CORE
Centre for Ocular Research & Education

UNIVERSITY OF WATERLOO
FACULTY OF SCIENCE
School of Optometry & Vision Science

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Protocol

EVALUATING THE PERFORMANCE OF PRECISION1 DAILY DISPOSABLE CONTACT LENS IN A GROUP OF HEAVY DIGITAL DEVICE USERS (PUG)

Funding source: ALCON (IIT)

Funding study number: IIT Proposal [redacted]

CORE protocol number: P/706/19/L

Protocol author: [redacted]

Principal investigator(s): Lyndon Jones

Role & printed name	Reviewed and approved	Date DD/MMM/YYYY
Principal investigator: [redacted]	[redacted]	
Protocol author: [redacted]		
Quality assurance: Jill Woods		

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Quality assurance: [redacted]		

Study Personnel

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DOCUMENT CHANGE HISTORY

Version date	Author	Description of change(s)
26Nov2019	[redacted]	Original protocol
29nov2019	[redacted]	Revisions following IRB review
12Dec2019	[redacted]	Updated Time to Haze measurement description (section 4.5.8) to be done using at 6/19 acuity.

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Confidentiality

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Disclaimer

This study will be conducted for research purposes only.

1 INTRODUCTION

Approximately 22% of new contact lens (CL) wearers cease contact lens wear within the first year, with handling (25%), poor distance (23%) and/or near vision (21%) and discomfort (21%) being the main reasons for discontinuation.[1] With today's ever-expanding access to digital devices, the number of potential CL wear drop-outs may further be affected by digital device use. A recent review found a higher prevalence of symptoms of eye strain, eye fatigue or blurred vision in CL wearers compared to non-CL wearers (65% vs 50%) when using digital devices.[2] The symptoms associated with digital device use in contact lens wear may be affected by multiple factors, including an insufficient blink rate or a poorly wetting contact lens.

Time to haze (TTH) is a metric that has been developed at CORE to measure the maximum time a contact lens wearer can keep their eye open without their vision becoming hazy (conducted just above contrast threshold level); it is a measure of how the drying of the CL surface with open eyes affects vision.

Alcon has recently introduced a new silicone hydrogel (SiHy) daily disposable contact lens (DD CL), called Precision1, which is manufactured from the verofilcon A material. Precision1 DD CLs use 'SMARTSURFACE Technology; which Alcon describe as *"a permanent, micro-thin, high-performance layer of moisture at the lens surface that helps support a stable tear film to deliver lasting visual performance from morning to night"*.[3]

The purpose of this study is to evaluate the performance of Precision1 DD CLs with regard to subjective symptoms (dryness, comfort, vision), lens fit and time to haze in CL wearers who identify themselves as heavy digital devices users (at least 6 hours of digital device use per day).

2 OBJECTIVES

The objectives of the study are:

- To assess subjective ratings for contact lens comfort, dryness and clarity of vision after insertion, after 6hrs of digital devices use and at the end of day in heavy digital devices users while wearing Precision1 for two weeks.
- To determine subjective satisfaction with Precision1 CLs when using digital devices.

The primary outcome variables for this study are:

- Subjective ratings of CL comfort, dryness, clarity of vision after insertion, after 6hrs or more using digital devices, and at the end of day (0 to 100 scale).

Other outcome variables of interest include

- Likert type questions exploring the satisfaction with Precision1 CLs when using digital devices.
- Lens fit
- Lens surface characteristics (wettability, pre-lens tear break-up time & deposits)
- Time to haze
- Conjunctival redness
- Visual acuity

3 HYPOTHESIS

Precision1 CLs will provide a satisfactory performance for heavy digital device users as reflected in subjective ratings for comfort, dryness and clarity of vision.

4 MATERIALS AND METHODS

4.1 STUDY DESIGN

4.1.1 OVERALL DESIGN

This is a prospective, non-masked, open-label, dispensing pilot study with three study visits on two study days. CL wearers who identify themselves as using digital devices for at least 6 hours on a typical day will be enrolled. Eligible participants will be dispensed with the Precision1 study lenses for a duration of 14±2 days, to be worn for at least 5 days a week and at least 10 hours per day:

- **Visit 1:** Screening and fitting of study lens (1.0 hour)
- **Visit 2:** Baseline & Dispense (0.5 hours; same day as and directly after V1)
- **Visit 3:** Day 14 Follow-up and study exit (1.0 hour)

4.1.2 MASKING

This is an open-label study that will not involve masking.

