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Centre for Ocular Research & Education

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Protocol

EVALUATING THE INITIAL LENS HANDLING EXPERIENCE OF NEOPHYTE CONTACT LENS WEARERS FITTED WITH PRECISION1 AND 1-DAY ACUVUE MOIST CONTACT LENSES (SALUKI)

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DOCUMENT CHANGE HISTORY

Version date	Author	Description of change(s)
21Nov2019	[redacted]	Original protocol
02Dec2019	[redacted]	After feedback from ethics: clarification of Visit 1 and Visit 1B-R, updated Table of contents.

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Confidentiality

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Disclaimer

This study will be conducted for research purposes only and is not intended to be used to support safety and efficacy in a regulatory submission.

1 INTRODUCTION

Contact lens (CL) dropout is a problem for established CL wearers but also in new wearers (neophytes).[1] A recent retrospective study on neophytes showed that 1 in 4 patients discontinued lens wear within the first 12 months with the primary reasons being vision (41%), comfort (36%) and lens handling problems (25%).[2]

Alcon has recently launched a new daily disposable contact lens (Precision1) and in this study the initial subjective handling experience of neophyte CL wearers will be determined. The handling experience with this new lens will be compared to a daily disposable lens which has been on the market for numerous years already (1-Day ACUVUE Moist).

2 OBJECTIVES

The objectives of the study are:

- Subjective ratings of lens handling for insertion and removal as determined during the handling training component of Visit 1 (Or Visit 1B-R) (i.e. the first exposure of the participants to handling contact lenses; 0 to 100 scale) for each lens.
- Additional "general" handling questions to be evaluated may include "Ease of opening package", "Ease of removing lens from package", "Ease of telling whether lens is inside/out" or "Stability on finger". These questions will be evaluated after training session (Visit 1 and Visit 1B-R)) and after 1 week of wear (Visit 2), using 0 – 100 ratings.

Primary Endpoint:

- Subjective ratings of lens handling for insertion and removal as determined during the handling training component during Visit 1 (and Visit 1B-R) (i.e. the first exposure of the participants to handling contact lenses; 0 to 100 scale)

Other Endpoints:

- Subjective ratings of comfort and handling after 1 week of wear, considering a "typical day" (0 to 100 scale)
- Lens preference after 1 week of wear for Handling for Insertion & Handling for Removal (Likert scale; including strongly prefer Lens1, slightly prefer Lens1, no preference, slightly prefer Lens2, strongly prefer Lens2)
- Subjective ratings (0 – 100 scale) of "general" handling questions, to be evaluated at Visit 1 and Visit 1B-R (based on initial training) & at Visit 2 (after 1 week of wear), including

"Ease of opening package", "Ease of removing lens from package", "Ease of telling whether lens is inside/out" and "Stability on finger".

3 RATIONALE

Although CL handling is an important factor to the success of CL use in neophytes, the handling experience of Precision 1 compared to a hydrogel daily CL is unknown.

4 HYPOTHESIS

Neophyte participants will have a superior handling experience for insertion, removal, overall handling and handling preference with Precision1 DD CLs when compared to 1-Day ACUVUE Moist DD CLs.

5 MATERIALS AND METHODS

5.1 STUDY DESIGN

5.1.1 OVERALL DESIGN

This is a prospective, double-masked, contralateral wear, dispensing, single-site study with 2 study visits over the course of 1 week. Eligible participants will wear the two study lens types (L1 & L2) contralaterally for approximately 1 week (6-10 days) at least 5 days and at least 6 hours/day.

5.1.2 RANDOMIZATION

A randomization schedule will be generated using a web-based program: (for example www.randomization.com) by CORE's Data management team, and provided to the research assistants for the study. The schedule will determine which lens type (L1 or L2) will be worn on which eye for each participant. In addition, start eye for insertion/removal training will also be randomized to prevent any potential bias due to handedness/dexterity. Study investigators and participants will remain masked to the lens randomization schedule until the study is completed and the database has been locked.

5.1.3 MASKING

Participants and Investigators will be masked to which lens type (brand) the participants will be wearing in each eye during the study in order to reduce bias towards or against any of the products. Lens packages/ blister will be overlabeled.

