active ocular disease. Neovascularization and corneal scars are the result of previous hypoxia, infection or inflammation and are therefore not active.

4.2.4 VULNERABLE POPULATION

This study will not be conducted in vulnerable populations.

4.2.5 REPEATED SCREENINGS

In some circumstances a repeated screening may need to be scheduled. Examples include, but are not limited to:

1. Incomplete information available at time of screening to determine eligibility (e.g. current lens brands worn, history from current eye care practitioner etc.)
2. Study procedures unable to be completed in time scheduled for visit;
3. Study products not available at the time of the screening visit;
4. A transient health condition which may affect the eye(s) (e.g. a common cold, active allergies, fatigue etc;)
5. The short term use of medications (e.g. antibiotics, antihistamines etc.)
6. Reassessment of baseline ocular conditions (e.g. corneal and/or conjunctival staining, scars etc.)

The maximum total number of screenings permitted will be 3 (1 screening and up to two repeated screenings).

4.3 STUDY MATERIALS

4.3.1 LENSES

The lens characteristics for the two study lenses are shown in Table 1.

Table 1: Lens characteristics

Lens	Proclear toric	Biofinity toric
Lens designator	Lens A (Control)	Lens B (Test)
Material	omafilcon B	comfilcon A
Replacement frequency	monthly	monthly
HC licence #	106824	70149
HC Device class	2	3
Dk/t (barrer/cm)	30.9	116
Sphere power (D)	+4.00 to – 9.00	+4.00 to -9.00
Cyl power (D)	-0.75, -1.25, -1.75, -2.25	-0.75, -1.25, -1.75, -2.25
Base curve (mm)	8.8	8.7
Diameter	14.4	14.5

4.3.2 ORDERING CONSUMABLES

Initial trial lenses will be ordered for each participant based on their habitual contact lens prescription; in addition, a small initial lens stock will be provided by CooperVision prior to the start of the study. Lenses used for fitting will not be reused at study visits. Additional lenses will be ordered by CORE if insufficient stock is on hand.

4.3.3 DISPOSING OF CONSUMABLES

Worn lenses collected during study visits will be discarded as per University of Waterloo regulations.

4.3.4 PRODUCT ACCOUNTABILITY

Accountability logs will be kept to include the number of lenses received, dispensed, unused and returned to sponsor (where relevant). All products dispensed to participants will be recorded in the study binder.

4.4 SCHEDULED AND UNSCHEDULED VISITS

This study has a total of 3 study visits, including the screening visit. The involvement for each participant will be approximately 3.5 hours across two separate visits to CORE. A summary of the study visits is shown in Table 2.

Table 2: Summary of visits

Visit number	Visits	Visit length	Visit Window
1	Screening, Lens fit (both lens types), Eligibility. Study lenses order (if applicable)	1.75 hrs	n/a
2	**Part A:** Lens insertion (LENS A). [redacted] lens assessments	1.75 hrs	V2 & V3 to be conducted on the same day
	Part B: 15 minute post insertion (LENS A). [redacted] lens assessments. Lens removal.		
3 & Exit	**Part A:** Lens insertion (LENS B). [redacted] lens assessments		
	Part B: 15 minute post insertion (LENS B). [redacted] lens assessments. Lens removal. Exit assessments		
Total		**3.5 hrs**	**n/a**
Early Exit	If applicable (e.g. participant discontinued)	0.5 hrs	If applicable

4.4.1 SCREENING (V1)

A documented informed consent process will be conducted with all participants prior to their enrolment in the study and prior to any data collection or measurements. All participants who sign the informed consent letter will be assigned a study ID number. The investigator will determine participant eligibility using the inclusion and exclusion criteria. Ineligible participants will be discontinued from the study. Participants will attend this visit wearing their **spectacles**.

Visit procedures (V1):

1. The participant will be required sign an Informed Consent Form prior to enrollment. When the participant has signed the consent form, the participant will be considered enrolled in the study.
2. Participant demographics and medical history (age, sex, medical conditions, medications, allergies).
3. Contact lens history (habitual lens information and wearing habits).
4. [redacted]
5. [redacted]
6. Full anterior ocular health examination (Including fluorescein; Efron scale).
7. Participant to insert LENS A [redacted] trial lens.