4.2 STUDY POPULATION

4.2.1 SAMPLE SIZE CALCULATION

The sample size required for a 2-tailed matched paired t-test to detect a change of 5 points in a 0-100 subjective rating scale, with α=0.05, power = 0.90, and an effect size of 0.60 is 32 to complete the study, i.e. a minimum sample size of 32 participants completing the study.

4.2.2 NUMBER OF PARTICIPANTS

Participants will be recruited / screened using CORE records and advertising approved by the UW Office of Research Ethics. Up to 35 participants who meet all eligibility criteria may be dispensed with Precision1 study lenses and asked to wear these lenses for 14±2 days, with a target of 32 completing the study. Participants who were screened but did not meet all eligibility criteria are not included in the number of participants (n=35) to be dispensed. Informed consent will be obtained for all participants prior to their enrolment in the study (Appendix 1).

4.2.3 INCLUSION AND EXCLUSION CRITERIA

A person is eligible for inclusion in the study if he/she:

1. Is between 18 and 40 years of age (inclusive) and has full legal capacity to volunteer;
2. Has read and signed an information consent letter;
3. Is willing and able to follow instructions and maintain the appointment schedule;
4. Is a heavy digital device user (at least 6 hours on a typical day using any combination of digital devices such as PC, laptop, smartphone, or tablet);
5. Is a habitual wearer of daily, spherical, soft contact lenses (no bifocal or multifocal contact lenses, no extended wear or monovision, not a current wearer of Precision1 lenses) for at least 5 days/week and at least 10 hours/day during the month prior to enrollment;
6. Has a vertex corrected spherical equivalent distance refraction that ranges between -0.50D to -6.00D in each eye;
7. Has a vertex corrected refractive cylinder of no more than -1.00D cylindrical correction in each eye after vertexing to the corneal plane;
8. Demonstrates an acceptable fit and achieves best corrected visual acuity of at least 0.20 log MAR in each eye with Precision1 contact lenses;

9. Is willing to wear Precision1 CLs at least 5 days per week and 10 hours per day throughout the study;

A person will be excluded from the study if he/she:

1. Is participating in any concurrent clinical or research study;
2. Has any known active* ocular disease and/or infection;
3. Has a systemic condition that in the opinion of the investigator may affect a study outcome variable;
4. Is using any systemic or topical medications that in the opinion of the investigator may affect a study outcome variable;
5. Has known sensitivity to the diagnostic pharmaceuticals to be used in the study;
6. Is pregnant, lactating or planning a pregnancy at the time of enrolment;
7. Is aphakic;
8. Has undergone refractive error surgery;

* 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 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.

Age >40 years is excluded because presbyopia and pre-presbyopia is highly prevalent in this population and will cause eyestrain which is unlikely to be improved with a change in contact lens material.

Pregnant and lactating women are not being excluded from the study due to safety concerns but due to fluctuations in refractive error and/ or visual acuity that occur secondary to systemic hormonal changes. It has further been shown that pregnancy could impact tear production, which could impact dry eye symptoms. Such fluctuations could affect data, thereby negatively affecting study data integrity.

4.2.4 REPEATED SCREENINGS

In some circumstances a repeated screening may need to be scheduled (Visit 1-R). 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 2, i.e. 1 re-screen is permitted.

4.3 STUDY MATERIALS

4.3.1 LENSES

All study lenses are approved by Health Canada. They will be worn bilaterally, and on a daily disposable basis, therefore no lens care solution is required.

Table 1: lens characteristics

Lens	Precision1
Material	verofilcon a
HC licence #	101910
Medical device class	2
Dk/t (barrer/cm)	100
Water content	51%
Sphere power (D)	-0.50 to -6.00 (0.25 steps)
Base curve (mm)	8.3
Diameter	14.2
Replacement schedule	Daily disposable

4.3.2 REWETTING DROPS

Participants will not be encouraged to use rewetting drops; however, those who habitually used rewetting drops will be allowed to continue using their normal drops. Rewetting drop use will be recorded at each visit.

4.3.3 ORDERING CONSUMABLES

Precision1 study lenses will be supplied by Alcon for the use in this study.

4.3.4 DISPOSING OF CONSUMABLES

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

4.3.5 PRODUCT ACCOUNTABILITY

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

4.4 SCHEDULED AND UNSCHEDULED VISITS

There will be three study visits, including a screening visit. Participants will attend the clinical site for a total of 2.5 hours. Participants will also be asked to complete at home ratings on Day 1, Day 7 and Day 10, to assess their experience with the study CL.

