



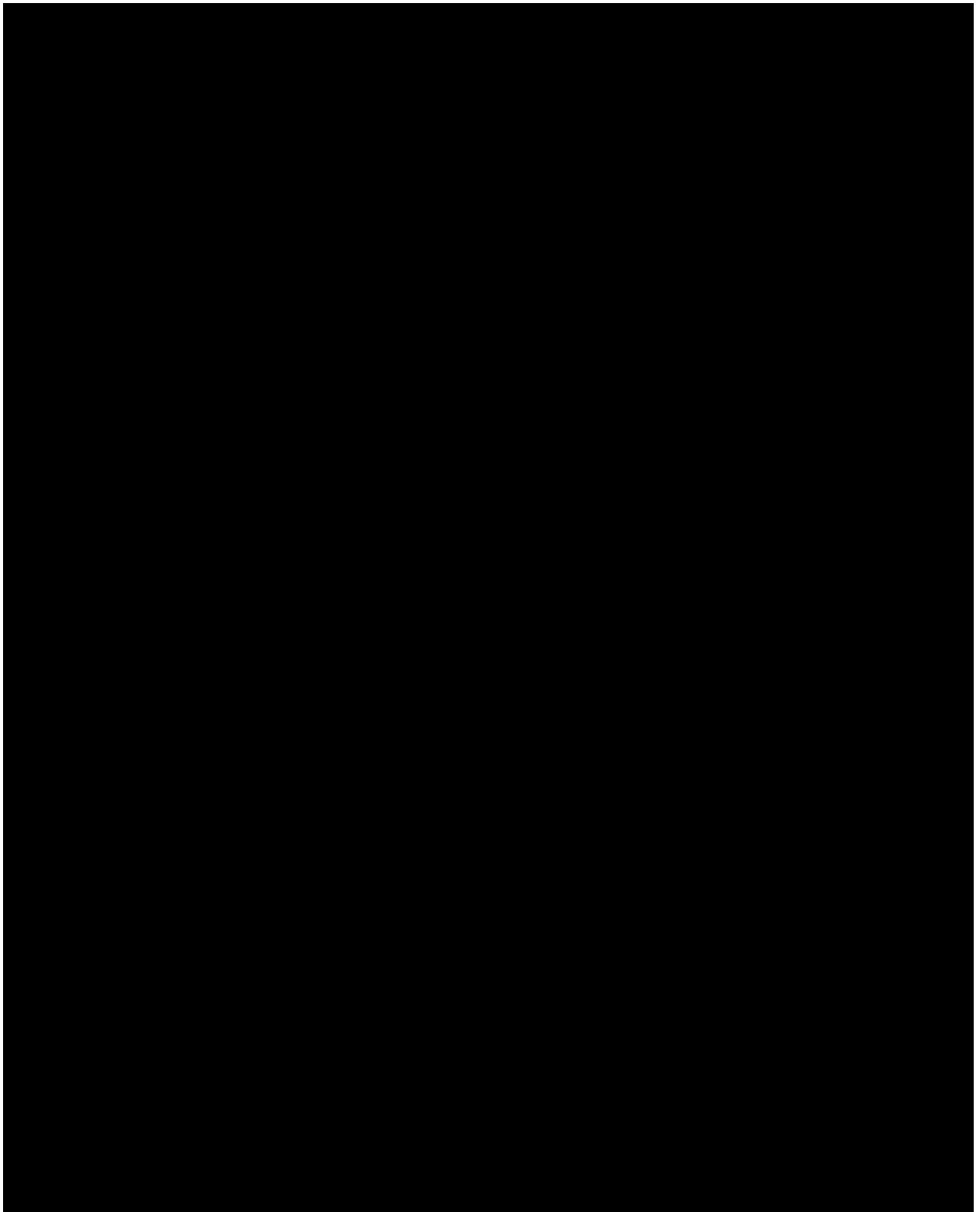
Final

Clinical Evaluation of clariti Monthly Toric and clariti® 1 day Toric

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Revision History

Document number	Date	Comments
EX-MKTG-137	6/16/2022	First draft (v 1.0)
EX-MKTG-137	6/16/2022	FINAL