8. Allow 5 minutes settling time.
9. [redacted]
10. Measure lens fitting characteristics ([redacted] overall fit acceptance).
11. Participant to remove LENS A and to insert trial toric LENS B [redacted].
12. Allow 5 minutes settling time.
13. [redacted]
14. Measure lens fitting characteristics [redacted] overall fit acceptance).
15. Participant to remove LENS B.
16. The investigator will confirm that the participant meets the eligibility specifications set out in the inclusion criteria and exclusion criteria and is eligible to continue in the study.
17. Instructions. The participant will be advised:
    - To attend V2 with their habitual spectacles.
    - That they are permitted to wear their habitual CLs every day from now on (end of screening visit) until the day of V2 (i.e. no habitual CL wear on day of V2 visit).
18. Confirmation of final lens powers for LENS A & B. If final lenses for either lens type are not in stock, lenses will be ordered.

[redacted]

4.4.2 STUDY VISITS (V2 & V3)

Study visits 2 and 3 to be conducted on the same day, with both study lens types in the final lens power as determined during the screening visit required to be available on site. Participants will attend this visit wearing their **spectacles and not having worn their habitual CLs on the day of this visit.**

Visit 2 (LENS A) – Visit Procedures:

1. Changes in health & medications
2. Lens insertion

Part A – post-insertion measurements

3. [redacted]

5. Lens fit assessment
   - [redacted]
   - Overall fit acceptance (0 – 4) and reason if Grade 2 or less.

Part B – 15 minutes-post insertion measurements

6. [redacted]

8. Lens fit assessment
   - [redacted]
   - Overall fit acceptance (0 – 4) and reason if Grade 2 or less.
9. Lens removal
10. [redacted]

Visit 3 (LENS B) – Visit Procedures:

1. Lens insertion

Part A – post-insertion measurements

2. [redacted]
   - [redacted]
   - [redacted]
   - [redacted]

[redacted]

4. Lens fit assessment
   - [redacted]
     - [redacted]
     - [redacted]
     - [redacted]
   - Overall fit acceptance (0 – 4) and reason if Grade 2 or less.

Part B – 15 minutes-post insertion measurements

5. [redacted]
   - [redacted]
   - [redacted]
   - [redacted]
   - [redacted]

[redacted]

7. Lens fit assessment
   - [redacted]
     - [redacted]
     - [redacted]
     - [redacted]
   - Overall fit acceptance (0 – 4) and reason if Grade 2 or less.
8. Lens removal
9. [redacted]
   - [redacted]
   - [redacted]
10. [redacted]
11. [redacted]

4.4.3 STUDY EXIT

The study exit form will be completed when a participant exits the study. This form will be completed either at study completion, or if the participant is discontinued from the study at another time. A study exit form must be completed for all participants who have taken a study ID number. If in the opinion of the investigator post-follow-up visits are required, the exit form will be completed after the last follow-up visit.

4.4.4 UNSCHEDULED VISITS

An unscheduled visit is defined as an interim visit requested by the participant or investigator due to an unanticipated problem. Data recorded at these visits will be entered into the database. Only relevant and applicable unscheduled visit information will be included in the final report as deemed necessary by the lead investigator.

4.5 STUDY PROCEDURES

A summary of the study procedures to be conducted at the different scheduled visits is listed in Table 3.

Table 3: Summary of procedures to be conducted at scheduled visits

	Screening	V2 (Lens A)	V3 (Lens B)
Informed Consent	√		
Demographics, concomitant medications and medical history	√		
Changes to health & medications		√	
Contact lens history and wear habits, including comfortable wear time	√		
[redacted]	√		
[redacted]	√		√
Trial lens fitting	√		
Lens fit assessment	√	√	√
[redacted]	√	√	√
Lens order (if applicable)	(√)		
[redacted]		√	√
[redacted]		√	√
[redacted]			√
[redacted]			√
Study Exit			√

4.6 DETAILS OF PROCEDURES

4.6.1 CASE HISTORY

Demographics:

Demographic information from the participant will be obtained, including age and sex.

Medical History:

At screening, information will be obtained from the participant about the current medication, allergies, and any medical conditions. At the beginning of the Follow-up visits, the participant will be asked about changes in their medication or health.

Contact Lens History:

Information will be obtained from the participant about the current contact lens type (lens name, brand, lens power), replacement frequency, contact lens care solution (if applicable), typical number of lens wear days per week, typical lens wear time per day (total and comfortable).

