CooperVision™

Refitting somofilcon A Sphere Contact Lens Wearers into fanfilcon A Sphere Lenses for 4-weeks of Wear

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Site Principal Investigat	

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EX-MKTG-101	February 28, 2019	First draft (v 1.0)
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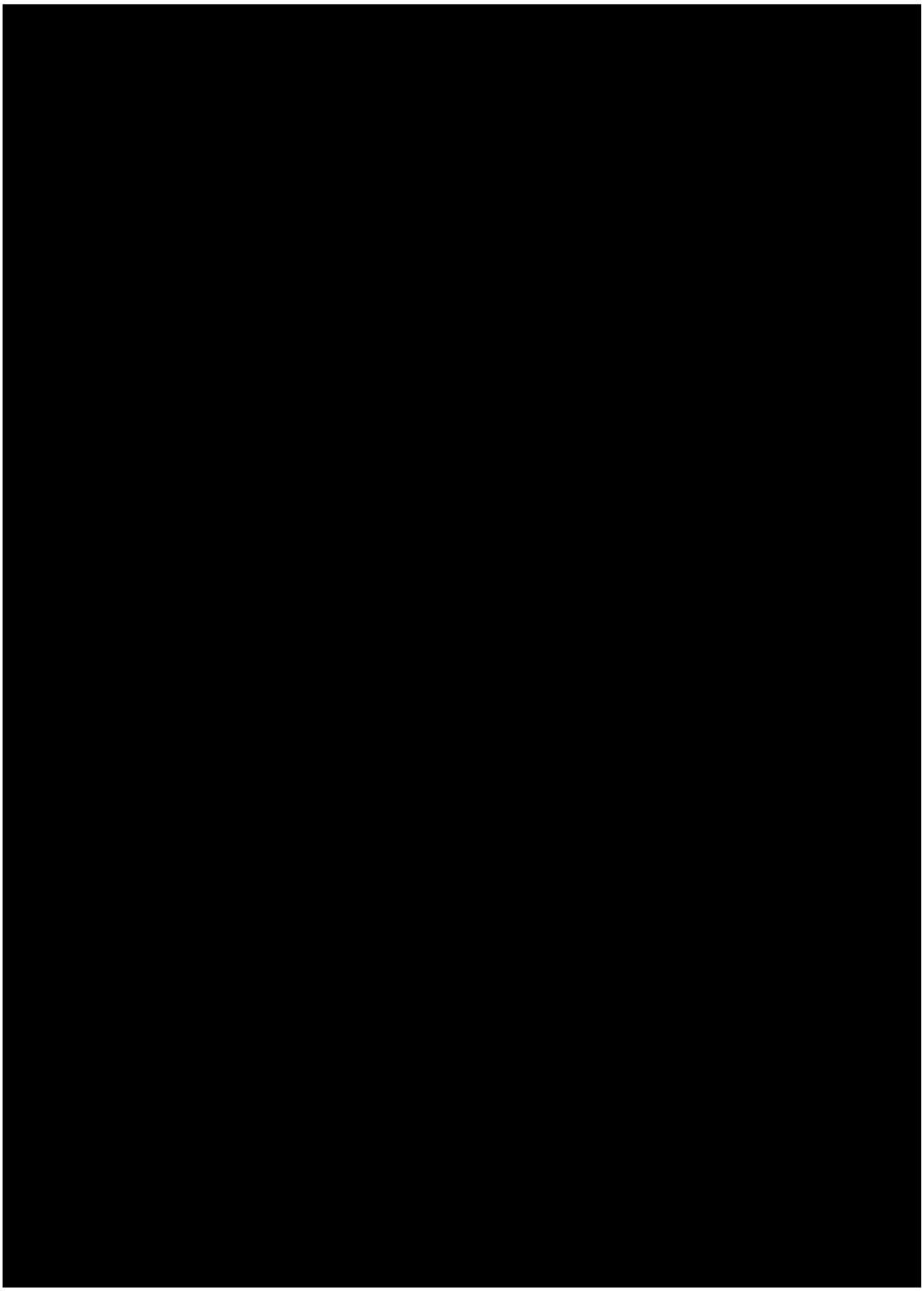