Protocol Synopsis

Protocol Number	EX-MKTG-137
Title	Clinical Evaluation of clariti Monthly Toric and clariti® 1 day Multifocal.
Name of Device(s) and (by USAN material)	Clariti Monthly Toric (somofilcon A), clariti 1-Day Toric (somofilcon A)
Indications for Use	<p>Approved for use:</p> <ul style="list-style-type: none"> • somofilcon A. (Daily wear) • somofilcon A. (Daily wear) <p>Indication for use in this study:</p> <ul style="list-style-type: none"> • 15 minutes daily wear
Study Design	Subject masked, interventional, prospective, direct refit, bilateral wear study.
Purpose	The aim of this non-dispensing fitting study is to evaluate the short term lens fit, vision performance and patient subjective experiences of the Clariti Monthly Toric when compared to the Clariti 1-Day Toric after 15 minutes of daily wear.
Study Duration	<p>The anticipated timeline for this study is as follows:</p> <ul style="list-style-type: none"> • Patient enrolment and completion: July 15 - Sept 15, 2022 Visits: V1: (BL/trial fit/lens order), V2: Dispense / evaluate P1 V3: 15 minutes. Evaluate P1/Dispense P2. V4: 15 minutes. Evaluate P2 / study exit
Patient Population	Habitual soft toric contact lens wearers who provide written informed consent and meet the protocol entrance criteria.
Sample Size	Target enrollment and completion is 37- 40 subjects.
Center Destination (Mexico)	School of Optometry Clinic, National Autonomous University (UNAM)
Number of Centers	Single Center
Patient Follow-up	<p>Subjects enrolled in this study will be followed up after the lens dispensing session:</p> <ul style="list-style-type: none"> • Post dispensing follow-up at 15 minutes for each study lens pair
Primary Endpoint	Subjective handling (insertion & removal)

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1 Introduction

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

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

Therefore, CooperVision is interested in comparing the short-term clinical performance and subjective acceptance of Clariti Toric Monthly contact lenses (**LENS A**) with Clariti 1-Day Toric (**LENS B**) silicone hydrogel lenses. A non-dispensing fitting study is proposed to evaluate the short-term clinical performance of these lenses.

2 Study Objective

The aim of this non-dispensing fitting study is to evaluate the short term lens fit, vision performance and patient subjective experiences of the Clariti Monthly Toric when compared to the Clariti 1-Day Toric after 15 minutes of daily wear.

The primary outcome variable is:

- Subjective handling ratings on insertion (assessed by subjects)



3 Study Hypothesis

3.1 Study Hypothesis

- Null hypothesis (Ho): There is no difference in clinical performance and subjective assessments between toric lens types.
- Alternative hypothesis (H1): There is a difference in clinical performance and subjective assessments between toric lens types.

4 Study Design

This is a subject masked, interventional, prospective, direct refit, bilateral wear study. It is anticipated that this study will involve 4 visits as follows: **V1:** (BL/trial fit/lens order), **V2:** Dispense / evaluate P1. **V3:** 15 minutes. Evaluate P1/Dispense P2. **V4:** 15 minutes. Evaluate P2 / study exit.

5 Investigational Sites

5.1 Number of Sites

This will be a single center investigational site in Mexico City. (Target 37- 40 subjects).

5.2 Investigator Recruitment

This study will be conducted at School of Optometry Clinic; National Autonomous University (UNAM) Mexico City. 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
- ICH Harmonized Tripartite Guideline for Good Clinical Practice
- Declaration of Helsinki

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 cetica@fesi.edu.mx.

6.3 Clinical Trial Registration

This study will be registered with clinical trials.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, (Appendix 1), 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 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.

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 in the clinic during the study to reduce if not eliminate the occurrence of adverse or potential adverse events. Patients will be given instructions from the study investigator regarding early symptoms and signs of adverse events and their contact information.

8 Materials and Methods

8.1 Participants

Habitual soft toric contact lens wearers that provide written informed consent and meet the protocol entrance criteria. Subjects will be recruited from the National Autonomous University School of Optometry databases who agree to voluntarily participate in the study (Appendix 2, timeline). All subjects will be screened to determine study eligibility. Each subject will be given a unique ID number. Additionally, all subjects must meet the study inclusion and exclusion criteria listed below.

Inclusion criteria

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

- 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
- Is not a habitual wearer of either study lens
- Has a contact lens spherical prescription between +4.00 to - 9.00 (inclusive) best corrected visual acuity of 20/30 or better in either eye
- Have contact lens prescription of no less than -0.75D of astigmatism and no more than -2.25 D 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

Exclusion Criteria

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

- A person was 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 less than -0.75D or more than -2.50 D of cylinder 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 front 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

CooperVision will provide the site with an inventory of both study lenses (**LENS A**) and (**LENS B**) to allow participants to be fit with the lens powers available for this study.