4.4.1 STUDY VISITS

A summary of study visits is shown in Table 2.

Table 2: Summary of visits

Visit #	Day/s	Visits	Duration (hours)
Visit 1	0	Screening and fitting	1.0
Visit 2	0	Baseline & Dispense. Instructions on "at home ratings"	0.5
Given to participant at Visit 2	Day 1, Day 7, Day 10	Subjective at-home ratings	0.5
Visit 3 & Exit	14 (-2/+2) after V2	Day 14 Follow-up	1.0

Visits that fall outside of the specified visit windows will be designated as minor protocol deviations and at the end of the study, the data collected during protocol deviations will be assessed for their suitability to be included in the analysis population.

4.4.2 SCREENING (VISIT 1)

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.

Participants will be assigned a study ID number after they sign the consent documentation process i.e. before their eligibility for the study has been confirmed. The investigator will determine participant eligibility using the inclusion and exclusion criteria. Ineligible participants will be discontinued from the study. The procedures to be performed are outlined below:

Participants will attend this visit having not worn their contact lenses for 12hrs prior to the visit.

1. Informed consent
2. Participant demographics and medical history:
    - *Age, Sex*
    - *Medical history/medications, Allergies*
3. CL wear & digital device use history
    - *Habitual contact lens wear (CL type, cleaning solution (if applicable), wear time and comfortable wear time; Eye drop / artificial tear use (if applicable))*
    - *Digital device use (device kind, combined duration)*
4. Unaided or with habitual spectacles; monocular & binocular logMAR distance high illumination high contrast visual acuity (HIHC VA)
5. Biomicroscopy examination
6. Auto refraction/auto keratometry
7. Sphero-cylindrical refraction, monocular & binocular logMAR distance HIHC VA
8. Best sphere refraction, monocular & binocular logMAR distance HIHC VA
9. Precision1 study lens fitting
    a. The contact lens power will be chosen based on the vertexed best sphere refraction.
    b. The participant will insert the lenses.
    c. Acceptability of lens fit (centration, movement, limbal coverage, overall; YES/NO) will be confirmed.
    d. Monocular over-refraction will be performed to determine if a different power is needed. If any changes are made, the above procedures will be repeated.
    e. The final lens powers for OD and OS and monocular & binocular logMAR distance HIHC VA will be recorded.

10. Confirm eligibility.

4.4.3 BASELINE & DISPENSE (VISIT 2)

Participants who successfully met all eligibility criteria will directly transition to Visit 2, while continuing to wear the pair of study lenses that has just been fitted.

1. Subjective post-insertion ratings (0-100 scale, where 100 means better performance; integer steps, both eyes rated together), to assess the first impression of Precision1 regarding:
    - *Comfort;*
    - *Dryness;*
    - *Clarity of vision;*
2. Lens fit & surface assessment
3. Time to haze
4. Lens dispense: Participants will be provided with a supply of Precision1 CLs to last them until their next study visit (12-16 days after V2).
5. At-home rating scales: Participants will receive at home rating scales, to be completed on Day 1, Day 7 and Day 10.
6. Participant instructions. The participants will be asked to:
    - *Wear the lenses at least 5 days per week and 10 hours per day throughout the study;*
    - *To complete subjective ratings at home to reflect their lens wear experience on Day 1 (the day after V2), Day 7 and Day 10 using a 0-100 scale, where 100 means better performance; integer steps, both eyes rated together). Ratings will be completed at lens insertion, after 6 hours of digital device use, and just before CL removal. Variables to be assessed are*:
        - *Comfort*
        - *Dryness*
        - *Clarity of vision*
    - *Attend V3 after 6 hours or more of Precision1 study lens wear;*

4.4.4 DAY 14 FOLLOW-UP & EXIT (VISIT 3)

Participant to attend visit after 6 hours or more of Precision1 study lens wear.

