Performance of Wearers of MyDay Sphere lenses after a Refit with MyDay Energys lenses for One Week (VIOLA)

Sponsor Study Code:	EX-MKTG-86
Protocol Date:	January 2018
Sponsor Company:	CooperVision, Inc.
Document Type:	Protocol
Study Category:	Post Market
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[redacted]	[redacted]
Clinical Site:	Multicenter

Protocol Sponsor: [redacted]

CooperVision Inc.

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1 Introduction

CooperVision (CV) produces a number of contact lens products including the MyDay brand. All MyDay Sphere lenses and MyDay Energys lenses feature CooperVision's exclusive Smart Silicone Technology. This combination of material technologies provides a contact lens with high oxygen permeability that is naturally wettable and offers unique comfortable experience.

This study is designed to evaluate how habitual or adapted wearers of MyDay Sphere lenses will perform following a refit with Comfilcon A aspheric lenses, a novel soft contact lens with digital zone optics design, over one week of daily wear. Lens wear experience overall and during digital device use will be assessed.

2 Study Objective

The aim of this study is to determine if habitual or adapted wearers of MyDay Sphere lenses can be confidently refit into MyDay Energys lenses and be successful after one week of daily wear.

Primary outcomes:

- Overall lens fit acceptance grade (Appendix 9)

Secondary outcomes:

- Lens centration & lens movement (Appendix 9)

[redacted]

3 Study Hypothesis

3.1 Study Hypothesis

- Null hypothesis (Ho): There is no difference in overall lens fit acceptance grade between MyDay Sphere and MyDay Energys lenses for the key variables measured.
- Alternative hypothesis (H1): There is a difference in overall lens fit acceptance grade between MyDay Sphere and MyDay Energys lenses for the key variables measured.

4 Study Design

This is a prospective, multi-center, open label, bilateral wear, one week dispensing study comparing the clinical performance of the MyDay Sphere lenses following a refit with MyDay Energys lenses.

Habitual wearers of MyDay Sphere lenses will be reviewed at Visit 1 to ensure optimal visual acuity is being achieved. If the visual acuity and power of the habitual MyDay Sphere lens is optimal, the participant will continue to wear MyDay Sphere in the same prescription for at least 7 days after which baseline variables will be collected. If an amendment of the power of the habitual MyDay Sphere is required, participants will be dispensed with the new power of the MyDay Sphere lenses to be worn for at least 7 days. In the instance where the participant habitually wears lenses which are not MyDay Sphere, the participant will be fit and dispensed MyDay Sphere lenses to be worn for at least 7 days.

After wearing MyDay Sphere lenses for at least 7 days in the study, all participant will return for baseline variables to be evaluated and will be then be dispensed with MyDay Energys. The participant will be asked to return for evaluation after 7-10days of lens wear. Participants will exit the study following the final evaluation of MyDay Energys.
This study will be open label. Over labeling of the blister packs is not required.

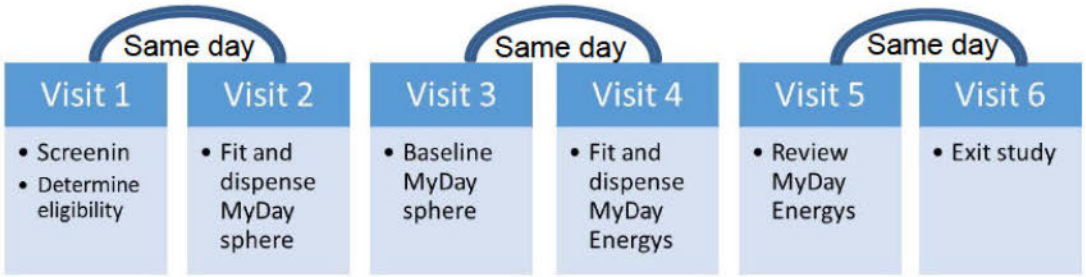


Figure 1 Study flow chart.