All subjects will be trial fitted and, if suitable, dispensed the first pair of the assigned lens brand assigned per a determined table (Appendix 3). The lenses used in this study are all FDA approved and marketed products. Details of the study contact lenses are shown in Table1.

Table1: Study lens parameters

Brand	Clariti Monthly Toric (LENS A)	Clariti 1-Day Toric (LENS B)
Manufacturer	CooperVision	CooperVision
Material	somofilcon A	somofilcon A
FDA Class	Group 5	Group 5
WC %	56%	56%
Base Curve (mm)	8.7	8.6
Lens Diameter (mm)	14.4	14.3
Sphere Power (D)	+4.00D to -9.00D (0.50D steps after -8.50D)	Plano to -6.00 (0.25 steps) -6.50 to -9.00 (0.50 steps) +0.25D to +4.00D. (0.25D steps)
Cyl Power (D)	-0.75, -1.25, -1.75, -2.25	-0.75, -1.25, -1.75, -2.25
Axis (degrees)	10° to 180° (10° steps)	10° to 180° (10° steps)
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 by participants will be discarded by the principal investigator at the end of the study.

8.2.6 Masking and Control of Study Materials

The contact lenses, (LENS A, and LENS B), will be masked to the subject only. The lenses will be removed from their blister pack by an assistant and transferred to an unmarked lens case to maintain the participants masked of the study lenses. Participants will then be instructed to remove the lenses from the lens case and insert them onto their eyes. It is not possible for the study investigators to be

masked because of the need to follow the specific lens fitting guide during the lens prescription optimization visit.

8.2.7 Ordering and Accountability of Study Materials

The study sponsor will supply the investigators with the study lenses to use during the study.

8.3 Visit Schedule and Procedures

This will be an interventional, subject masked, bilateral, non-dispensing fitting study. Participants will be examined at two different points over the course of one day, V1 (lens dispensing), V2 (15 minutes post lens settling). Participants will wear two different pairs of lenses with **LENS A** fitted first to all participants, followed by **LENS B**. Anterior ocular health examination will be performed at baseline without the use of fluorescein*.

** Fluorescein will not be used before lens dispensing to prevent potential eye discomfort that could influence subjective comfort ratings after lens fitting and settling. However, fluorescein will be instilled at the last visit upon lens removal.*

The following outline identifies the two study visits and the general procedures, (Appendix 5), to be conducted at each visit for each day of the study and recorded in the case report forms (Appendix 6):

8.3.1 Visit 1: Baseline / Trial Fit / Lens order

- Subjects should attend this visit wearing their **spectacle** lenses
- Explanation of the study.
- Sign informed consent form.
- Collect habitual toric lens brand information
 - Brand
 - Power(s)
 - Replacement schedule (daily, 2-week, monthly)
- Anterior ocular health examination (Slit lamp without fluorescein).
- Insert trial toric **LENS A**, evaluate the fit and optimize the prescription if needed.
- [REDACTED]
- [REDACTED]
- Order final **LENS A**.
- Remove **LENS A** and insert trial toric **LENS B**. Evaluate fit and optimize the prescription if needed.
- [REDACTED]
- [REDACTED]
- Order final **LENS B**.

8.3.2 Visit 2: Lens dispensing (Fit LENS A / Evaluate)

- Subjective assessments
 - Handling on insertion (0 -10 scale).
 - [REDACTED]
 - [REDACTED]
 - [REDACTED])
- [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]
 - [REDACTED] [REDACTED]
 - [REDACTED]
 - [REDACTED] [REDACTED]
 - [REDACTED]

8.3.3 Visit 3: [REDACTED] (Evaluate LENs A)

8.3.4 Visit 3: Lens dispensing (Fit LENS B / Evaluate)

- Subjective assessments
 - Handling on insertion (0 -10 scale).
 - [REDACTED]
 - [REDACTED]
 - [REDACTED]

8.3.5 Visit 4: [REDACTED] (Evaluate LENS B / Study Exit)

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.

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.