1. Collect unused study CLs;
2. Changes in medical history/medications;
3. Compliance with # of CL wear days/hours per day (total & comfortable) and # hours of digital device use over past 2 weeks and for V3 visit day;
4. Collect and review at-home ratings;
5. Study CL logMAR HIHC VA for OD, OS and OU;
6. Subjective ratings (0-100 scale, where 100 means better performance; integer steps, both eyes rated together), to assess a typical day in the past 2 weeks for insertion, after 6 hours of digital device use, and just before CL removal.
    - *Comfort*
    - *Dryness*
    - *Clarity of vision*
7. Satisfaction (4-point Likert scale: strongly disagree, slightly disagree, slightly agree, strongly agree) with Precision1 CLs overall and when using digital devices on a typical day in the past 2 weeks
8. Lens fit & surface assessment
9. Time to haze
10. Lens removal
11. Biomicroscopy examination

4.4.5 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-study follow-up visits are required, the exit form will be completed after the last follow-up visit.

Exit monocular and binocular distance (HIHC VA logMAR) will be recorded with either the participant's spectacles, refraction or habitual contact lenses. An exit biomicroscopy assessment will be conducted if not already completed on the same day for a concurrent study visit.

After the exit assessments have been completed, the participant and investigator will complete the study completion and remuneration forms. At this time the participant will be considered as having exited the study.

4.4.6 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

Table 3 summarizes the procedures at each visit. The order of procedures is described in sections 4.4.2 to 4.4.4.

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

Procedure	Visit 1	Visit 2	Visit 3
	Screening	Baseline & Dispense	Day 14 Follow-up
Informed consent	X		
Participant demographics (age, sex)	X		
Medical history and medications	X		
Changes in medical history/ medications			X
Contact lens history	X		
Digital device use history	X		
HIHC VA (logMAR) (unaided or with habitual spectacles)	X		
Biomicroscopy	X		X
Auto refraction/auto keratometry: horizontal and vertical K readings	X		
Subjective refraction	X		
HIHC VA (logMAR) (study CL)	X		X

Study lens fitting	X		
Eligibility	X		
Subjective ratings (Post-insertion re Comfort, Dryness & Vision)		X	
Lens performance (fit, wettability, pre-lens TBUT, deposition)		X	X
Time to haze		X	X
Study lens dispense		X	
Subjective at-home ratings (Comfort, Dryness & Vision) provided		X	
Review of compliance (CL wear, digital device use, completion of home ratings)			X
Subjective ratings (Comfort, Dryness & Vision)			X
Satisfaction ratings (Likert scale for agreement)			X
Collection of unused study lenses			X
Study Exit			X

4.5.1 CASE HISTORY

Demographics:

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

Medical History:

At screening, information will be obtained from participants about the current medication, allergies, and any medical conditions. At visit 3 participants 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, lens wear days and use of artificial tears. Participants will be asked their typical total wear time (hours/day) and comfortable wear time (hours/day).

Digital device use:

Participants will be asked about their typical use of digital devices (total hours/day of all devices combined), and to identify the kind of devices (e.g. smartphone, computer, laptop, tablet) they use.

4.5.2 SUBJECTIVE RATINGS

Subjective ratings:

At visit 2, participants will be provided with subjective rating 0-100 questionnaires to assess their first impression with the study CLs post insertion regarding comfort, dryness and clarity of vision.

At the end of visit 2, they will be provided with at-home questionnaires to subjectively rate the experience with the study lenses regarding comfort, dryness and clarity of vision using a 0-100 scale (integer steps; both eyes together), where 100 means better performance. This questionnaire will be completed at home on Days 1, 7 and 10 after Visit 2 (i.e. Day 0), at three different time-points on each of these days: directly after insertion, after 6 hours of digital device use, and at the end of day just before lens removal. In addition, times of lens insertion, first notice of discomfort, and lens removal will be collected.

The same questionnaire will be provided to the participants during V3 to assess their overall 'typical day' experience during the past 2 weeks.

Satisfaction with study CL:

Satisfaction (4-point Likert scale: strongly disagree, slightly disagree, slightly agree, strongly agree) with Precision1 CLs overall and while using digital devices on a typical day in the past 2 weeks will be assessed for the following questions:

- *The study lenses provide good vision all day long;*
- *The study lenses provide good comfort all day long;*
- *I am satisfied with the comfort the study lenses provide when I use digital devices for ≥6 hours;*
- *I am satisfied with the vision the study lenses provide when I use digital devices for ≥6 hours;*
- *I don't experience eye strain when I wear the study lenses and use digital devices for ≥6 hours.*
- *I don't experience eye fatigue (tired eyes) when I wear the study lenses and use digital devices for ≥6 hours.*
- *I don't experience episodes of blurred vision when I wear the study lenses and use digital devices for ≥6 hours.*

- *Overall, these lenses provide good performance when using digital devices for ≥6 hours.*

4.5.3 VISUAL ACUITY

Visual acuity for distance will be measured using high contrast computer-generated acuity charts in high illumination. Participants will be asked to read letters that progressively decrease in size on a computer screen located at a distance of 6 meters.

