Final

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

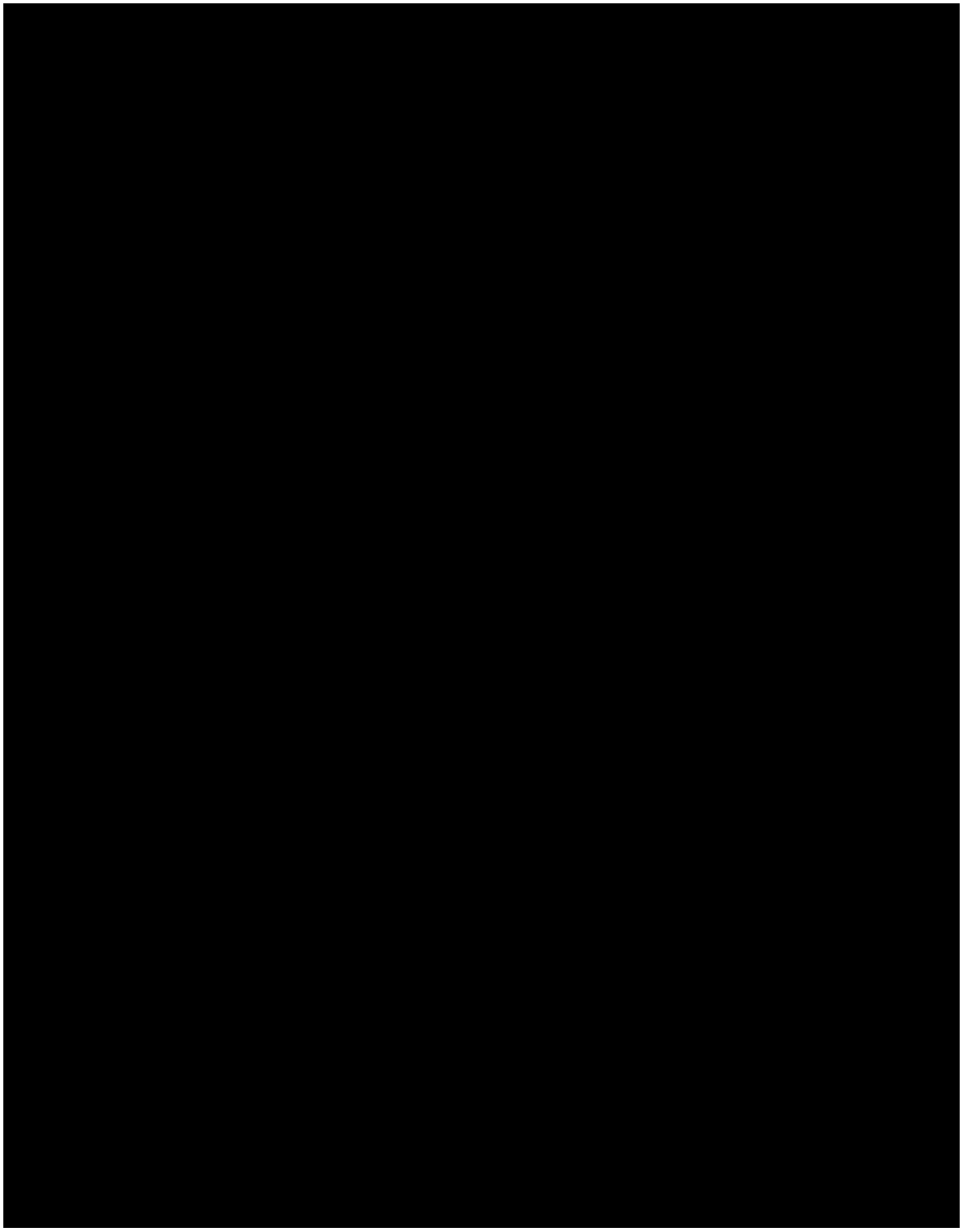
Sponsor Study Code:	EX-MKTG-136
Protocol Date:	April 23, 2022
Sponsor Company:	CooperVision, Inc.
Document Type:	Protocol
Study Category:	Post Market
Start Date:	May 2022
Finish Date:	July 2022
Clinical Site:	School of Optometry Clinic, National Autonomous University (UNAM), Mexico City