[redacted]

[redacted]

4.6.5 LENS FIT ASSESSMENTS

The lens fit will be assessed at the slit lamp biomicroscope during the screening visit (for both trial lenses) and for V2 and V3 (for each of the study CLs, both post insertion and after 15 minutes). Assessments will include:

- [redacted]

- Overall fit acceptance (0 – 4) and reason if Grade 2 or less.
    - 0 = Should not be worn
    - 1 = Borderline but unacceptable
    - 2 = Min. acceptable, early review
    - 3 = Not perfect but OK to dispense
    - 4 = Perfect

[redacted]

[redacted]

[redacted]

[redacted]

5 MONITORING PROTOCOL ADHERENCE

All personnel involved in this study will be listed on a delegation log and their training will be documented. Consent documentation will be reviewed by personnel not involved in the consent process. Visit windows will be reviewed when determining the analysis cohort. All adverse events and protocol deviations will be reviewed by the Lead Investigator. Serious adverse events and major protocol deviations will be reviewed by the Principal Investigator.

6 POTENTIAL RISKS AND BENEFITS TO HUMAN PARTICIPANTS

This is a minimal risk study because of the use of marketed products and standard optometric assessments or investigational lens /products/device.

Contact lenses in this study will be worn on a daily wear basis, for approximately 15-30 minutes, on a single day only. Adverse events and/ or complications in daily wear of soft contact lenses

can occur (eg: inflammation and infection). When contact lenses are worn on a daily wear basis there is a small risk of an adverse event compared to not wearing contact lenses. When contact lenses are worn on an extended wear basis, there is a significantly increased risk of an adverse reaction compared with wearing contact lenses on a daily wear basis.

Fluorescein is used in this study to assess the ocular surface. Although rare, it is possible that participants may have an allergic reaction to the dye. They will be advised of the fluorescein use in the consent document and will be instructed to advise the investigator if they have a known allergy to fluorescein.

Additionally, it is possible that participants may experience temporary discomfort associated with the study procedures /products including: light sensitivity, dryness, and foreign body sensation.

Some measurements will be conducted at close distance with the investigator (within 2m for some assessments). To reduce the risk of airborne illness (including COVID-19), CORE has implemented a series of on-site safety procedures, including maintaining physical distancing as much as possible, frequent handwashing, optional face masks, frequent room and equipment hygiene, and air filtration equivalent to medical examination rooms.

Participants will not benefit directly from taking part in this study. This study may help the study sponsor to better understand the performance of the products being used in this study.

7 ADVERSE EVENTS

See CORE SOP012 AE Reporting for a description of the reporting of adverse events.

Any observations taking place prior to determining that a participant meets all inclusion/ exclusion criteria for the study and which are not related to the performed study procedures are not considered an AE. An AE can be any unfavourable and unintended sign, symptom, or disease temporarily associated with a study procedure, whether there is a causal relationship or not.

Adverse events (AE) may be classified as ‘unanticipated adverse device effects,’ ‘serious adverse events,’ ‘significant adverse events,’ or ‘non-significant adverse events,’ as defined below, Table 4.

A number of conditions may result in temporary suspension until resolution. These include corneal infiltrates, corneal staining, limbal injection, bulbar injection or tarsal conjunctival abnormalities.

Table 4: Classification of types of adverse event

Classification	Definition
Serious Adverse Event	Those events that are life-threatening, or result in permanent impairment of a body function, or permanent damage to a body structure or necessitate medical (therapeutic) or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.
Significant Adverse Event	Those non-serious adverse events that occur with contact lens usage that are not sight-threatening but are usually symptomatic and may warrant therapeutic management and /or temporary or permanent discontinuation of contact lens wear.
Non-Significant Adverse Events	Those less severe non-serious adverse events that occur with contact lens usage that are not sight-threatening, may or may not be symptomatic and may warrant palliative management, such as ocular lubricants or temporary interruption of contact lens wear.
Unanticipated Adverse Device Effect	Adverse events in a study that were not previously identified in the protocol in terms of nature, severity, or degree of incidence. An Unanticipated Serious Adverse Device Effect is an unanticipated adverse event that is serious in nature and caused by or associated with the device and is considered reportable.

AE classification, coding (for reporting to the sponsor) and reporting details, plus examples, are provided in Table 5.