4.5.4 AUTOREFRACTION

Participants will be asked to focus on a target while seated at an instrument that measures their approximate spectacle prescription and corneal shape.

4.5.5 SUBJECTIVE REFRACTION

Participants will be asked to read a letter chart from a distance through lenses placed in front of their eyes. They will also be asked to compare clarity of their vision between different lenses placed in front of their eyes. This procedure aids to determine their spectacle and/or contact lens prescription.

4.5.6 SLIT LAMP BIOMICROSCOPY

The participant will be seated behind a slit lamp and the following may be assessed at any visit:

External adnexa anomalies:

Any current observations of the anterior eye (e.g. pterygium, pinguecula, etc) will be recorded.

Cornea:

Any current or past corneal observations (such as infiltrates, old scars, etc) will be documented.

Conjunctival redness:

Ocular redness will be assessed for the bulbar and limbal conjunctiva using the EFRON grading scale (0 to 4, 0 = normal; 0.1 increments).

Corneal and conjunctival staining with fluorescein:

Corneal staining will be assessed for 5 zones, by grading type (0-4, 0.5 steps), extent (0-4, 0.5 steps) and depth (0-4, integer steps);

Lens edge related conjunctival staining and conjunctival indentation will be assessed for 4 zones (0-4, 0.5 steps);

Palpebral conjunctival hyperemia and roughness:

The redness and roughness of the upper and lower eyelids (tarsal plate zone 2) will be assessed using the Efron grading scale (0 to 4, 0 = normal/ uniform satin appearance; 0.25 steps).

4.5.7 LENS FIT & SURFACE ASSESSMENT

Contact lens fit:

Lens fit will be assessed to ensure acceptable lens fit with study lenses at the screening visit.

At V2 and V3, lens centration and movement will be assessed as follows

- *Lens centration (scale: optimal, slight decentration, moderate decentration but not encroaching limbus, excessive & occasionally encroaching limbus);*
- *Lens movement for primary gaze (-2 = Unacceptably tight; -1 = Slightly tight but acceptable; 0 = Optimal; +1 = Slightly loose but acceptable; +2 = Unacceptably loose); lens tightness on push-up test (0-100 scale, with 50 being optimal; 5-point steps);*

Contact lens wettability, pre-lens tear break-up time and deposits:

Contact lens wettability and deposits will be graded with study lenses at V2 and V3:

- *Surface wettability (0-4 scale in 0.25 steps; 0 being excellent);*
- *Pre-lens tear break up time (TBUT), average of 3 measures (seconds)*
- *Surface deposits (0-4 scale in 0.25 steps; 0 being excellent);*

4.5.8 TIME TO HAZE

Time to haze and number of blinks to clear while wearing study CLs will be measured at V2 and V3, using a computerized chart capable of displaying letters at varying contrast levels at a distance of 1m. Participants will be seated in front of the chart and 5 letters of a given acuity size (6/19) will be displayed. Participants will be asked to read the letters while the contrast of the letters will be reduced until the participant cannot read all 5 letters anymore. The contrast will be adjusted back to the last level where participants can still read all 5 letters. The following measurements will be taken:

- *Time to haze (seconds): After 3 consecutive blinks, the participant is asked to keep their eyes open while continuously looking at the row of letters. The time until at least one letter is no longer "legible" is measured using a stopwatch.*

- *Blinks to clear (integer count): Starting immediately after first observation of haze, the participant is given verbal instructions at 1s intervals to blink until all 5 letters are clear again. The number of blinks it takes for the subject to clear the letters is counted.*

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.

Contact lenses in this study will be worn on a daily wear (and daily disposable) basis. Adverse events and/ or complications in daily wear of soft contact lenses can occur (e.g. inflammation and infection). Complications that may occur during the wearing of contact lenses include discomfort, dryness, aching or itching eyes, excessive tearing, discharge, hyperemia and variable or blurred vision. More serious risks may include photophobia, iritis, corneal edema or eye infection. Although contact lens-related infections are very infrequent, the possibility does exist. The incidence of infection due to daily-wear soft lenses is 0.035%. Almost always an infection will occur only in one eye. Thirty five million Americans who currently wear contact lenses assume this risk.