[redacted]

Revision History

Document number	Date	Comments
EX-MKTG-136	4/15/2022	First draft (v 1.0)
EX-MKTG-136	4/22/2022	FINAL
EX-MKTG-136	4/23/2022	FINAL UPDATED

PERSONNEL & FACILITTIES



Protocol Synopsis

Protocol Number	EX-MKTG-136
Title	Clinical Evaluation of clariti Monthly Multifocal and clariti® 1 day Multifocal.
Name of Device(s) and (by USAN material)	Clariti Monthly Multifocal (somofilcon A), clariti 1-Day Multifocal (somofilcon A)
Indications for Use	**Approved for use:** • somofilcon A. (Daily wear) • somofilcon A. (Daily wear) **Indication for use in this study:** • 15 minutes daily wear
Study Design	Single-blind, (participant 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 Multifocal when compared to the Clariti 1-Day Multifocal after 15 minutes of daily wear.
Study Duration	The anticipated timeline for this study is as follows: • Patient enrolment and completion: May 3 - June 17, 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 contact lens wearers who currently wear multifocal contact lenses, sphere contact lenses for monovision, or use spectacles for near vision correction, that provide written informed consent and meet the protocol entrance criteria.
Sample Size	Target enrollment and completion is **40** subjects.
Center Destination (Mexico)	School of Optometry Clinic, National Autonomous University (UNAM)
Number of Centers	Single Center
Patient Follow-up	Subjects enrolled in this study will be followed up after the lens dispensing session: • Post dispensing follow-up at 15 minutes for each study lens pair
Primary Endpoint	Subjective comfort on insertion. Subjective handling (insertion & removal)
[redacted]	[redacted]

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1 Introduction

Silicone hydrogel materials make up the majority of contact lens fits, and refits as recently reported (*Contact Lens Spectrum* market data). [1] For 2021, silicone hydrogels were reported in usage at 69%, with soft multifocal lenses at 14% versus 12% in 2020. When comparing soft contact lens fits & refits in 2021 by replacement schedules, the daily disposable modality continues to lead in terms of prescribing by soft lens replacement schedule (range of 43% to 51%). [1] Daily disposable contact lenses are able to provide many benefits to contact lens wearers when compared with frequent replacement lens modality. [2] These include the convenience of not having to clean and disinfect lenses after each use and the ability to have spare, replacement contact lenses readily available in the event of loss or damage. When a new lens is worn each day, there is significantly less spoliation from lens surface deposits. [3,4,5.]

Soft multifocal contact lenses, (MFCLs), are a great option for new and established presbyopes, offering good vision performance with the added benefit of improved cosmesis and convenience compared to spectacles, and provide them the flexibility to change-up their vision correction.[6] CL manufacturers are continually innovating in this area, with the increased availability of soft MFCLs with novel designs in a range of replacement frequencies from daily disposable 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 Monthly Multifocal, (**LENS A**), to the Clariti 1-Day Multifocal, (**LENS B**), silicone hydrogel contact 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 Multifocal when compared to the Clariti 1-Day Multifocal after 15 minutes of daily wear.

The primary outcome variable is:

- Subjective comfort ratings on insertion (assessed by subjects)

[redacted]

3 Study Hypothesis

3.1 Study Hypothesis

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

4 Study Design

This is a 40-subject, single-blind, (participant 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 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 ceticafesi@gmail.com.

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 contact lens wearers who currently wear multifocal contact lenses, sphere lenses for monovision, or sphere lenses for distance vision correction and use spectacles for near vision correction, 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:

1. Is at least 42 years of age and has full legal capacity to volunteer.

2. Has read and signed an information consent letter.

3. Self-reports having a full eye examination in the previous two years.

4. Anticipates being able to wear the study lenses for at least 8 hours a day, 5 days a week.

5. Is willing and able to follow instructions and maintain the appointment schedule.

6. Habitually wears multifocal soft contact lenses, or sphere lenses for monovision, or sphere lenses for monovision, or sphere lenses for distance vision correction and use spectacles for near vision correction, for the past 3 months minimum.