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1 Introduction

According to a 2018 international contact lens prescribing report, silicone hydrogel materials accounted for 76% of soft lenses prescribed and for more than 90% of fits in some markets. In the US for 2018, silicone hydrogel lenses have a reported usage at 69% of fits. Data from Contact Lens Spectrum's market research in the US showed that, across all contact lens designs, most of the reported fits and refits are with soft spherical contact lenses (49% versus 48% in 2017). CooperVision's Avaira Vitality™ sphere lenses use a third generation silicone hydrogel material which makes the lens inherently wettable with no surface treatments, and uses naturally wettable building blocks to improve compatibility between silicone and hydrophilic domains. This, combined with the higher water content of Avaira Vitality™ ensures a high performing, comfortable lens.

Clariti Elite sphere lenses are part of a generation of silicone hydrogel portfolio from CooperVision which will be discontinued from the market in the near future. Therefore, CooperVision is interested in evaluating the clinical performance of existing wearers of Clariti Elite sphere lenses after a refit with Avaira Vitality™ silicone hydrogel sphere lenses over 4-weeks of daily wear.

2 Study Objective

The aim of this prospective study is to evaluate the clinical performance of habitual wearers of Clariti Elite sphere lenses after a refit with Avaira Vitality sphere lenses for 4 weeks of daily wear.

The primary variables of interest are:

- Lens fitting characteristics

The secondary variables of interest are:

- Wearing times (average and comfortable)

3 Study Hypothesis

3.1 Study Hypothesis

- Null hypothesis (H_o): There is no difference in lens performance between the study lenses for the key variables tested.
- Alternative hypothesis (H_1): There is a difference in lens performance between the study lenses for the key variables tested.

4 Study Design

This is a prospective, subject masked; bilateral, 4-week refit study comparing the fitting characteristics of Clariti Elite sphere lenses, (somofilcon A), against Avaira Vitality silicone hydrogel sphere lenses (fanfilcon A). A total of 40 subjects will be enrolled with the aim of completing 34.

Subject's will be evaluated at the first visit and then fitted with both study lenses to confirm lens fit and optimize visual acuity if needed. At the second visit, the first pair of study lenses, (e.g. somofilcon A), will be dispensed and worn for 4-weeks. After 4-weeks of daily wear with the first pair, subjects will return for a third evaluation and then fitted with the second pair, (e.g. fanfilcon A), of study lenses for 4-weeks. A fourth visit will be scheduled after 2-weeks of lens wear. A fifth and final visit will be scheduled after 4-week of lens wear. The study timeline is shown in Appendix 2.

5 Investigational Sites

5.1 Number of Sites

This will be a single-center investigational site in Mexico City. (Target 40 subjects, complete 34).

5.2 Investigator Recruitment

This study will be conducted at the National Autonomous University of Mexico. Av. de los Barrios no. 1, Los Reyes Iztacala, Tlalnepantla Edo. de México. Código Postal 54090. The Investigators will be required to fulfil the following criteria:

- Licensed Optometrist with at least two years of contact lens fitting experience.
- Experienced Investigators who will be trained in Good Clinical Practice (GCP) by the principal investigator.
- In-office email or fax.
- Willingness to follow the study protocol and to co-operate with the study monitors.

This clinical study is designed to be in conformance with the ethical principles in the Declaration of Helsinki, with the ICH guidelines for Good Clinical Practice (GCP) and all the applicable local guidelines.