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.

A dye (fluorescein) normally used for eye exams is being used in this study. Although rare, it is possible that participants may have an allergic reaction to the dye. This could cause discomfort to their eye.

Participants are advised to inform the investigator of any sensitivities to any ophthalmic drops or study products.

Additionally, it is possible that participants may experience temporary discomfort associated with the study procedures /products including: burning and stinging, blurred vision, sandiness or grittiness, light sensitivity, dryness, itching, crusty eyes and foreign body sensation.

Participants may not benefit directly from taking part in this study. Participants will have the opportunity to try a different type of soft contact lenses at no cost to them, to see whether it provides them with improved symptoms during digital device use.

Information from this study may help researchers come up with new soft contact lens designs to help others in the future. This study may help the study sponsor to better understand the performance of the products being used in this study, particularly during digital device use.

7 ADVERSE EVENTS

See CORE SOP012_v02 for a description of all adverse events, including management and reporting.

Any observations taking place prior to determining that a subject 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.

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. Participants discontinued from a study will be reimbursed $20 per hour for their active involvement in the study (including the initial screening visit). 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 4.2.2.
- 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.

- Positive slit lamp finding: Participants may be permanently discontinued from the study depending on the severity of the condition and on the judgement of the investigator.
- 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.
- Instillation of topical ocular medication: The participant will be discontinued if they elect to use a topical ocular medication during the study unless that topical ocular medication is prescribed for a limited duration (less than two weeks) to treat a transient condition; in this case the participant may remain an active participant (at the discretion of the investigator) after stopping topical ocular medication following resolution of the ocular condition).
- 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.

9 STUDY COMPLETION AND REMUNERATION

At the last scheduled protocol visit a study completion form will be completed, which requires the signatures of both the participant and the investigator.

Once their involvement in the study is complete, participants will be informed about receiving feedback following study completion in the Letter of Appreciation.

Participant remuneration will be $60 for completing the study this includes $50 for active time and $10 for completing the at-home questionnaires.

10 STATISTICAL ANALYSIS AND DATA MANAGEMENT

10.1 STATISTICAL ANALYSIS

All data will be analyzed by CORE at the University of Waterloo. Data analysis will be conducted using Statistica, SPSS, or other appropriate software.

Descriptive statistics will be provided for all primary outcome variables as well as information regarding baseline variables (e.g. age, sex).

Subjective ratings, lens fit assessments and time to haze will be compared between Visit 2 (Precision1 Dispense) and Visit 3 (2-week follow-up) using either Paired t-tests or Wilcoxon matched pairs, or using ANOVA, as applicable; statistical significance will be set at 5%. The appropriate tests will be selected based on tests of normality - non-parametric tests will be used for data not showing a normal distribution. For assessments conducted for each eye separately, the right eye will be used for analysis if there is no difference between eyes.

Binomial testing will be conducted to analyze Likert questionnaires (strongly agree, slightly agree, slightly disagree, strongly disagree) to determine whether participants had a positive or negative experience with the test lens.

Additional analysis may be conducted.

10.2 DATA MANAGEMENT

All study data will be recorded on paper CRFs. Data from this study will be entered in an electronic database and 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.

At the completion of the study CORE may provide a copy of the study data to the funding company. 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. 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 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. Records of training will be kept at CORE.

12 STUDY MONITORING

Study monitoring will be conducted throughout the study. In addition study records may be inspected at CORE by 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.

Study monitoring will include, but may not be limited to:

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

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), 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 Conference on Harmonisation; Good Clinical Practice
- http://iris.uwaterloo.ca/ethics/human/guidelines/index.htm
- http://iris.uwaterloo.ca/ethics/human/ethicsReview/UWStatement.htm
- http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

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

CORE 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 Committee (CREC) 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_v02 Clinical data management.

14 REPORT

A report will be completed after data collection has been completed.

15 REFERENCES

1. Sulley A, Young G, Hunt C, et al. Retention rates in new contact lens wearers. *Eye & Contact Lens*. 2018;44:S273-S282
2. Sheppard AL, Wolffsohn JS. Digital eye strain: prevalence, measurement and amelioration. *BMJ Open Ophthalmol* 2018;3:e000146
3. Alcon press release; accessible at https://www.alcon.com/media-release/alcon-launch-precision1-daily-disposable-contact-lenses-it-continues-deliver-vision. Last accessed on 26-Aug-2019.