7. Has refractive astigmatism no higher than -0.75DC.

8. Is presbyopic and requires a reading addition of at least +0.75D and no more than +2.50D.

9. Can be fit and achieve binocular distance vision of at least 20/30 Snellen (or +0.20 logMAR) which participants also deem to be ‘acceptable’, with the available study lens parameters (powers +4.00 to -6.00DS) (see Table 1).

Exclusion Criteria

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 that contraindicates contact lens wear.

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 contact lens wear or a study outcome variable.

5. Has known sensitivity to the diagnostic sodium fluorescein used in the study.

6. Self-reports as pregnant, lactating or planning a pregnancy at the time of enrolment.

7. Has undergone refractive error surgery or intraocular surgery.

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

Age ≥ 42 years is an inclusion criterion because presbyopia is unlikely in persons aged < 42 years and, if present, may not be due solely to presbyopic changes representative of the wider population.

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

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 i.e., sphere +4.00D to - 6.00D, in 0.25D steps, in both add powers.

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 Multifocal (LENS A)**	**Clariti 1-Day Multifocal (LENS B)**
Manufacturer	CooperVision	CooperVision
Material	somofilcon A	somofilcon A
FDA Class	Group 5	Group 5
WC %	56%	56%
Base Curve (mm)	8.6	8.6
Lens Diameter (mm)	14.1	14.1
Sphere Power (D)	+4.00 to -6.00 (0.25 steps)	+4.00 to -6.00 (0.25 steps)
Add Power (D)	Low, High (see fitting guide)	Low, High (see fitting guide)
Wearing schedule	Daily wear	Daily wear

8.2.2 Contact Lens care

Since this is a non-dispensing fitting study no contact lens care will be required. However, in the event that the study lenses need to be rinsed during the insertion process, preserved saline solution will be used.

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

- Explanation of the study.
- Sign informed consent form.
- [redacted]
- Insert trial **LENS A**, evaluate the fit and optimize the prescription if needed.
- [redacted]
- Order final **LENS A**.
- Remove **LENS A** and insert trial **LENS B**. Evaluate fit and optimize the prescription if needed.
- [redacted]
- Order final **LENS B**.

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

- Subjective assessments
  - [redacted]
  - Comfort on insertion (0 -10 scale)
  - [redacted]
- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

8.3.3 Visit 3: [redacted] (Evaluate LENS A)

- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

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

- Subjective assessments
  - [redacted]
  - ➢ Comfort on insertion (0 -10 scale)
  - [redacted]
- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

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

- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

[redacted]

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	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 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]

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

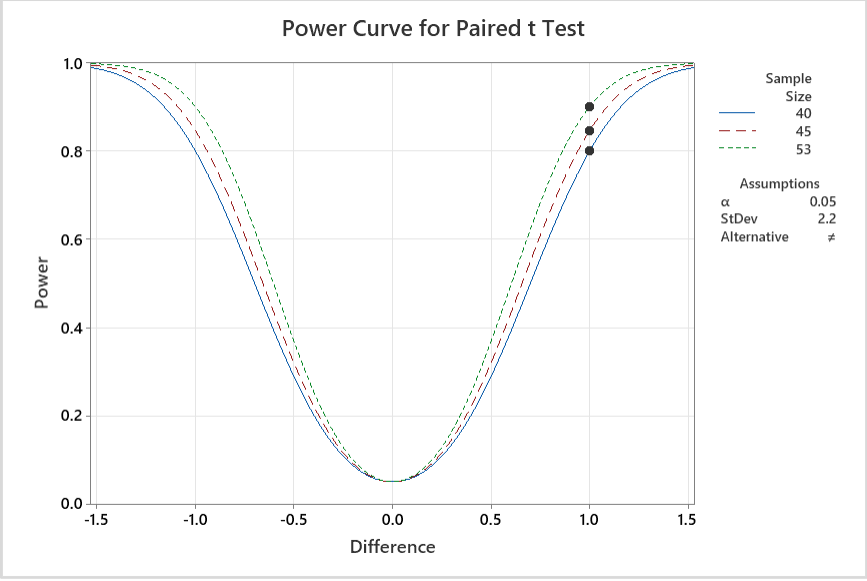
10.1 Statistical analysis

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

The sample size was calculated using data of lens comfort at insertion on day 1 collected in a previous study that evaluated the clariti 1day multifocal lens (CooperVision, data on file). Figure 1 shows the sample size determination for a paired t-test, (alpha=0.05), in order to detect a difference [redacted] Assuming a standard deviation of 2.2, a sample size of 40 completed subjects provides 80% power to detect a difference of 1.0 points on a 0 - 10 scale in subjective comfort ratings at insertion.