5.2 STUDY POPULATION

5.2.1 SAMPLE SIZE CALCULATION

The sample size required for a 2-tailed matched paired t-test to detect a change of 5 points in subjective ratings of handling for insertion and removal, with α=0.05, power = 0.90, and an effect size of 0.60 is 32 to complete the study and be eligible for data analysis (a sample size of 32 participants excluding possible dropouts and screen failures).

Up to 60 participants may be randomized to and dispensed with 1-Day ACUVUE Moist and Precision1 DD CLs, to account for potential drop-out in neophytes e.g. due to adaptation/ handling issues.

5.2.2 NUMBER OF PARTICIPANTS

Up to 60 participants may be recruited using CORE records and advertising approved by the UW Office of Research Ethics. Up to 60 participants may be randomized to and dispensed with study products, with a target of number of 32 participants completing the study. Informed consent will be obtained for all participants prior to their enrolment in the study (Appendix 1).

5.2.3 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 inclusively 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 neophyte who has no history of any previous contact lens handling experience;
5. Has a refraction cyl ≤1.00DC in either eye (after vertexing to corneal plane);
6. Has visual acuity ≤0.20 logMAR each eye with study lenses;
7. Demonstrates acceptable fit with study lenses;
8. Demonstrates the ability to successfully insert and remove the study lenses 3 times for each eye (contralateral CL handling, so that each lens type inserted and removed 3x on same eye);
9. Is willing to wear study CLs at least 5 days per week and 6 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 (by self-report);
7. Is aphakic;
8. Has undergone refractive error surgery;
9. Has taken part in another clinical research study within the last 14 days;
10. Any ocular and/or systemic conditions or concomitant medication to contraindicate contact lens wear or be expected to interfere with the primary outcome variables.

* 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.

5.2.4 REPEATED SCREENINGS

In some circumstances a repeated screening (Visit 1R) 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. incomplete information about medical history.)
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 (per subject) will be 3.

5.3 STUDY MATERIALS

5.3.1 LENSES

Details on the lens type used in this study are listed in Table 1.

Table 1: Lens characteristics

Lens	Precision 1	1-Day Acuvue Moist
Material	Verofilcon A	Etafilcon A
Manufacturer	Alcon	Johnson & Johnson
HC licence #	101910	2519
Dk/t (barrer/cm)	100 (-3.00D)	25.5 (-3.00D)
Sphere power (D)	-0.50D to -6.00D	-0.50D to -6.00D
Base curve (mm)	8.3	8.5
Diameter	14.2	14.2
Replacement schedule	daily	daily

5.3.2 LENS CARE SYSTEM

A lens care system is not needed, because the lenses will be worn on a daily disposable basis and will be discarded at the end of each lens wear day.

5.3.3 REWETTING DROPS

Participants will not be provided with rewetting drops.

5.3.4 ORDERING CONSUMABLES

Precision1 lenses will be supplied by Alcon for the use in this study. A research assistant at CORE will order 1 day Acuvue Moist lenses from Johnson & Johnson, the cost for these lenses is included in the budget.

5.3.5 DISPOSING OF CONSUMABLES

Worn lenses collected during study visits and unworn lenses returned will be discarded as per University of Waterloo regulations. Contact lenses that were not dispensed to study participants may be returned to the sponsor, re-used for research purposes at CORE, or destroyed.

5.3.6 PRODUCT ACCOUNTABILITY

Accountability logs will be kept to include the number of lenses received, dispensed and unused. All products dispensed to participants will be recorded in the study binder using individual study participant accountability logs.

5.4 SCHEDULED AND UNSCHEDULED VISITS

This study has a total of 2 study visits, including the screening visit.

5.4.1 SCREENING

The investigator will determine participant eligibility using the inclusion and exclusion criteria. All participants who sign the consent letter will be assigned a study ID number. Ineligible participants will be discontinued from the study.

5.4.2 STUDY VISITS

Table 2 shows the summary of the 2 study visits. The total time commitment for each participant is 2hr 45 min. Participants who did not complete the handling training successfully at Visit 1, will return for Visit 1B-R (1hr) visit for additional handling training.