6 Ethics Review / Statement of Compliance

6.1 Relevant Standards / Guidelines

This implementation document has been developed in accordance with the following:

- ISO 14155 Clinical Investigation of Medical Devices for Human Subjects, Parts 1 & 2, 2011.
- ICH Harmonized Tripartite Guideline for Good Clinical Practice E6, 1996.
- Declaration of Helsinki
- COFEPRIS Applicable Guidelines

6.2 Institutional Review Board

This study will be conducted in accordance with Institutional Review Board regulations (U.S. 21CFR Part 56.103) or applicable IEC regulations. Copies of all IRB/IEC correspondence with the investigator/sponsor will be kept on file. The study will commence upon approval from the following Ethics Committee: Comisión de Ética de la FESI. Avenida de los Barrios no. 1, Los Reyes Iztacala, Tlalnepantla Edo. de México. CP 54090. Telephone number 56-23-12-20 and email address jrjf@unam.mx.

6.3 Clinical Trial Registration

This study will be registered with clinicaltrials.gov in accordance with section 801 of the Food and Drug Administration (FDA) Act which mandates the registration of certain clinical trials of drugs and medical devices.

6.4 Informed Consent

Informed consent shall be obtained in writing from the subject and the process shall be documented before any procedure specific to the clinical investigation is carried out.

7 Potential Risks and Benefits to Human Subjects

There may be direct benefits to the subjects in this study such as improved vision, comfort, convenience, and cosmetic advantage. Participation in a study may contribute to scientific research information that may be used in the development of new contact lens products. In addition, subjects will receive an examination of the front part of their eyes and may have the opportunity to try a different type of soft contact lenses and/or different lens care products at

no cost to them. The contact lens materials used in this study are commercially available as daily or extended wear. This study will investigate participants' wearing schedule intended for daily wear (NOT extended wear) similar to the average wearing time of 10-16 hours for daily wear lenses.

This study is considered to be a non-significant risk study based on United State Food and Drug administration (FDA) and International Standards Organization (ISO) guidelines because the study devices used as intended in this study (daily wear) don't represent a potential for serious risk to the health, safety or welfare of the subject, and (2) it is not an implant, (3) it is not used to support or sustain human life, (4) it is not of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise prevents impairment of human health, (5) does not present a potential for serious risk to the health, safety or welfare of the subject (Appendix 2).

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 day-wear soft lenses is 0.035%. Almost always an infection will occur only in one eye. This risk is assumed by 35-million Americans who currently wear contact lenses.

Routine clinical procedures including auto-refraction, auto-keratometry, visual acuity, anterior ocular health assessment, and contact lens fitting will be used. In addition, high magnification imaging of the lens fit may be made using 35 mm or digital cameras, in vivo confocal microscopy, and/or specular microscopy. Patients will be monitored every two weeks until the end of the study to reduce if not eliminate the occurrence of adverse or potential adverse events. Patients will be given instructions from their ECP regarding early symptoms and signs of adverse events and their contact information.

8 Materials and Methods

8.1 Participants

Approximately 40 habitual soft contact lens wearers will be enrolled. Each subject will be required to attend up to five scheduled study visits over a period of approximately two months.

Each subject will be given a unique ID number. Additionally, all subjects must meet the study inclusion and exclusion criteria listed below.

8.1.1 Inclusion criteria

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

- Is between 18 and 40 years of age (inclusive)
- Has had a self-reported visual exam in the last two years
- Is an adapted soft contact lens wearer

- Has a contact lens spherical prescription between – 0.25 to – 8.00 (inclusive)
- Have no less than -0.75D of astigmatism in both eyes.
- Can achieve best corrected spectacle distance visual acuity of 20/25 (0.10 logMAR) or better in each eye.
- Can achieve a distance visual acuity of 20/30 (0.18 logMAR) or better in each eye with the study contact lenses.
- Has clear corneas and no active ocular disease
- Has read, understood and signed the information consent letter.
- Patient contact lens refraction should fit within the available parameters of the study lenses.
- Is willing to comply with the wear schedule (at least 5 days per week, > 8 hours/day assuming there are no contraindications for doing so).
- Is willing to comply with the visit schedule