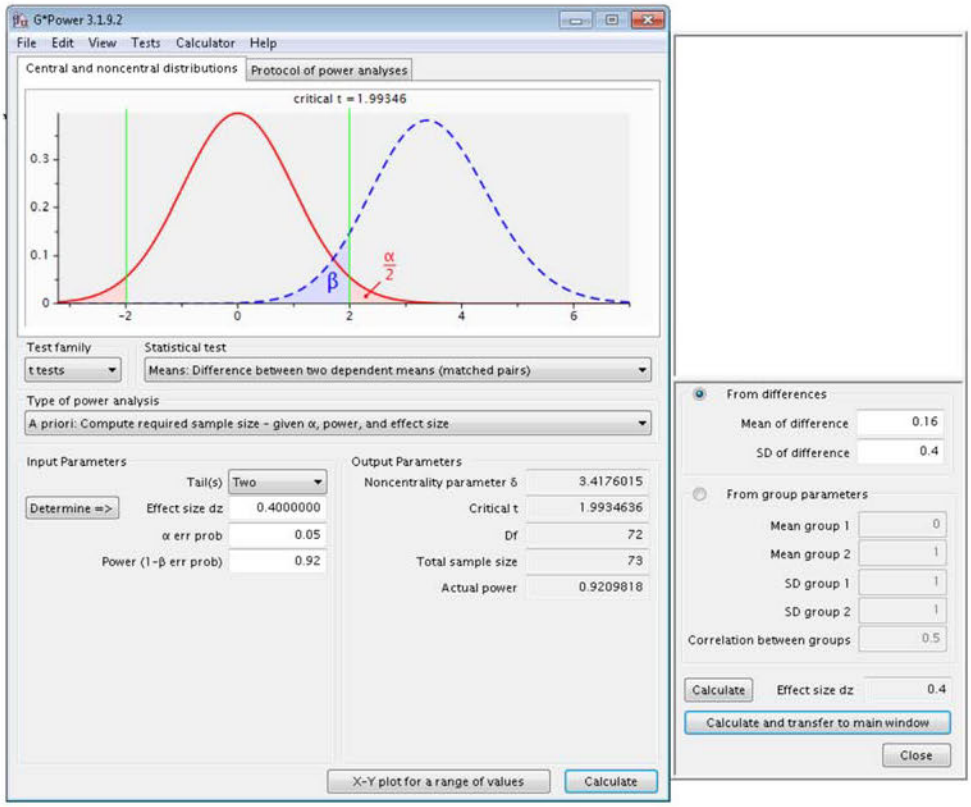
5 Study Population

5.1 Sample Size Calculation

A sample size calculation was made based on the primary outcome variable of lens fit acceptance grade, using data from a previous study: EX-MKTG-63. In this previous study the lenses compared were Biofinity and Biofinity Energys and for lens fit acceptance the difference between mean results

was 0.16, with a standard deviation of not greater than 0.4. For alpha 0.05, a sample size of 73 provides power of 92%. This variable will be graded using a 0-4 scale with 0.5 steps.

Therefore, to allow for drop-outs and protocol deviations affecting inclusion in the analysis cohort, dispensing to 80 participants will be targeted.



6 Investigational Sites

6.1 Number of Sites

This study design considers 5 sites and 80 subjects to complete the study.

6.2 Investigator Recruitment

The principal investigator and co-investigators at each site 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 already trained principal investigator.
- In-office email and either document scanning capabilities 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 E6 guidelines for Good Clinical Practice (GCP) and all the applicable local guidelines.

7 Ethics Review / Statement of Compliance

7.1 Relevant Standards / Guidelines

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

- ICH E6- International Conference on Harmonization: Good Clinical Practice (GCP)
- Declaration of Helsinki

7.2 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 Institutional Review Board: Sterling Institutional Review Board; Telephone number: (888) 636-1062 and email address: info@sterlingirb.com.

7.3 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.

7.4 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.

8 Potential Risks and Benefits to Human Subjects

There may be direct benefits to the subjects in this study, such as improved vision and/or comfort. 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 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 (1) do not represent a potential for serious risk to the health, safety or welfare of the subject, and (2) are not implants, (3) are not used to support or sustain human life, (4) are not of substantial importance in diagnosing, curing, mitigating or treating disease or otherwise prevents impairment of human health.

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 pain, 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 and only current soft lens wearers will be recruited for this study.

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. Patients will be monitored frequently until the end of the study to reduce the occurrence of adverse or potential adverse events. Patients will be given instructions from their investigator regarding early symptoms and signs of adverse events.