Table 2: Summary of visits

Visit code	Visits
1	Part A: Screening, Lens fitting (1hr) Part B: Handling training, Questionnaires, Lens dispensing (1hr)
1B-R	*OPTIONAL: Handling Training (both CL types) & Dispense (only if px did not pass handling training at Visit 1) (1hr)*
2	Follow-up and Exit (45 min)

Visit 1 -Part A - Screening and lens fitting (1hr)

The participant will attend the study visit wearing spectacles. The participant's eligibility for the study will be determined, including the following:

- Informed consent procedure
- Participant demographics (age, sex)
- Participant medical history/medications
- With habitual spectacles, logMAR high illumination high contrast visual acuity (HIHC VA) for OD, OS & OU
- Biomicroscopy examination (Efron scale)
    - External adnexa anomalies
    - Cornea & anterior eye assessment for scars, infiltrates
    - Bulbar & limbal redness
    - Corneal & conjunctival staining with fluorescein dye
    - Palpebral conjunctival hyperemia & roughness
- Auto refraction/auto keratometry: horizontal and vertical K readings;
- Subjective refraction/ best sphere refraction;
- ***Randomization:*** Lens type:
    - Precision 1 and 1-Day Acuvue Moist lenses will be randomized to one eye each;
- Study lens fitting –Lens types will be fit according to the randomization table – the investigator will insert and remove the lenses
    - logMAR high illumination high contrast visual acuity (HIHC VA) for OD, OS & OU;

    - Power optimization if applicable;
    - Lens fit assessment (Overall Lens Fit acceptance (0-4, 0.5 steps), Lens Wettability (0-4, 0.25 steps), Lens Tightness (0-100, 1 step), Lens Centration (0-3, 1 step)
    -
- Confirmation of eligibility to continue to Visit 1 Part B.

Visit 1 – Part B – Handling training, questionnaires and lens dispensing (1hr)

- ***Randomization:*** Eye for contralateral handling:
    - Start eye for insertion/removal training will be randomized to prevent any potential bias due to handedness/dexterity
    - Participant opens the lens blister packs and practices insertion & removal;
    - Insertion & removal with each lens needs to be successful 3x to be allowed to leave site with CLs
- **Confirmation of eligibility** – capable of insertion/removal of CLs; participants who are NOT able to remove/insert the study lenses 3x will be offered to attend a re-training session (Visit 1B-R), at which the training will be repeated. Only those participants able to insert/remove lenses at Visit 1 (or Visit 1B-R) will continue in the study.

- ***PRIMARY OUTCOME VARIABLE*** *(only if participants have passed the CL handling training):* subjective post-handling training ratings (0-100 scale, where 100 means better handling) for ***each eye individually***. Separate ratings and comments for:
    - Ease of insertion
    - Ease of removal
    - General handling questions (not primary outcome variable)
- LogMAR HIHC VA for OD, OS and OU *(If returning for Re-training: habitual spectacles, if lenses are dispensed today: study CL)*
- Lens wear instructions *(only after a successful training)*
- Booking of Follow-up visit*(only after a successful training)*
- Lens dispense (equal number of pairs as there are days until next visit day, plus 3 spare pairs in case of handling issues); each px will keep the same lens type (L1 or L2) for each eye as randomized to for handling training (e.g. if Precision1 was used on OD for training, Precision1 will be worn on OD for 1 week of wear) *(only after a successful training)*

Visit 1B-R: Handling Re-Training (optional) (1hr)

- Those participants who did not pass the handling training at Visit 1 will repeat this training, following the same randomization schedule as determined during Visit 1. If a participant passes the handling training (i.e. they successfully inserted and removed each lens 3x), the remaining steps from Visit 1, starting at "***PRIMARY OUTCOME VARIABLE",*** will be completed.

- ***PRIMARY OUTCOME VARIABLE*** *(only if participants have passed the CL handling training):* subjective post-handling training ratings (0-100 scale, where 100 means better handling) for ***<u>each eye individually</u>***. Separate ratings and comments for:
    - Ease of insertion
    - Ease of removal
    - General handling questions (not primary outcome variable)
- LogMAR HIHC VA for OD, OS and OU *(If returning for Re-training: habitual spectacles, if lenses are dispensed today: study CL)*
- Lens wear instructions *(only after a successful training)*
- Booking of Follow-up visit*(only after a successful training)*
- Lens dispense (equal number of pairs as there are days until next visit day, plus 3 spare pairs in case of handling issues); each px will keep the same lens type (L1 or L2) for each eye as randomized to for handling training (e.g. if Precision1 was used on OD for training, Precision1 will be worn on OD for 1 week of wear) *(only after a successful training)*
- *Participants who were unable to successfully complete the insertion/removal training will exit the study now.*

Visit 2: 1-week follow-up and study exit, day 6-10 days after Visit 1 or Visit 1B-R

Participant to attend visit after 2 hours or more of contralateral study lens wear.