8.1.2 Exclusion Criteria

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

- Has a CL prescription outside the range of the available parameters of the study lenses.
- Has a spectacle cylinder of ≥ 1.00D in either eye.
- Has a history of not achieving comfortable CL wear (5 days per week; > 8 hours/day)
- Has contact lens best corrected distance vision worse than 20/25 (0.10 logMAR) in either eye.
- Presence of clinically significant (grade 2-4) anterior segment abnormalities
- Presence of ocular or systemic disease or need of medications which might interfere with contact lens wear.
- Slit lamp findings that would contraindicate contact lens wear such as:
    - Pathological dry eye or associated findings
    - Pterygium, pinguecula, or corneal scars within the visual axis
    - Neovascularization > 0.75 mm in from of the limbus
    - Giant papillary conjunctivitis (GCP) worse than grade 1
    - Anterior uveitis or iritis (past or present)
    - Seborrheic eczema, Seborrheic conjunctivitis
    - History of corneal ulcers or fungal infections
    - Poor personal hygiene
- Has a known history of corneal hypoesthesia (reduced corneal sensitivity)
- Has aphakia, keratoconus or a highly irregular cornea.
- Has Presbyopia or has dependence on spectacles for near work over the contact lenses.
- Has undergone corneal refractive surgery.
- Is participating in any other type of eye related clinical or research study.

8.2 Study Materials

8.2.1 Contact lens

All subjects will be trial fitted and, if suitable, dispensed the clariti® elite sphere and Avaira Vitality™ sphere lenses. The study lenses and solutions will be provided by the Sponsor. Details of the contact lenses are shown in Table 1.

Table1: Study lenses

	clariti® elite sphere	Avaira Vitality™ sphere
Manufacturer	CooperVision Inc.	CooperVision Inc.
Material	somofilcon A	fanfilcon A
WC %	56%	55%
Base Curve	8.6 mm	8.4 mm
Lens Diameter	14.2 mm	14.2 mm
Lens Power Sphere	– 0.25 to – 10.00	– 0.25 to – 10.00
Wearing schedule	Daily wear	Daily wear

8.2.2 Contact Lens care

OPTI-FREE® PureMoist® multipurpose disinfecting solution and lens cases (Alcon, Fort Worth, TX) will be provided to all subjects for care and maintenance of the contact lenses during the study.

8.2.3 Storage of Study Medications/Treatments

There are no unapproved investigational products used in this study requiring special storage accommodations.

8.2.4 Clinical Supply Inventory

There are no unapproved investigational products used in this study requiring special inventory requirements.

8.2.5 Disposal of Consumables

This study dispenses consumables (lenses) to participants for use during the study. Study lenses worn for 4-weeks of daily wear by participants will be collected at the last visit and destroyed.

8.2.6 Masking and Control of Study Materials

The study contact lenses will be **masked to the subject only**. Study lenses will be transferred, by an assistant, out of their packaging to unmarked new contact lens cases filled with unpreserved sterile saline just prior to dispensing to maintain subject masking of the study lenses.

8.2.7 Ordering and Accountability of Study Materials

The study lenses and solutions will be provided by the sponsor. If additional lenses are required, the study sponsor will re-supply the investigator as requested.

8.3 Visit Schedule and Procedures

8.3.1 Visit 1: Baseline visit (Fit Clariti Elite lenses/ Avaira Vitality lenses)

The following evaluations will be performed to assess eligibility according to the Inclusion and Exclusion Criteria at the baseline visit only:

- The subjects should attend the first visit wearing their spectacle lenses. If they are not wearing their spectacle lenses, please reschedule the visit.
- The subject will be required to read and sign an Informed Consent Form prior to enrolment. When the subject has signed the consent form, the subject will be considered to be enrolled on to the study.
- The person explaining the consent and Investigator should also sign the consent form. Provide the subject with a copy and keep the original in the subject's paper chart or scan into the subject's electronic medical record (EMR) file.
- The subject is assigned with a Subject ID number. Subjects must be enrolled sequentially.
- Full anterior segment ocular health will be established

Visit 1a: Baseline Spectacle Lenses

[redacted]

- Complete the eligibility checklist.
- If at this point the subject is found to be ineligible, then complete an Exit form and exit the subject from the study.