9 Materials and Methods

9.1 Participants

Up to 120 subjects may be screened for this study. All potential subjects will be habitual wearers of MyDay Sphere or will be adapted to this lens for at least one week as part of the study. Each subject will be required to attend up to six study visits scheduled on three days over a period of approximately 2-3 weeks.

Each subject will be given a unique ID number. All subjects who sign a consent document will be included in the subject enrollment log which will include; subject ID, date of consent, date of screening, date of study completion, date of discontinuation (if required), reason for discontinuation (if required).

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:

- Is between 18 and 35 years of age (inclusive)
- Has read and signed the informed consent letter
- Is willing and anticipated to follow instructions and maintain the appointment schedule
- Habitually wears soft spherical contact lenses with a power between -1.00D to -6.00D (inclusive) for a minimum 5 days per week, 10 hours per day *and* anticipates no difficulty wearing contact lenses for 7 days per week, 10 hours per day.
- Habitually wears or is able to be adequately refit into MyDay Sphere lenses
- Demonstrates an acceptable fit with the study lenses
- Is correctable to a distance visual acuity of 0.20 logMAR (approximately 20/30) or better (in each eye) with the study contact lenses
- Uses digital devices, (e.g. computer, tablet, smart phone, iPad), for more than 4 hours a day, 5 days a week.
- Manifest cylindrical spectacle refraction does not exceed -0.75DC in either eye
- Has clear corneas and no active ocular disease
- Has a contact lens refraction that fits within the available parameters of the study lenses.

Exclusion Criteria

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

- Is participating in any concurrent clinical research study
- Has a history of not achieving comfortable CL wear (5 days per week; > 8 hours/day)
- Has a systemic condition that, in the opinion of the investigator, may affect the study measures
- Is using any systemic or topical medications that in the opinion of the investigator may affect the study measures.
- Presents with slit lamp findings or clinically significant anterior segment abnormalities that would contraindicate contact lens wear such as:
    - Pathological dry eye or associated findings
    - Significant 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 (or history in past year)
    - Seborrheic eczema of eyelid region, Seborrheic conjunctivitis
    - History of corneal ulcers or fungal infections
    - Poor personal hygiene
- Has a known history of corneal hypoesthesia (reduced corneal sensitivity)
- Has a known sensitivity to the diagnostic pharmaceuticals to be used in the study
- Has aphakia, keratoconus or a highly irregular cornea.
- Has presbyopia or has dependence on spectacles for near work over the contact lenses.

- Has undergone refractive surgery.
- Is pregnant, lactating or planning a pregnancy (by verbal communication) at the time of enrolment
- Has participated in any other type of eye related clinical or research study within the last 7 days
- Is habitually using rewetting/ lubricating eye drops (more than once per day)

9.2 Study Materials

9.2.1 Contact lenses

All subjects will be trial fitted and, if suitable, dispensed the MyDay Sphere and the MyDay Energys lens brand. The study lenses will be provided by the Sponsor. Details of the contact lenses are shown in Table 1.

Table1: Study lenses

Brand	MyDay Sphere **(Control)**	MyDay Energys **(Test)**
Manufacturer	CooperVision	CooperVision
Material	stenfilcon A	stenfilcon A
Water Content	54%	54%
Base Curve	8.4	8.4
Lens Diameter	14.2	14.2
Lens Powers Sphere	-1.00 to - 6.00 (0.25 steps)	-1.00 to - 6.00 (0.25 steps)
Replacement schedule	Daily disposable	Daily disposable

9.2.2 Contact Lens care

No lens care systems are required as this study involves the use of daily disposable contact lenses.

9.2.3 Rewetting/ lubricating eye drops

Participants will be asked not to use rewetting/ lubricating eye drops during the study.

9.2.4 Storage of Study Medications/Treatments

There are no unapproved investigational products, medications or treatments used in this study requiring special storage accommodations. Room temperature storage is recommended for all study products.

9.2.5 Clinical Supply Inventory

There are no unapproved investigational products used in this study requiring special inventory requirements. Study product will be accounted for using the product accountability forms provided to each site by CooperVision.

9.2.6 Disposal of Consumables

This study dispenses consumables (lenses) to participants for use during the study. MyDay Sphere lenses will be dispensed for use over at least 1 week, MyDay Energys lenses will dispensed for use over approximately 1 week. All unused lenses will be collected and returned to the sponsor.

