



CooperVision

FINAL

## Fitting Evaluation of Hydrogel and Silicone Hydrogel Sphere Design Contact Lenses.

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**Clinical Site:** School of Optometry Clinic, National  
Autonomous University (UNAM), Mexico City

**Protocol Sponsor:**

**Site Principal Investigator:**

### Revision History

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EX-MKTG-79	1/12/2017	First draft (v 1.0)
EX-MKTG-79	1/13/2017	Second draft (v 2.0)
EX-MKTG-79	1/13/2017	Final

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EX-MKTG-79 Fitting Evaluation of Hydrogel and Silicone Hydrogel Sphere Design Contact Lenses.

## PERSONNEL & FACILITIES

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## Protocol Synopsis

Protocol Number	EX-MKTG-79
Title	Fitting Evaluation of Hydrogel and Silicone Hydrogel Sphere Design Contact Lenses.
Name of Device(s) and (by USAN material)	Biomedics XC (omafilcon A), Proclear (omafilcon A), Clariti® elite (somofilcon A)
Indications for Use	<p><b>Approved for use:</b></p> <ul style="list-style-type: none"> <li>• omafilcon A (Daily wear, monthly replacement)</li> <li>• somofilcon A (Daily wear, monthly replacement)</li> </ul> <p><b>Indication for use in this study:</b></p> <ul style="list-style-type: none"> <li>• daily wear for all lens types</li> </ul>
Study Design	Prospective, non-dispensing, double masked, randomized, bilateral, daily wear in each study pair.
Purpose	The aim of this non-dispensing fitting study is to evaluate the short term lens fit, vision performance and patient subjective experiences of three monthly replacement sphere lenses.
Study Duration	<p>The anticipated timeline for this study is as follows:</p> <ul style="list-style-type: none"> <li>• Patient enrolment: February- March, 2016</li> <li>• Visits: V1 (Dispensing), V2 (1 hour post lens settling) for each lens pair.</li> </ul>
Patient Population	Habitual soft contact lens wearers with myopia that provide written informed consent and meet the protocol entrance criteria.
Sample Size	Target enrollment and completion is <b>40</b> subjects total.
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"> <li>• Post dispensing follow-up at 1 hour for each study lens pair</li> </ul>
Primary Endpoint	High contrast visual acuity
Secondary Endpoints	Lens fitting characteristics, subjective ratings, preference, and ocular response.

## Table of Contents

<b>1</b>	<b>Introduction .....</b>	<b>6</b>
<b>2</b>	<b>Study Objective .....</b>	<b>6</b>
<b>3</b>	<b>Study Hypothesis .....</b>	<b>6</b>
3.1	Study Hypothesis.....	6
<b>4</b>	<b>Study Design .....</b>	<b>6</b>
<b>5</b>	<b>Investigational Sites.....</b>	<b>6</b>
5.1	Number of Sites.....	6
5.2	Investigator Recruitment.....	7
<b>6</b>	<b>Ethics Review / Statement of Compliance.....</b>	<b>7</b>
6.1	Relevant Standards / Guidelines .....	7
6.2	Institutional Review Board .....	7
6.3	Clinical Trial Registration .....	7
6.4	Informed Consent .....	7
<b>7</b>	<b>Potential Risks and Benefits to Human Subjects .....</b>	<b>8</b>
<b>8</b>	<b>Materials and Methods.....</b>	<b>8</b>
8.1	Participants.....	8
	Inclusion criteria .....	8
8.2	Study Materials.....	9
8.2.1	Contact lens.....	9
8.2.2	Contact Lens care.....	10
8.2.3	Storage of Study Medications/Treatments .....	10
8.2.4	Clinical Supply Inventory.....	10
8.2.5	Disposal of Consumables .....	10
8.2.6	Masking and Control of Study Materials.....	10
8.2.7	Ordering and Accountability of Study Materials.....	10
8.3	Visit Schedule and Procedures.....	11
8.3.1	Visit 1 after dispensing (Fit lenses / Evaluate [e.g. P1]) .....	11
8.3.2	Visit 2 after 1 hour (Assess lenses / Study exit) .....	12
<b>9</b>	<b>Adverse Event Reporting.....</b>	<b>12</b>
9.1	Adverse Response Definitions.....	12
9.2	Procedures for Adverse Events .....	14
9.3	Reporting Adverse Events .....	15
9.4	Discontinuation from the Study .....	15
<b>10</b>	<b>Statistical Analysis.....</b>	<b>15</b>
10.1	Statistical analysis .....	15

<b>11</b>	<b>Data Quality Assurance .....</b>	<b>16</b>
11.1	Study monitoring .....	16
11.2	Record keeping .....	16
11.3	Record retention .....	16
11.4	Data Entry / Data Management .....	16
11.5	Confidentiality .....	16
11.6	Publication .....	16
<b>12</b>	<b>Study Costs and Subject Compensation.....</b>	<b>17</b>
<b>13</b>	<b>Appendixes.....</b>	<b>18</b>

## 1 Introduction

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Biomedics XC is part of an older generation of a hydrogel contact lens portfolio from CooperVision which will be discontinued soon.