Visit 1 b: Fitting Clariti Elite lenses/ Avaira Vitality lenses

If subject is eligible, complete the Enrollment from. The subjects will undergo a trial fit in both eyes with the Clariti Elite and Avaira Vitality lenses, (according to manufacturer's fitting guides) [redacted]

Reorder final lens if appropriate. [redacted]

If the lenses are not suitable to be dispensed then the subject will be discontinued and an Exit form will be completed.

8.3.2 Visit 2: Dispense Clariti Elite Lenses

- Data is only collected on the final pair of study lenses dispensed after the power has been assessed and if needed corrected.
- Record the parameters of the lenses, lens type and power, on the Dispensing CRF [redacted]
- The performance of the lenses should be assessed after 10-15 minutes settling time. The following variables will be assessed [redacted]:
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - Lens Fit
    - Lens centration (centered/slightly decentered/substantially decentered)
    - Corneal coverage [Y/N]
    - Post-blink movement (0 - 5 Likert scale)
    - Lens tightness. Push up test (0% to 100%, 50% optimum)
    - Overall fit acceptance (0 - 4) and reason if Grade 2 or less.
- To be successfully dispensed, subjects must show > Grade 2 lens fit acceptance with the trial fit lens and must be correctable to 20/30 (0.18 logMAR) distance visual acuity or better in each eye with the study contact lenses.
- Lost or damaged study lenses may be replaced. Note which lens was replaced, date of replacement and reason for replacement on the Lens Replacement Log, [redacted]

- The subject will be instructed to wear the lenses on a daily wear basis, (at least 40 hours per week), until the 4-week follow-up appointment, unless they experience a problem which warrants lens removal.
- The Investigator or a clinical assistant will review instructions and warnings for lens wear, when to remove lenses, and other important issues with the participant.
- Participants, who appear unable or unwilling to follow instructions to a degree that, in the Investigator's opinion, jeopardises the participant's wellbeing or the validity of the study, will be discontinued. The reason for discontinuation will be documented.
- The subject will be discharged and asked to return for a follow-up visit (V3) after 4 weeks of wear.

8.3.3 Visit 3: 4-week follow-up Clariti Elite / dispense Avaira Vitality

The 4-week follow-up visit will be scheduled four weeks **(28 + 2 days)** from the initial lens dispensing date. The subject should wear the lenses for a minimum of 2 hours prior to the appointment. If the subject attends without lenses or with less than 2 hours of lens wear on that day and they are not having any problems with their lenses, the visit should be rescheduled, if possible within the visit window.

Visit 3a: Lens Evaluation Clariti Elite lenses

- The following clinical test variables will be recorded on the Follow-Up Visit CRF:
    - Wearing times:
        - Wearing time today (hours).
        - Average daily wearing time (hours/day)
        - Average comfortable wearing time (hours/day)
        - Number of days/week (lenses are worn).
    - [redacted]

- [redacted]
- Lens Fit
  - Lens centration (centered/slightly decentered/substantially decentered)
  - Corneal coverage [Y/N]
  - Post-blink movement (0 - 5 Likert scale)
  - Lens tightness. Push up test (0% to 100%, 50% optimum)
  - Overall fit acceptance (0 - 4) and reason if Grade 2 or less.
  - Remove study lenses and perform slit lamp examination
- [redacted]

Visit 3b: Dispense Avaira Vitality Lenses

The study subjects will undergo a trial fit in each eye with the second pair of study lenses.

- The performance of the second pair of study lenses should be assessed after 10 - 15 minutes settling time. The same variables as those collected on *visit 2, section 8.3.2* will be assessed.