9.2.7 Masking and Control of Study Materials

The study contact lenses will be not be masked to the participant. Study lenses will be dispensed in blisters without the lens box. The investigator will not be masked.

9.2.8 Ordering and Accountability of Study Materials

The MyDay Sphere and MyDay Energys lenses will either be provided by the sponsor or sourced locally by the site, whichever makes logistical sense at the time. The sites are responsible for completing accountability logs for all lenses received, dispensed and returned.

9.3 Visit Schedule and Procedures

This study has 6 scheduled study visits (including the screening and exit visit), which are conducted on 3 visit days (Table). The total time commitment for scheduled visits is expected to be up to 4 hours.

[redacted]

Table 2: Summary of visits

Visit code	Visit schedule	Visit Description	Duration (hrs)
1		Screening to determine eligibility and to and establish optimum power of MyDay Sphere	1 (1.5 if fitting both lenses)
2*		Dispense MyDay Sphere**	0.5
3	≥7 days after V1	Review MyDay Sphere and baseline data collection	0.5
4		Fit and Dispense MyDay Energys***	0.5
5	7-10 days after V2	Review MyDay Energys	1
6		Study exit****	

**Note: Visit 2 is only necessary if a change in MyDay Sphere lens power is required, or if a fit with MyDay Sphere is required for adaptation*

***Note: Visit 2 can be concurrent to Visit 1*

****Note: Visit 4 is concurrent to Visit 3*

*****Note: Visit 6 can be concurrent to Visit 5*

9.3.1 Visit 1: Screening and establish optimum power of MyDay Sphere

Participants will attend a screening visit during which the subject will be required to read and sign an informed consent for prior to enrolment. When the subject has signed the consent form, the subject will be considered to be enrolled in the study. The investigator should also sign the consent form. The subject will be provided with a copy of the consent and the original will be kept in the subject's paper chart. It may also be scanned into the subject's electronic medical record (EMR) file.

Participants will be assigned a study ID number when they sign the informed consent document, and before their eligibility for the study has been confirmed. Subjects must be enrolled sequentially. The subject enrollment log will be updated. Ineligible participants will be discontinued from the

study. Depending on the participant's habitual lens type, participants may follow the following procedures and visits outlined (illustrated in Figure 2).