Table 5: Contact lens adverse event classification, coding and reporting guide

Code	Condition	Reporting
Serious Adverse Events		
01	Presumed infectious keratitis or infectious corneal ulcer	For all serious AEs: Notify sponsor as soon as possible, **within 24 hours;** ORE reporting will be **within 24 hours** as per requirements
02	Permanent loss of ≥ 2 lines of best spectacle corrected visual acuity (BSCVA)	
03	Corneal injury that results in permanent opacification within central cornea (6mm)	
04	Uveitis or Iritis (e.g. presence of anterior segment inflammation as described in ISO 11980, Annex B)	
05	Endophthalmitis	
06	Hyphema	
07	Hypopyon	
08	Neovascularization within the central 6mm of cornea	
00	Other serious event	
Significant Adverse Events		
11	Peripheral (outside central 6mm), non-progressive, non-infectious ulcer	Notify sponsor as soon as possible, **within 5 working**
12	Symptomatic corneal infiltrative event	

13	Superior epithelial arcuate lesions (SEALs) involving epithelial split	**days**; ORE reporting as per requirements
14	Corneal staining ≥ dense coalescent staining up to 2mm in diameter (e.g. moderate, ISO 11980 grade 3)	
15	Corneal neovascularization ≥ 1.0mm vessel penetration (e.g. ≥ ISO 11980 Grade 2), if 2 grade change from baseline	
16	Any temporary loss of ≥ 2 lines BSCVA for ≥ 2wks	
17	Any sign and/or symptom for which participant is administered therapeutic treatment or which necessitates discontinuation of lens wear for ≥ 2 weeks	
10	Other significant event	
Non-significant Adverse Events		
21	Conjunctivitis (bacterial, viral or allergic)	Notify sponsor as soon as possible, **within 5 working days**; ORE reporting as per requirements
22	Papillary conjunctivitis if ≥ mild scattered papillae/follicles approximately 1mm in diameter (e.g. ISO 11980 Grade 2), if 2 grade change from baseline	
23	Asymptomatic corneal infiltrative events	
24	Any sign and/or symptom for which temporary lens discontinuation for > 1 day is recommended (if not already classified)	
20	Other sign and/or symptom warranting classification as a non-significant adverse event	

7.1 NORMAL OR ADAPTIVE SYMPTOMS

Transient symptoms such as end-of-day dryness, lens awareness, itching or burning or other discomfort may occur with contact lens wear and may occasionally reduce wearing time. These are not reported as adverse events unless in the investigator's opinion they are unexpected in nature, severe or have a high rate of occurrence.

7.2 PROCEDURES FOR ADVERSE EVENTS

Treatment of an adverse event will depend on its nature and severity. Based on the clinical judgment of the investigator, the adverse event will be managed within CORE or may be referred to an eye care practitioner external to CORE. The investigator will attempt to determine whether the reaction is related to the test device or a result of other factors. An adverse event form will be completed for each adverse event. Whenever possible, the adverse event will be photo-documented.

Expenses incurred for medical treatment as part of study participation will be paid by the sponsor (bills and prescription receipts kept). The participant must be followed until resolution or no further change is anticipated and/or referred for further care with the appropriate health care professional and/or recorded as being under appropriate health care as per investigator's discretion. A written report will be completed indicating the subsequent treatment and resolution of the condition.

7.3 REPORTING ADVERSE EVENTS

All potential Significant, Serious and Unanticipated Adverse Device Effects that are related or possibly related to participant's participation will be reported to the Principal Investigator and the sponsor within 24 hours of the investigator becoming aware of the event. The Investigator will report the event to the ORE as per ORE requirements (by fax, mail/delivery, phone, or email). All fatal or life threatening events will be reported immediately to the ORE.

Significant and Non-Significant Adverse Events will be reported to the sponsor as soon as possible, but no later than 5 working days after the occurrence. The Investigator will report the event to the ORE as per ORE requirements (by fax, mail/delivery, phone, or email).
Sponsor contact details are:

[redacted]

Details of all adverse events will be included in the study report.