8.3.4 Visit 4: Follow-up Avaira Vitality (After 2 weeks of wear)

The 2-week follow-up visit for pair 2 will be scheduled two weeks **(14 + 2 days)** from the initial lens dispensing date for pair 2. The subject should wear the lenses for a minimum of 2 hours

prior to the appointment. If the subject attends without lenses or with less than 2 hours of lens wear on that day and they are not having any problems with their lenses, the visit should be rescheduled, if possible within the visit window. The same variables as those collected on section **8.3.3** (visit 3a) will be assessed at this visit.

8.3.5 Visit 5: Follow-up Avaira Vitality (After 4 weeks of wear / exit)

The 4-week follow-up visit for pair 2 will be scheduled four weeks **(28 + 2 days)** from the initial lens dispensing date for pair 2. The subject should wear the lenses for a minimum of 2 hours prior to the appointment. If the subject attends without lenses or with less than 2 hours of lens wear on that day and they are not having any problems with their lenses, the visit should be rescheduled, if possible within the visit window. The same variables as those collected on section 8.3.3 (visit 3a) will be assessed at this visit. In addition, a lens preference question between habitual, (Clariti Elite Asphere), and test lenses, (Avaira Vitality sphere), will be asked at the end of this visit.

- The Study Exit Form must be completed when a subject exits the study. This will occur either at study completion, i.e. at Visit 5, or if the subject is discontinued from the study at another time. If there are records entered into the clinics own patient chart system the exit date should be recorded on these source documents. A Study Exit Form must be completed for all subjects who have taken a study ID number. Post-study follow-up visits will be scheduled if the Investigator judges this is necessary.
- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - Post-study follow-up requirement (Y/N). If yes, the reason and date of the follow-visit must also be recorded.
- If the subject is being exited due to discontinuation, further details need to be recorded on the exit form.

9 Adverse Event Reporting

9.1 Adverse Response Definitions

Adverse Event (AE): An AE refers to any untoward medical occurrence (sign, symptom or disease) in a trial subject that does not necessarily have a causal relationship with the study device. AEs may be classified as 'unanticipated adverse device effects,' 'serious AEs,' 'significant AEs,' or 'non-significant AEs,' as defined below. AE classification, coding (for reporting to the sponsor) and examples are provided in the following table of Contact Lens Adverse Event Classification and Reporting:

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.
Unanticipated Adverse Device Effect	Adverse events in a clinical trial 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.
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.

Code	Condition	Potential AE Classification	Reporting
01	Presumed infectious corneal ulcer	SERIOUS	Notify sponsor as soon as possible, **within 24 hrs;** IRB reporting as per requirements
02	Permanent loss of ≥2 lines of best spectacle corrected visual acuity (BSCVA)	SERIOUS	
03	Corneal injury that results in permanent opacification within central cornea (6mm)	SERIOUS	
04	Neovascularization within the central 6mm of cornea	SERIOUS	
05	Uveitis or Iritis	SERIOUS	