- Collect unused study CLs;
- Changes in medical history/medications;
- LogMAR HIHC VA for OD, OS and OU with study lenses
- Compliance (# of CL wear days; total and comfortable hours of wear);
- Subjective ratings for wear experience with **both CLs** (0-100 scale, where 100 means better performance; integer steps, ***<u>ratings for each eye individually for a typical day in the last week</u>***);
    - Comfort (at insertion and just before removal)
    - Handling (insertion & removal)
    - General handling questions
- Preference ratings between study lenses:
    - Comfort
    - Handling for insertion
    - Handling for removal
    - Overall
    - Willingness to purchase
- Lens fit assessment (Overall Lens Fit acceptance (0-4, 0.5 steps), Lens Wettability (0-4, 0.25 steps), Lens Tightness (0-100, 1 step), Lens Centration (0-3, 1 step)
- Lens removal

<u>Study Exit</u>:

- Biomicroscopy examination (Efron scale) - SAFETY
    - *External adnexa anomalies*
    - *Cornea & anterior eye assessment for scars, infiltrates*

- *Bulbar & limbal redness*
- *Corneal & conjunctival staining with fluorescein dye*
- *Palpebral conjunctival hyperemia & roughness*

- Exit logMAR HIHC VA for OD, OS and OU (habitual spectacles) - SAFETY;
- Study exit forms & remuneration.

5.4.3 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.

5.5 STUDY PROCEDURES

Table 3 summarizes the procedures at each visit. The order of procedures is described in sections 5.4.2.

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

Procedure	Visit 1 Screening, fitting, handling training, CL dispense	Visit 1B-R Additional handling training	Visit 2 1-week follow up and Exit
Informed consent	X		
Participant demographics (age, sex)	X		
Medical history and medications	X		
Changes in medical history/ medications		X	X
HCVA (logMAR) (habitual spectacles)	X		X
Biomicroscopy examination	X		X
Auto refraction/auto keratometry: horizontal and vertical K readings	X		
Subjective refraction/ best sphere refraction	X		
Fitting of study lenses	X		
Assessment of lens fit	X		X
Randomization	X		
Lens insertion/ removal training	X	X	
Subjective post-handling training ratings	X	X	

HCVA (logMAR) (Contact lenses)	X	X	X
Lens wear instructions and lens dispense	X	X	
Confirm eligibility	X	X	
Collection of unused study lenses			X
Compliance questions			X
Subjective ratings for wear experience and preference ratings			X
Lens removal			X
Study exit documentation			X

5.5.1 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 visits 1B-R and Visit 2 participants will be asked about changes in their medication or health.

5.5.2 SUBJECTIVE RATINGS

Subjective ratings:

After a successful insertion/ removal training at Visit 1 or Visit 1B-R, participants will complete subjective post-handling training ratings (0-100 scale, where 100 means better handling) for ***each eye individually***. Separate ratings and comments for:

- Ease of insertion
- Ease of removal

A Visit 2, participants will be provided with subjective rating questionnaires for wear experience with both CLs (0-100 scale, where 100 means better performance; integer steps, ratings for ***each eye individually*** for a typical day in the last week);

- Comfort (at insertion and just before removal)
- Handling (insertion & removal)

- General" handling questions, to be evaluated at Visit 1 (based on initial training) & at Visit 2 (after 1 week of wear), including

    - “Ease of opening package”,
    - “Ease of removing lens from package”,
    - “Ease of telling whether lens is inside/out”
    - “Stability on finger”
- Preference ratings between study lenses: (Likert scale; including strongly prefer L1, slightly prefer L1, no preference, slightly prefer L2, strongly prefer L2)
    - Comfort
    - Handling for insertion
    - Handling for removal
    - Overall
    - Willingness to purchase

5.5.3 VISUAL ACUITY

Visual acuity will be measured using high contrast computer-generated acuity charts. Participants will be asked to read letters that progressively decrease in size on a computer screen located at a distance of 6 meters. Measurements will be taken during the subjective refraction, with study lenses and habitual spectacles.