8 DISCONTINUATION FROM THE STUDY

Participants may be discontinued at the discretion of the investigator or sponsor in consideration of participant safety or protocol compliance, or at discretion of the participant. [redacted] Upon discontinuing, a participant will be offered the option of their data being withdrawn from future statistical analysis. The following is a list of possible reasons for discontinuation from the study:

- Screening failure: Participants will be discontinued if they do not meet the inclusion and exclusion criteria outlined in section 4.2.3.
- Unacceptable performance with products to be used in study: Participants may be discontinued if they are unable to achieve acceptable comfort and /or vision with the study products.
- Adverse event: If a participant experiences an adverse event during the study they may be discontinued based on the clinical judgement of the investigator.
- Symptoms: If the participant has persistent symptoms they may be discontinued based on the clinical judgement of the investigator.
- Disinterest, relocation or illness: The participant may choose to discontinue due to reasons within or beyond their control.
- Violation of protocol or non-compliance: The participant will be discontinued if they are unable or unwilling to follow the protocol specified visit schedules and/or study procedures.
- Lost to follow-up: The participant will be discontinued if they cannot be contacted and do not return for a final exit visit, and if the investigator has made a reasonable effort to contact the participant for a final study visit.
- Premature termination of the study by the sponsor, CORE or the Office of Research Ethics at the University of Waterloo.

A discontinuation form, stating the reason for discontinuation will be completed, which requires the signatures of both the participant and the investigator except where the participant is lost to follow-up in which case only the signature of the investigator is required.

All discontinuations including their reasons will be included in the final report.

[redacted]

[redacted]

10 STATISTICAL ANALYSIS AND DATA MANAGEMENT

10.1 STATISTICAL ANALYSIS

All data will be analysed by CORE at the University of Waterloo. Unmasked data analysis will be conducted using Statistica and / or SPSS, or other appropriate software. Descriptive statistics will be provided on information regarding baseline variables (age, sex, etc.). Table 6 lists the primary outcome variables and anticipated statistical procedures. [redacted]. The OD data will be analysed for certain assessments that are conducted for each eye separately, for example [redacted] lens fit.

[redacted]

Table 6:Statistical procedures

Variable	Analysis	Statistical test
[redacted]		
Lens Fit assessments	Descriptive and other statistics	Mean, Median*, Standard Deviation, Minimum, Maximum, Frequency count
	Effect of treatment on outcome variable within subjects (comparison between study lenses) Effect of time on ratings *(comparison over time)*	Friedman Wilcoxon matched pairs test Paired t-test
[redacted]		

A binomial test will be used to analyze the results for the count data of subjective preferences. Where relevant, the number of "no preference" responses will be evenly distributed to the two options on the basis they would be equally likely to choose either.

The final study report will include a table that lists the final lens prescription for the two lens types by participant, in order to determine the count and percentage of matching prescriptions between both lens types.

No analysis will be conducted on biomicroscopy data as this is only collected for safety purposes.

10.2 DATA MANAGEMENT

Data from this study will be retained by CORE for a minimum of 25 years on a password-protected server. After 25 years, data will be disposed of in accordance with the guidelines laid out by the University of Waterloo. More details regarding storage procedures are provided in CORE SOP014 Clinical data management.

At the completion of the study CORE will provide a copy of the study data to the sponsor when requested. Data will typically be sent using a secure file share system operated by the University of Waterloo called Sendit which uses 128bit (or 256bit) SSL encryption. This system provides a secure way to transfer files when email is not appropriate, whether because of file size, file type or concerns over security. Sendit includes features such as password protection, a restricted time period for download, IP logging and email notification of download. Files may be encrypted prior to transmission at the request of the sponsor. Using this method means that data files are only stored on University of Waterloo servers during the transfer.

10.3 COMMENTS ON SOURCE DOCUMENTS

Data analysis will not be conducted on comments which have been recorded in the source documents. Only highlighted comments will be entered into the study database. Only relevant and applicable comments will be included in the final report as deemed necessary by the lead investigator.

11 PROTOCOL TRAINING

All study personnel will be required to complete training prior to their involvement in the study. A series of training modules will be developed for the study and records of training will be kept at CORE.

12 STUDY MONITORING

Status reports will be provided to the study sponsor by email on a regular basis.

Status reports will include:

- The number of participants screened, enrolled, and randomized (i.e. assigned a study ID number), discontinued and completed.
- Details of protocol deviations.
- Reports of unintended events.

Study monitoring will be conducted by CORE personnel. Consent documentation will be reviewed by a person not involved in the consent process. To improve data integrity, data entry will be conducted by one person and a second person will visually compare the data entry to the source documents. All adverse events and protocol deviations will be reviewed by the Lead Investigator. All significant and serious adverse events and all major protocol deviations will be reviewed by the Head of Clinical Research and the Principle Investigator and reported to the

sponsor and the Office of Research Ethics at the University of Waterloo according to reporting requirements..