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
α = 0.05 Assumed standard deviation of paired differences = 2.2

Results

Difference	Sample Size	Target Power	Actual Power
1	40	0.80	0.800497
1	45	0.84	0.846619
1	53	0.90	0.901035

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.

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

13 Appendixes

APPENDIX 1 – STATEMENT OF INFORMED CONSENT

APPENDIX 2 – STUDY TIMELINE

APPENDIX 3 – LENS RANDOMIZATION

APPENDIX 4 – LENS REPLACEMENT LOG

APPENDIX 5 – GRADING & MEASUREMENT SYSTEM

APPENDIX 6 – CRF's / UNSCHEDULED VISIT & ADVERSE EVENT FORM

APPENDIX 1 – STATEMENT OF INFORMED CONSENT

APPENDIX 2- STUDY TIMELINE

TASK	April-2022	May-2022	June-2022	July-2022
Generate study Protocol.	April 12- 16			
Protocol EC submission.	April 18-22			
Protocol EC approval.		May 2		
V1: (BL/trial fit/lens order)		May 3-20		
V2-V4: (Dispense and evaluate both pairs of lenses)		May 30 – June 17		
Data analysis			June 20-25	
Study report.				July 4-8

APPENDIX 3 – RANDOMIZATION TABLE

APPENDIX 4– STUDY LENS REPLACEMENT LOG

Date	Investigator Initials	Subject Initials	Visit Just Prior to Lens Replacement	Number of Days Lens was Worn prior to Replacement	Lens Replaced (check one)	Reason
Click here to enter a date.					☐ Right ☐ Left ☐ Both	
Click here to enter a date.					☐ Right ☐ Left ☐ Both	
Click here to enter a date.					☐ Right ☐ Left ☐ Both	
Click here to enter a date.					☐ Right ☐ Left ☐ Both	
Click here to enter a date.					☐ Right ☐ Left ☐ Both	
Click here to enter a date.					☐ Right ☐ Left ☐ Both	
Click here to enter a date.					☐ Right ☐ Left ☐ Both	
Click here to enter a date.					☐ Right ☐ Left ☐ Both	
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Click here to enter a date.					☐ Right ☐ Left ☐ Both	

APPENDIX 5 – GRADING & MEASUREMENT SYSTEM

Variable	Assessment Method	Grading/Measurement System
Wearing Times		
Average # of days lenses worn in a week	Enter the number of days lenses are worn during the week.	Days per week
Average Daily Wearing Time	Typical time of day when lenses inserted and removed.	Time of day to nearest half hour
Average # of hours of wear per day	Enter the number of hours lenses are worn per day.	Hours per day
Average Comfortable Wearing Time	Typical time of day when subject first experiences LENS Awareness or irritation.	'Does CL comfort deteriorate during wear?' (tick-box). If yes, record time of day to nearest half hour when first aware of lenses
Typical Removal Time	Typical time of day when subject removes the lens.	Time of day to nearest half hour
Subjective Assessments (Questions asked by the investigator and recorded)		
Comfort, dryness, handling, lens fit, vision satisfaction.	Assessed by subject on a 0-10 scale.	0-10 scale Comfort: (10= can't feel) Dryness: (10=no dryness) Handling: (10=very easy) Fit stability (10=very stable) * Vision: (10=very satisfied)
Vision Quality	Assessed by subject on a 0-10 scale.	Vision quality: (10=Excellent vision, totally sharp)
Night Vision Quality	Assessed by subject on a 0-10 scale.	Vision quality: (10=Excellent vision, totally sharp)
Vision Stability	Assessed by subject on a 0-10 scale.	Vision stability: (10=perfectly stable, not fluctuating, changing)
Satisfaction	Subject's assessment of various symptoms on a 4-point Likert scale.	1. Completely satisfied 2. Somewhat satisfied 3. Somewhat dissatisfied 4. Completely dissatisfied
Preference	Subject's preference for one of two contact lenses.	Forced choice: Study lenses or Habitual
Vision		
Distance VA – High contrast	Measured using Snellen or logMAR chart.	Snellen or logMAR visual acuity (VA) to nearest letter.
Lens Surface assessed using slit lamp		
Front Surface Wettability	Lens surface viewed with a slit lamp, white diffuse light and broad beam under low-medium magnification.	0 – 4 0=poor 4=excellent