5.5.4 AUTOREFRACTION

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

5.5.5 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 your vision between different lenses placed in front of your eyes. This procedure aids to determine their spectacle and/or contact lens prescription.

5.5.6 LENS PERFORMANCE

Contact lens fit:

Overall Lens Fit acceptance will be assessed to ensure acceptable lens fit with the study lenses using a 0-4 scale (0.5 step, 0= perfect lens fit), in addition, Lens Tightness (0-100, 1 step – 100 = no movement) and Lens Centration (0-3, 1 step, 0= optimally centred) will be collected.

Contact lens wettability:

Contact lens wettability will be graded using e.g. 32x magnification, on a 0-4 scale, 0 = excellent wettability, 0= no deposits (0.25step).

5.5.7 SLIT LAMP BIOMICROSCOPY

The participant will be seated behind a slit lamp and the following will be assessed:

Cornea:

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

Corneal and conjunctival staining:

A sodium fluorescein strip, wetted with a few drops of saline, will be applied to the superior bulbar conjunctiva of both eyes. Staining will be graded using the Efron grading scale (0 to 4, 0 = normal) in 0.1 scale increments, while viewing with cobalt blue light through a Wratten no. 12 barrier filter.

Bulbar and limbal hyperemia:

Ocular redness will be assessed for the bulbar and limbal conjunctiva using the EFRON grading scale (0 to 4, 0 = normal; 0.1 increments). Redness will also objectively be assessed using an imaging technique provided by the Oculus K5M.

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).

6 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.

7 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 will have the opportunity to try two different types of soft contact lenses at no cost to them. They will be trained on lens handling for lens insertion and removal and will be provided with instructions to safely wear daily disposable contact lenses.

Participation in this study may contribute to scientific research information that may be used in the development of new contact lens products. Information from this study may help researchers and the funding company to better understand if the use of specific daily disposable lens types in neophyte lens wearers.

8 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.

9 DISCONTINUATION FROM THE STUDY

Participants may be discontinued at the discretion of the investigator 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 5.2.3.
- 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.
- 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 may be discontinued if they elect to use a topical ocular medication during the study;
- 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 CORE or the Office of Research Ethics at the University of Waterloo.

A discontinuation form (ADMIN 3), 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.

10 STUDY COMPLETION AND REMUNERATION

At the last scheduled protocol visit a study completion form (ADMIN 2) 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 (ADMIN 1).

Participant remuneration will be $55 for completing the study. If participants attended an additional visit for lens handling training (Visit 1B-R), they receive an additional $20 for their involvement in the study for a maximum of $75 for completing the study.

11 STATISTICAL ANALYSIS AND DATA MANAGEMENT

11.1 STATISTICAL ANALYSIS

All data will be analyzed by CORE at the University of Waterloo. Descriptive statistics will be provided on information regarding baseline variables (e.g. age, gender). Differences between lenses and differences over time will be compared 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.

Subjective ratings for lens handling with Precision1 and 1-Day ACUVUE Moist as determined at study Visit 1 (or Visit 1B-R) (after successfully completing the lens handling training) will also be compared using superiority testing, with a margin of 5 points on a 100-point scale.

11.2 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.

11.3 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.

12 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.

13 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.

14 STUDY MANAGEMENT

14.1 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/

14.2 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.

14.3 CLINICAL TRIAL REGISTRATION

CORE will register this study with clinicaltrials.gov.

14.4 PROTOCOL DEVIATIONS

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

14.4.1 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;
- 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.

14.4.2 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).

14.4.3 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.

14.5 PREMATURE TERMINATION OF THE STUDY

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

14.6 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.

14.7 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.

15 REPORT

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

16 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. Eric B. Papas, Lisa Keay, Blanka Golebiowski; Estimating a Just-Noticeable Difference for Ocular Comfort in Contact Lens Wearers. Invest. Ophthalmol. Vis. Sci. 2011;52(7):4390-4394. doi: 10.1167/iovs.10-7051.
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.