Therefore, CooperVision is interested in switching wearers of the Biomedics XC brand into the Proclear hydrogel or Clariti® elite silicone hydrogel contact lenses. A non-dispensing fitting study is proposed to evaluate the clinical performance of these lenses.

## 2 Study Objective

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The aim of this non-dispensing study is to evaluate the short term lens fit, vision performance and patient subjective experiences of three monthly replacement sphere lenses.

The key variables of interest are:

- High contrast distance visual acuity
- Lens fitting characteristics and preference
- Subjective comfort ratings and preference
- Subjective handling ratings and preference (insertion & removal assessed by subjects)

*\* Lens fit preference judged by the study investigator*

## 3 Study Hypothesis

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### 3.1 Study Hypothesis

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- Null hypothesis (Ho): There is no difference in high contrast visual acuity, lens fitting characteristics, and subjective assessments between lens types.
- Alternative hypothesis (H1): There is a difference in high contrast visual acuity, lens fitting characteristics and subjective assessments between lens types.

## 4 Study Design

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This is a 40-subject, double masked, randomized, bilateral, non-dispensing fitting trial comparing hydrogel and silicone hydrogel lens materials. It is anticipated that this study will involve 2 visits for each lens pair, as follows: Visits: V1 (lens dispensing), V2 (1 hour post lens settling). Each subject will be randomized to wear each pair bilaterally in a series of three short fitting comparisons.

## 5 Investigational Sites

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### 5.1 Number of Sites

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

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## 5.2 Investigator Recruitment

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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

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### 6.1 Relevant Standards / Guidelines

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

- ICH Harmonized Tripartite Guideline for Good Clinical Practice
- Declaration of Helsinki

### 6.2 Institutional Review Board

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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 [jrf@unam.mx](mailto:jrf@unam.mx).

### 6.3 Clinical Trial Registration

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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

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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

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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

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### 8.1 Participants

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Adapted soft contact lens wearers with myopia will be recruited for the study for a minimum of **40** completed. 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:

- 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 CL wearer who is not wearing any of the study lenses.

- Has a CL spherical prescription between - 1.00 and - 6.00 (inclusive)
- Has a spectacle cylinder up to 0.75D in each eye.
- 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.
- Is willing to comply with the visit schedule.

### **Exclusion Criteria**

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

- Has never worn contact lenses before.
- Currently wears rigid gas permeable contact lenses.
- Has a history of not achieving comfortable CL wear (5 days per week; > 8 hours/day)
- Has a CL prescription outside the range of - 1.00 to - 6.00D
- Has a spectacle cylinder  $\geq 1.00$ D of cylinder in either eye.
- Has contact lens best corrected distance vision worse than 20/25 (0.10 logMAR) in either eye.
- Presence of clinically significant (grade 2-4) anterior segment abnormalities.
- Presence of ocular or systemic disease or need of medications which might interfere with contact lens wear.
- Slit lamp findings that would contraindicate contact lens wear such as:
  - Pathological dry eye or associated findings
  - Pterygium, pinguecula, or corneal scars within the visual axis
  - Neovascularization > 0.75 mm in from of the limbus
  - Giant papillary conjunctivitis (GCP) worse than grade 1
  - Anterior uveitis or iritis (past or present)
  - Seborrheic eczema, Seborrheic conjunctivitis
  - History of corneal ulcers or fungal infections
  - Poor personal hygiene
- Has a known history of corneal hypoesthesia (reduced corneal sensitivity)
- Has aphakia, keratoconus or a highly irregular cornea.
- Has Presbyopia or has dependence on spectacles for near work over the contact lenses.
- Has undergone corneal refractive surgery.
- Is participating in any other type of eye related clinical or research study.

## **8.2 Study Materials**

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### **8.2.1 Contact lens**

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

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and marketed products. Details of the study contact lenses are shown in Table1 and will be provided by the Sponsor.

**Table1: Study lens parameters**

Brand	Biomedics XC	Clariti Elite Aspheric	Proclear Monthly
Manufacturer	CooperVision	CooperVision	CooperVision
Material	Omafilcon A	Somofilcon A	Omafilcon A
WC %	60%	56%	62%
Base Curve	8.5	8.6	8.6
Lens Diameter	14.2	14.2	14.2
Lens Powers	-1.00 to - 6.00 (in 0.25 steps)	-1.00 to - 6.00 (in 0.25 steps)	-1.00 to - 6.00 (in 0.25 steps)
Replacement schedule	Daily	Daily	Daily

### **8.2.2 Contact Lens care**

Since this is a non-dispensing fitting study no contact lens care will be required.