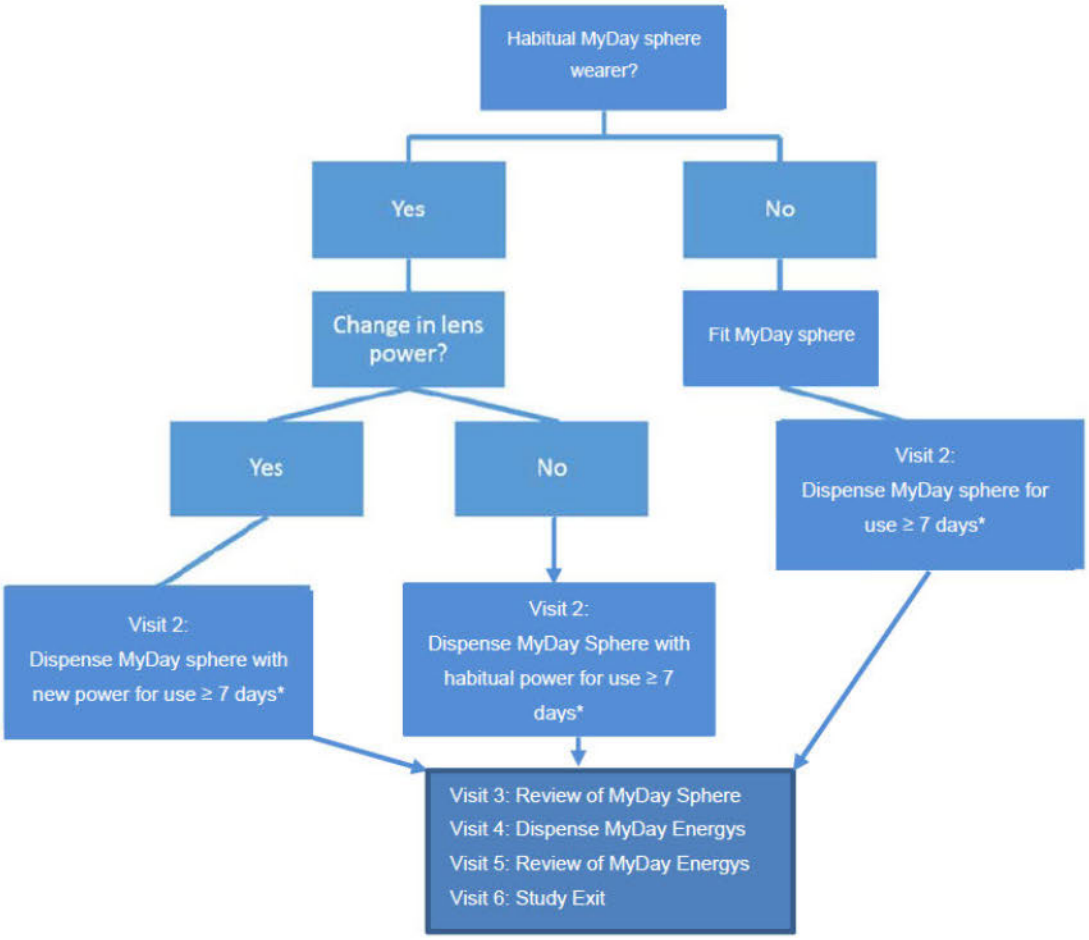


Figure 2: Flow chart for participants depending on habitual lens type.

Habitual MyDay Sphere wearers (Visit 1):

Participants that habitually wear MyDay Sphere lenses will attend Visit 1 wearing their own MyDay Sphere lenses for **at least 2 hours** prior to the visit.

Data to be collected:

- Participant demographics, including Race and Ethnicity
- Habitual contact lens type and prescription
- Wearing times with habitual lenses:
    - Wearing time today (hours).
    - Average daily wearing time (hours/day)
    - Number of days/week (lenses are worn)
- Health and medication.

- [redacted]
- [redacted]
- Remove contact lens
- Automated refraction and keratometry
- [redacted]
- [redacted]
  - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
  - [redacted]
    - [redacted]
  - [redacted]
- If at this point the subject is found to be ineligible, then complete an Exit form and exit the subject from the study.
- Eligibility will be confirmed and the participant continues right away with **Visit 2**

Habitual wearers of other lenses:

Participants that habitually wear other soft lens types will be asked to attend Visit 1 wearing their glasses. Participant demographics, including their contact lens history, wear schedule, health and medication will be recorded. The following procedures will then be conducted:

- Participant demographics, including Race and Ethnicity, habitual contact lens type and prescription, wear schedule, health and medication.
- [redacted]
- [redacted]
- [redacted]
- [redacted]
  - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
  - [redacted]
    - [redacted]
  - [redacted]

- [redacted]
- Eligibility will be confirmed and the participant continues right away with **Visit 2**

In some circumstances a repeated screening may need to be scheduled. Examples include, but are not limited to:

- Study procedures unable to be completed in time scheduled for visit;
- Study products not available at the time of the screening visit;
- A transient health condition which may affect the eye(s) (e.g. a common cold, active allergies, fatigue etc.);
- The short term use of medications (e.g. antibiotics, antihistamines etc.);
- Reassessment of baseline ocular conditions (e.g. corneal and/or conjunctival staining, scars etc.).

The maximum total number of screenings permitted per participant will be two.

9.3.2 Visit 2: Dispense MyDay Sphere

- Insert MyDay Sphere lenses (For habitual MyDay wearers, ensure to use updated power if an overrefraction was found)

[redacted]

- Fit assessment of MyDay Sphere

[redacted]

  - Centration: Optimum, decentration acceptable, decentration unacceptable

[redacted]

  - Post-blink lens movement, 0-4, 1 step, 0 = Insufficient, unacceptable movement

[redacted]

  - Overall fit acceptance 0-4, 0.5 step, 0 = Should not be worn
  - If overall fit acceptance ≤ 2, provide reason
- Provide sufficient MyDay Sphere to wear daily for at least 7 days
- After at least 7 days of MyDay Sphere, participant returns for **Visit 3** wearing MyDay Sphere for at least 2 hours on that day

[redacted]