06	Endophthalmitis	SERIOUS	
07	Hyphema	SERIOUS	
08	Hypopyon	SERIOUS	
09	Persistent epithelial defect	SERIOUS	
00	Other serious event	SERIOUS	
11	Peripheral non-infectious ulcer (outside central 6mm)	SIGNIFICANT	Notify sponsor as soon as possible, within 5 working days; IRB reporting as per requirements
12	Symptomatic corneal infiltrative events	SIGNIFICANT	
13	Superior epithelial arcuate lesions (SEALs) involving epithelial split	SIGNIFICANT	
14	Any temporary loss of ≥2 lines BSCVA for ≥2wks	SIGNIFICANT	
15	Corneal staining ≥ dense coalescent staining up to 2mm in diameter (i.e. moderate staining)	SIGNIFICANT	
16	Corneal neovascularization ≥ 1.0mm to 1.5mm vessel penetration (if 2 Grade change from baseline)	SIGNIFICANT	
17	Any sign and/or symptom for which subject is administered therapeutic treatment or which necessitates discontinuation of lens wear for ≥ 2 weeks	SIGNIFICANT	
10	Other significant event	SIGNIFICANT	
21	Conjunctivitis: bacterial, viral, allergic	NON-SIGNIFICANT	
22	Papillary conjunctivitis if ≥ mild scattered papillae/follicles approximately 1mm in diameter (if 2 Grade change from baseline)	NON-SIGNIFICANT	
25	Asymptomatic corneal infiltrative events	NON-SIGNIFICANT	
26	Localized allergic reaction	NON-SIGNIFICANT	
27	Contact dermatitis	NON-SIGNIFICANT	
28	Any sign and/or symptom for which temporary lens discontinuation for > 1 day is recommended	NON-SIGNIFICANT	
20	Other non-significant sign and/or symptom	NON-SIGNIFICANT	

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 they are unexpected in nature, severity or rate of occurrence.***

9.2 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 subject may be referred to an ophthalmologist for treatment. 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. If both eyes are involved, a separate Adverse Event Form will be completed for each eye. 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 subject must be followed until resolution and a written report completed indicating the subsequent treatment and resolution of the condition.

9.3 Discontinuation from the Study

All discontinuations will be fully documented on the appropriate CRF Exit and Adverse Event forms as needed. Participants will be followed until resolution (in most instances) and are free of the ophthalmic insert related complications or other ocular pathology. When possible study lenses involved in an Adverse Event will be returned to the sponsor in a new tightly sealed contact lens case, and labeled with the subject identification and stored in Unisol non-preserved saline.

9.4 Reporting Adverse Events

All potential **Serious and Unanticipated Adverse Device Effects** that are related or possibly related to subject participation in the investigation will be reported to the Principal Investigator and the sponsor within 24 hours of the investigator becoming aware of the event. The Principal Investigator will report the event to the EC/IRB as soon as possible (by fax, mail/delivery, phone, or email), but within 10 business days of becoming aware of the problem. *All fatal or life threatening events will be reported immediately to the IRB.*

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. [redacted]

[redacted]