Variable	Assessment Method	Grading/Measurement System
Lens surface deposits assessed using the slit-lamp		
Front Surface Deposits	Lens surface deposits viewed with a slit lamp, white diffuse light and broad beam under low-medium magnification.	0 Clean, no deposits 1 5 or less small deposits (<0.1 mm) 2 > 5 deposits of <0.1 mm size or film covering 25-50% of surface 3 Deposits of between 0.1 and 0.5 mm or film covering 50-75% of surface 4 Deposits of 0.5 mm or larger or film covering more than 75% of surface
Lens Fit- assessed using slit lamp		
Lens Centration	Lens centration will be recorded by degree and direction in the primary position.	0 Centered - optimal 1 Decentered slightly 2 Substantially decentered (≥0.5mm) If decentered, direction(s) will be recorded as: Superior, Inferior, Nasal, Temporal
Corneal Coverage	Assessed in primary gaze.	Y Yes, full corneal coverage at all times N No, incomplete corneal coverage
Post-Blink Movement	Assessed immediately after the blink - lower lid to be depressed only if necessary, for observation.	0 Insufficient, unacceptable movement 1 Minimal, but acceptable movement 2 Optimal movement 3 Moderate, but acceptable movement 4 Excessive, unacceptable movement
Lens orientation in primary position of gaze	Slit lamp, with 10x magnification. Nasal mislocation is recorded as (+) and temporal as (-)	Mislocation of the axis mark on the lens relative to the 6 o'clock position, zero rotation, measured in degrees.
Overall stability	Slit lamp, with 10x magnification.	(0–4 scale), where 0=very poor, 4= excellent
Rotational recovery in degrees after 60 seconds	Slit lamp, with 10x magnification.	LENS Ability to return to its original position measured 60 seconds after manually rotating the lens 45^0 degrees temporally. Rotational recovery (RR) is assessed by manually rotating the lens 45° temporally from the primary gaze orientation (PGO) and allowing one minute (60 seconds) for the lens to recover. The absolute difference between the position of the lens following the recovery period and the PGO is taken as the measure of interest.
Overall Fit Acceptance	Assessed by the Investigator based on lens fit alone (i.e., not comfort or vision).	0 Should not be worn 1 Borderline but unacceptable 2 Min. acceptable, early review 3 Not perfect but OK to dispense 4 Perfect

Variable	Assessment Method	Grading/Measurement System
Biomicroscopy		
Limbal & Bulbar Hyperemia	Assessed using slit lamp with white light, low-medium magnification. (Use Brien Holden Vision Institute grading scales for reference) ½ grades recorded.	0 NONE: No injection present 1 VERY SLIGHT 2 SLIGHT 3 MODERATE 4 SEVERE
Lower palpebral hyperemia	Assessed using slit lamp with white light, low-medium magnification. (Use Brien Holden Vision Institute grading scales for reference) ½ grades recorded.	0 NONE: No injection present 1 VERY SLIGHT 2 SLIGHT 3 MODERATE 4 SEVERE
Corneal Infiltrates	Assessed using slit lamp with diffuse white light, low-medium magnification.	0 NONE: No infiltrates 1 TRACE: One faint peripheral infiltrate that does not stain. 2 MILD: A few mild infiltrates 3 MODERATE: Multiple dense infiltrates 4 SEVERE: Marked infiltrates with overlying staining.
Other Slit Lamp Findings	This section is intended to capture less commonly observed clinical entities such as conjunctival infection, EKC, corneal ulcers, LENS Adhesions, and recurrent erosions. The complication should be identified, described and graded by severity using the 0-4 scale.	0 None 1 Trace 2 Mild 3 Moderate 4 Severe

APPENDIX 6 – CRF's / UNSCHEDULED VISIT & ADVERSE EVENT FORM