9.3.3 Visit 3: Baseline MyDay Sphere review

Visit 3 occurs ≥7 days after visit 2. The following procedures will be conducted during this visit to determine the baseline MyDay Sphere performance:

- Changes to health or medication

[redacted]

- Fit assessment of MyDay Sphere

[redacted]

  - Centration: Optimum, decentration acceptable, decentration unacceptable

[redacted]

  - Post-blink lens movement, 0-4, 1 step, 0 = Insufficient, unacceptable movement

[redacted]

  - Overall fit acceptance 0-4, 0.5 step, 0 = Should not be worn
  - If overall fit acceptance ≤ 2, provide reason
- Remove contact lenses
- [redacted]

[redacted]

- Participant continues right away with **Visit 4**

9.3.4 Visit 4: Fit and Dispense MyDay Energys

Visit 4 occurs after Baseline MyDay Sphere data have been collected. At this visit, MyDay Energys will be fit dispensed. The following procedures will be conducted:

- Changes to health or medication (not required if completed on same day already)

- [redacted]
  - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
    - [redacted]
  - [redacted]
    - [redacted]
  - [redacted]
- Fit MyDay Energys

[redacted]

- Fit assessment of MyDay Energys

  [redacted]

  - Centration: Optimum, decentration acceptable, decentration unacceptable

    [redacted]

  - Post-blink lens movement, 0-4, 1 step, 0 = Insufficient, unacceptable movement

    [redacted]

  - Overall fit acceptance 0-4, 0.5 step, 0 = Should not be worn
  - If overall fit acceptance ≤ 2, provide reason

[redacted]

- Provide sufficient MyDay Energys to wear daily for at least 7 days (maximum 10 days)

[redacted]

- After 7-10 days of MyDay Energys wear, participant returns for **Visit 5** wearing MyDay Energys for at least 2 hours on that day

9.3.5 Visit 5: Review MyDay Energys

Visit 5 occurs after the participant has worn MyDay Energys for 7-10 days. Participants will attend this visit wearing MyDay Energys for at least **2 hours**. The following procedures will be conducted at this visit:

- Changes to health or medication

[redacted]

[redacted]

- Fit assessment of MyDay Energys

  [redacted]

  - Centration: Optimum, decentration acceptable, decentration unacceptable

    [redacted]

  - Post-blink lens movement, 0-4, 1 step, 0 = Insufficient, unacceptable movement

    [redacted]

  - Overall fit acceptance 0-4, 1 step, 0 = Should not be worn
  - If overall fit acceptance ≤ 2, provide reason

- [redacted]

  [redacted]

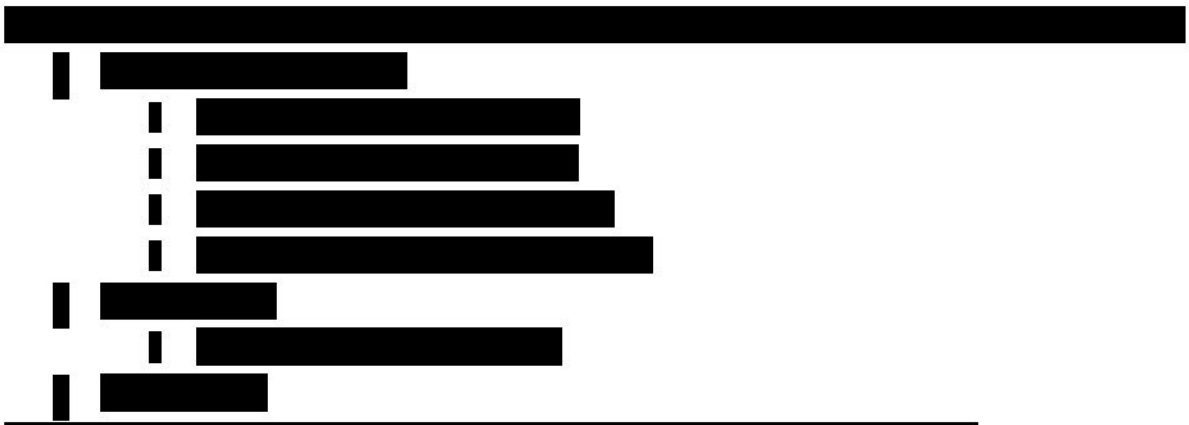
  [redacted]