In addition study records may be inspected at CORE by the sponsor, the sponsor's designate, the Office of Research Ethics at the University of Waterloo, and by regulatory authorities in Canada and the United States, namely Health Canada and the United States Food and Drug Administration (FDA); however, no records containing identifiable/personal information will be permitted to leave the custody of CORE.

13 STUDY MANAGEMENT

13.1 STATEMENT OF COMPLIANCE

This clinical study is designed to be in compliance with the ethical principles in the Declaration of Helsinki, with the ICH guidelines for Good Clinical Practice (GCP) (ICH E6 R2), with ISO 14155:2020 Clinical Investigation of Medical Devices for Human Subjects, with the University of Waterloo's Guidelines for Research with Human Participants and with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2nd Edition.

- Declaration of Helsinki
- ICH E6 - International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guidelines for Good Clinical Practice
- ISO 14155:2020 - International Organization for Standardization Clinical investigation of medical devices for human subjects – Good clinical practice
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)
- https://uwaterloo.ca/research/office-research-ethics/research-human-participants

13.2 ETHICS REVIEW

This protocol will be submitted to and reviewed through the Office of Research Ethics (ORE) at the University of Waterloo. Notification of ethics clearance of the application is required prior to the commencement of the study.

13.3 CLINICAL TRIAL REGISTRATION

The sponsor will register this study with clinicaltrials.gov.

13.4 PROTOCOL DEVIATIONS

Protocol deviations are unanticipated or unintentional changes to a study after it has received prior sponsor approval and ethics clearance. Protocol deviations can be major or minor.

13.4.1 MAJOR PROTOCOL DEVIATIONS

Major protocol deviations may impact the research protocol, information consent document or other study materials, usually cannot be anticipated ahead of time and are often necessary to ensure the safety and welfare of the participants.

The following are examples of protocol deviations that must be reported to the ORE:

- Changes in procedures initiated to eliminate immediate risks/hazards to participants;
- Enrollment of participants outside the protocol inclusion/exclusion criteria whether agreed to or not by the sponsor;
- Medication / device / intervention errors (i.e. incorrect drug or dosage of drug / incorrect contact lens(es) dispensed / incorrect care system dispensed);
- Inadvertent deviation in specific research intervention procedures or timing of the research intervention which could impact upon the safety or efficacy of the study-related intervention or upon the experimental design;
- Information consent documentation violations: no documentation of informed consent; incorrect version of, or incomplete, informed consent documentation used.

13.4.2 MINOR PROTOCOL DEVIATIONS

Protocol deviations caused by or which originate with research participants are considered minor, and normally are not reported to the ORE unless these result in increased risk to the participant(s). The following are examples of protocol deviations that are considered minor and do not require reporting to the ORE:

- Logistical or administrative aspects of the study (e.g., study participant missed appointment, change in appointment date);
- Inadvertent deviation in specific research intervention procedures or timing of the research intervention which would not impact upon the safety or efficacy of the study-related intervention or upon the experimental design (i.e., missing a measurement during a session that is not considered critical for the study).

13.4.3 REPORTING AND DOCUMENTING PROTCOL DEVIATIONS

Major protocol deviations must be reported to the ORE within 7 days of the deviation occurring (or its discovery) using the Protocol Deviation Report Form 107 (PDRF). Information from the PDRF is provided to the Clinical Research Ethics Board (CREB) at the next monthly meeting.

All protocol deviations (major and minor) occurring during the study will be documented and included in the final report.

13.5 PREMATURE TERMINATION OF THE STUDY

The sponsor, CORE or the Office of Research Ethics at the University of Waterloo may terminate the study at any time for any reason.

13.6 STUDY PARTICIPANT RECORDS

Study participant records will be completed to comply with GCP guidelines. Records will contain:

- Unique study acronym and/or code;
- Participant ID;
- Date enrolled;
- Confirmation by investigator that participant met eligibility criteria;
- Confirmation that participant received a signed and dated copy of informed consent;
- Exit date;
- Investigator's signature confirming study exit.

13.7 RETENTION OF STUDY RECORDS AND DATA

Records and data from this study will be retained for a minimum of 25 years. Details regarding storage procedures are given in CORE SOP014 Clinical data management.

14 REPORT

A report will be sent to the sponsors according to terms described in the study contract.

15 REFERENCES

1. Navascues-Corago M, *et al*. Determination of the minimal clinically important difference (MCID) for contact lens-related subjective responses. BCLA Clinical Conference. Manchester 2023.