10 Statistical Analysis and Sample Size

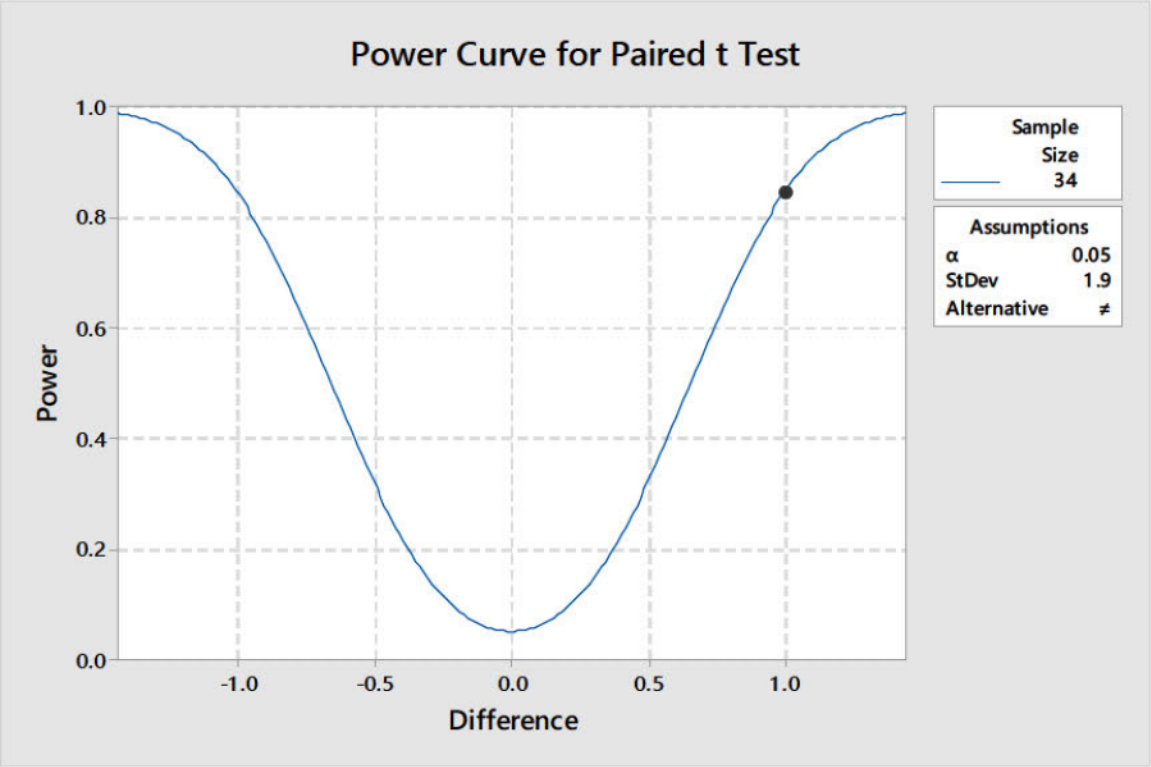
10.1 Statistical analysis

Summary statistics will be produced (e.g. mean, standard deviation). Differences between lenses will be compared using Paired t-tests. Paired t-tests / analysis of variance for normal (interval/continuous) data, Wilcoxon's signed ranks test for non-normal (ordinal) data, chi-squares test for nominal data. A binomial test will be used to evaluate lens preference questions. All participants who are evaluated will be used in the analysis. In the event of missing data, individual data points will be excluded in the analysis and not extrapolated from the collected data.

10.2 Sample size

A sample size was calculated using data from a previous study. Assuming a standard deviation of 1.9 points, with 84% power and an alpha level of 0.05, a sample size of 34 subjects is required to detect a difference of 1.0 points, (0-10 scale), between lenses [redacted] 40 subjects will be enrolled to account for potential drops outs or discontinuations.

Figure 1. Sample size calculation (Minitab 16 Statistics software)



11 Data Quality Assurance

11.1 Study monitoring

A site visit or discussion may be conducted during the course of the study as appropriate. Prior to final data freeze, a close-out visit/discussion may be warranted to check for accuracy and completeness of records. The sponsor or sponsor's representatives will be authorized to gain access to the source documentation for the purposes of monitoring and auditing the study.

11.2 Record keeping

Detailed records of all study visits will be made using the electronic Case Report Forms (CRFs).

11.3 Record retention

Following study completion, data will be available in electronic and/or paper format for audit, sponsor use, or subsequent analysis. The original clinical raw data (including completed CRFs and Informed Consent forms) will be retained according to guidelines set forth in the general work agreement with the site. The Sponsor will be notified and consulted if ever the files are to be destroyed. In the event that this implementation document is indicated for design verification and validation purposes, as indicated on the title page, all original raw data forms and completed CRF's will be forwarded to the sponsor at completion of the final report.

11.4 Data Entry / Data Management

Data will be entered into an electronic spreadsheet. Study staff will only be able to modify the data file via password entry. The investigators will be responsible for the data integrity, and complete data entry for each visit as well as the take home questionnaires. The investigator will send the data collected to the study sponsor within 5 business days after the last subject completes the final visit.

11.5 Confidentiality

This study is confidential in nature. All information gathered during this study is proprietary and should be made available only to those directly involved in the study. Information and reports arising from this project are the property of the sponsor.

All records will also be handled in accordance with HIPAA (1996).

11.6 Publication

The investigators will not be permitted to publish or present at scientific meetings results obtained from the clinical study without prior written consent from the sponsor.

12 Study Costs and Subject Compensation

[redacted]

13 Appendices

[redacted]