- Remove contact lenses
- [redacted]

- Participant continues to the Study Exit Visit (Visit 6)

9.3.6 Visit 6: Study Exit

Visit 6 is completed when the participant exits the study. This may occur after study completion (i.e. after Visit 5), or if the participant discontinues from the study. The following procedures will be conducted at this visit:

- Remove study lenses (if applicable)
- 
- 
- Study completion or discontinuation form (as appropriate)
    - If there are records entered into the clinic's own patient chart system the exit date should also be recorded on these source documents.
    - If the subject is being exited due to discontinuation, further details need to be recorded on the Study Exit Form
- Post-study follow-up visits will be scheduled if the Investigator judges this is necessary.
    - Post-study follow-up requirement (Y/N). If yes, the reason and date of the follow-visit must also be recorded.
- Remuneration

10 Adverse Events and their Reporting

10.1 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. Adverse events can be ocular or non-ocular.

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.***

10.2 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 study device/procedure 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.

10.3 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 to the designated medical monitor of 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 and the study coordinator as soon as possible, but no later than 5 working days after the occurrence.

Sponsor medical monitor contact details are:

Contact:	Jose A. Vega, CooperVision
Email:	javega@coopervision.com
Phone:	(925) 621-3761 / Fax: (925) 621-2487
Address:	6150 Stoneridge Mall Drive, Suite 370. Pleasanton, CA 94588

10.4 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 and they are free of the study-related complications or other ocular pathology, where possible. When possible, the 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's study ID number and stored in multipurpose solution.

11 Statistical Analysis

11.1 Statistical analysis

Descriptive statistics will be provided on information regarding baseline variables (e.g., age, gender). Differences between lenses and over time will be compared using Paired t-tests. Paired t-tests /analysis of variance for normal (interval/continuous) data. The appropriate test will be selected based on tests of normality. Means and standard deviations will be provided for each variable.

[redacted] All participants who were 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.

12 Data Quality Assurance

12.1 Study monitoring

A site visit or discussion may be conducted during the course of the study as appropriate. Prior to final data lock, a close-out visit/discussion may be warranted to check for accuracy and completeness of records. Prior to data export for analysis there will be a discussion to confirm the cohort to be analyzed, with specific discussion around the data integrity in cases of protocol deviations and adverse events. 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.

12.2 Record keeping

Detailed records of all study visits will be made using the paper Case Report Forms (CRFs). Each subject will be identified on the CRFs with a study ID number which will not contain any identifying information such as initials and date of birth.

12.3 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. After the study closeout visit, the sites will send the original CRFs to the sponsor. 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.

12.4 Data Entry / Data Management

Data will be entered on paper CRFs. The clinical investigators will be responsible for the data integrity and the completeness of data entry for each visit. The sites will make an attempt to scan/email or fax all the paper CRFs to the Centre for Ocular Research & Education within ONE BUSINESS DAY of the visit date. The CORE personnel will review all CRFs for integrity and completeness and email or fax data queries back to the site as necessary. The site should make an attempt to answer all data queries within TWO business days of receipt. The CORE will review and enter all data into a database and study staff will only be able to modify these data via password entry.

[redacted]

[redacted]

[redacted]

12.5 Confidentiality

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). No identifying information will be collected on the CRFs or any of the documentation provided to the Centre for Ocular Research and Education or to the sponsor.

12.6 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.

13 Study Costs and Subject Compensation

CVI will compensate the Investigators, (principal investigators), and the subjects, (each a “Subject” and together the “Subjects”), for their time and participation in this voluntary study. Payments to the Clinical Investigator are per visit with a total of 3 visits for 60 subjects.

Clinical Site will receive the payment for the subjects and are responsible for distributing each subject’s compensation (checks). Complete outline/details of the payment compensation are detailed in the Clinical Study Agreement with each Clinical Site.

There will be no payments to the Clinical Site for unscheduled visits, unless Subjects are visiting regarding an adverse event. Data from unscheduled office visits, if mandated by your clinic, can be collected and entered using the unscheduled visit form.

Expenses incurred for medical treatment as part of study participation will be paid by CVI (bills and prescription receipts kept). The subject must be followed until resolution and a written report is completed indicating the subsequent treatment and resolution of the condition.