### **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 study contact lenses will be masked to both the subject and the investigator. The study lenses will be removed from their blister pack by an assistant and transferred to an unmarked lens case to maintain subject and investigator masking of the study lenses. Next, subjects will be instructed to insert the lenses directly from the lens case.

### **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 a randomized, double masked, bilateral, non-dispensing fitting study. Participants will be examined at two different points over the course of one day, V1 (lens dispensing), V2 (1 hour post lens settling). They will wear three different pairs of lenses in randomized fashion. Anterior ocular health examination will be performed at baseline without the use of fluorescein\*.

Next, the study lenses will be dispensed and fit evaluated. After 1 hour of wear, lens fit assessments will be collected and the lenses removed. Anterior ocular health examination will be performed with fluorescein and the subjects exited from the study. This same procedure will be repeated at a different day for each lens pair.

*\* 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 1 hour 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 after dispensing (Fit lenses / Evaluate [e.g. P1])

- Explanation of the study
- Sign informed consent form
- Anterior ocular health examination (Slit lamp without fluorescein)
- Insert lenses from pair # 1
- Visual acuity
  - High contrast, monocular logMAR
  - High contrast, binocular log MAR
- Subjective assessments
  - Handling on insertion (0 -100 scale). **Subject to insert study lenses and rate handling.**
  - Comfort on insertion (0 -100 scale)
  - Burning/stinging (0 – 100 scale)
  - Comfort preference (right vs. left)
- Lens fit assessment
  - Lens centration (optimum, decentration acceptable, decentration unacceptable)
  - Corneal coverage [Y/N]
  - Post blink movement (0-5 Likert scale)
  - Lens tightness on push-up test (0% - 100% in 5% steps)
  - Overall fit acceptance (0 – 4) and reason if Grade 2 or less.
  - Investigator's fit preference

### 8.3.2 Visit 2 after 1 hour (Assess lenses / Study exit)

- Subjective assessments
  - Comfort on insertion (0 -100 scale)
  - Comfort preference (right vs. left)
  - Handling on removal (0 -100 scale)
- Lens fit assessment
  - Lens centration (optimum, decentration acceptable, decentration unacceptable)
  - Corneal coverage [Y/N]
  - Post blink movement (0-5 Likert scale)
  - Lens tightness on push-up test (0% - 100% in 5% steps)
  - Overall fit acceptance (0 – 4) and reason if Grade 2 or less.
  - Investigator's fit preference
  - Lens removal by subject
- Anterior ocular health examination with fluorescein
- Study exit form must be completed
- Subjects will be required to come to the clinic on a separate day to be fitted with the other study lenses.
- The same procedure as section 8.3.1 and 8.3.2 will be performed for the rest of the lens pairs.

## 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, <b>within 24 hrs</b> ; IRB reporting as per requirements
02	Permanent loss of $\geq 2$ 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 $\geq 2$ lines BSCVA for $\geq 2$ wks	SIGNIFICANT	
15	Corneal staining $\geq$ dense coalescent staining up to 2mm in diameter (i.e. moderate staining)	SIGNIFICANT	

16	Corneal neovascularization $\geq 1.0\text{mm}$ to $1.5\text{mm}$ 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 $\geq 2$ weeks	SIGNIFICANT	
10	Other significant event	SIGNIFICANT	
21	Conjunctivitis: bacterial, viral, allergic	NON-SIGNIFICANT	
22	Papillary conjunctivitis if $\geq$ mild scattered papillae/follicles approximately $1\text{mm}$ 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

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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.

Sponsor contact details are:

Contact:



### 9.4 Discontinuation from the Study

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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

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### 10.1 Statistical analysis

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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.

A sample size of 33 subjects was calculated which provides 80% power to detect a difference of half a line in logMAR high contrast visual acuity (HCVA). The critical alpha level for statistical significance will be set at  $p \leq 0.05$ , with adjustment for multiple comparisons. All participants who are evaluated in the study will be used in the analysis. In the event of missing data, individual numbers points will be excluded in the analysis and not extrapolated from the collected data.

## 11 Data Quality Assurance

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### 11.1 Study monitoring

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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

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

### 11.3 Record retention

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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

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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

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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

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

## 12 Study Costs and Subject Compensation

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CVI will compensate the Investigator, (principal investigator), 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 subject visit with a total of 2 visits for each lens pair, (total 6 visits), for 40 subjects. The study lenses will be provided by the sponsor to the Clinic Site. Clinical Site will receive the payment for the Subjects and are responsible in distributing the subject’s compensation.

Complete outline/details of the payment compensation are detailed in the Clinical Study Agreement. The statistical analysis, and study final report are “one-time costs” There will be no payments to the Clinical Site for interim visits, unless Subjects are visiting regarding an adverse event. Data from interim 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.

## 13 Appendixes

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