AE classification, coding (for reporting to the sponsor) and examples are provided in the following table of Contact LENS Adverse Event Classification and Reporting:

Code	Condition	Potential AE Classification	Reporting
01	Presumed infectious corneal ulcer	SERIOUS	
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,

12	Symptomatic corneal infiltrative events	SIGNIFICANT	within 5 working days; IRB reporting as per requirements
13	Superior epithelial arcuate lesions (SEALs) involving epithelial split	SIGNIFICANT	
14	Any temporary loss of ≥ 2 lines BSCVA for ≥ 2 wks	SIGNIFICANT	
15	Corneal staining \geq dense coalescent staining up to 2mm in diameter (i.e. moderate staining)	SIGNIFICANT	
16	Corneal neovascularization \geq 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 \geq 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 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.



9.4 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.

10 Statistical Analysis

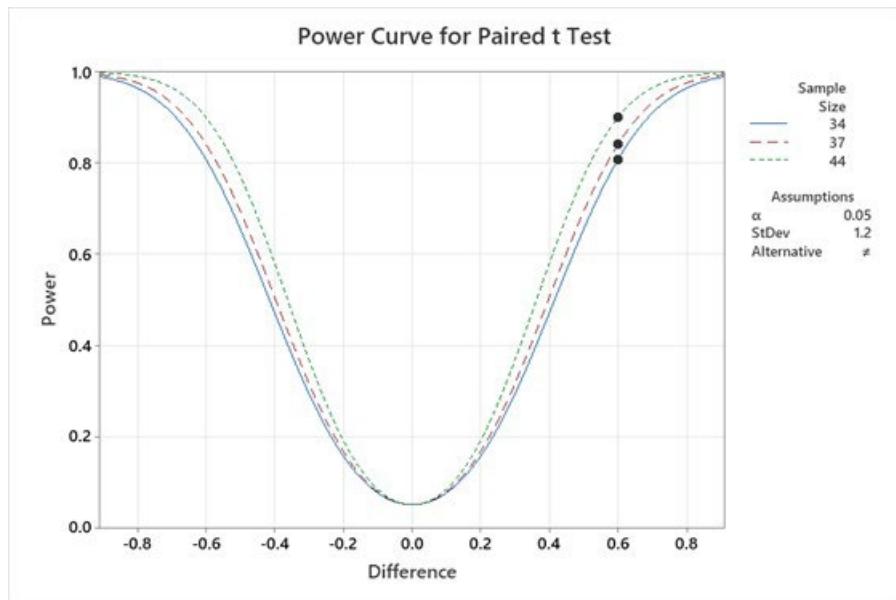
10.1 Statistical analysis

Summary statistics will be produced, (e.g., mean, standard deviation), by the principal investigator (GIO). 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 Chi-Square test will be used to evaluate lens preference questions. All participants who are evaluated in the study will be used in the analysis. In the event of missing data individual number of points will be excluded in the analysis and not extrapolated from the collected data. The critical alpha level for statistical significance will be set at $p \leq 0.05$, with adjustment for multiple comparisons.

10.2 Sample size

Figure 1 shows the sample size determination for a paired t-test, ($\alpha=0.05$), in order to detect a difference in mean subjective handling scores between lenses. Assuming a standard deviation of 1.2, a sample size of about 37 completed subjects provides 84% power to detect a difference in subjective handling ratings of 0.6 points on a 0 - 10 scale. In order to account for potential subject dropouts or AEs, 10%-15% should be added to the sample size. Therefore, 40 subjects should be enrolled with the aim to complete 37.

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



Paired t Test

Testing mean paired difference = 0 (versus ≠ 0)

Calculating power for mean paired difference = difference

$\alpha = 0.05$ Assumed standard deviation of paired differences = 1.2

Results

Difference	Sample Size	Target Power	Actual Power
0.6	34	0.80	0.807778
0.6	37	0.84	0.841192
0.6	44	0.90	0.900031

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. A full report will be provided by the investigator at the mutually agreed timeline after the study completion date.

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.

Protocol Amendment

The table below lists the changes to be implemented on this study protocol.



New revision No.	Section (s) to be amended and details.
1.	<p>The study protocol currently indicates that assessment of subjective comfort will be collected using a 0 -10 visual analog scale with two anchors on each end of the scale.</p> <p>It is recommended to change to a 0 -100 visual analog scale with descriptors at different intervals.</p> <p>The change to be implemented will apply to sections 2.0, 8.3.2, 8.3.3, 8.3.4, and 8.3.5 of the study protocol.</p>

Table 1. Changes to protocol EX-MKTG-137

A large rectangular area of the page is completely blacked out with a thick black marker, obscuring several rows of text that would normally be present in the table body. The redaction is roughly rectangular, covering from approximately [365, 113] to [585, 705].