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FINAL

Clinical Evaluation of Biomedics® Monthly toric and Avaira Vitality™ toric

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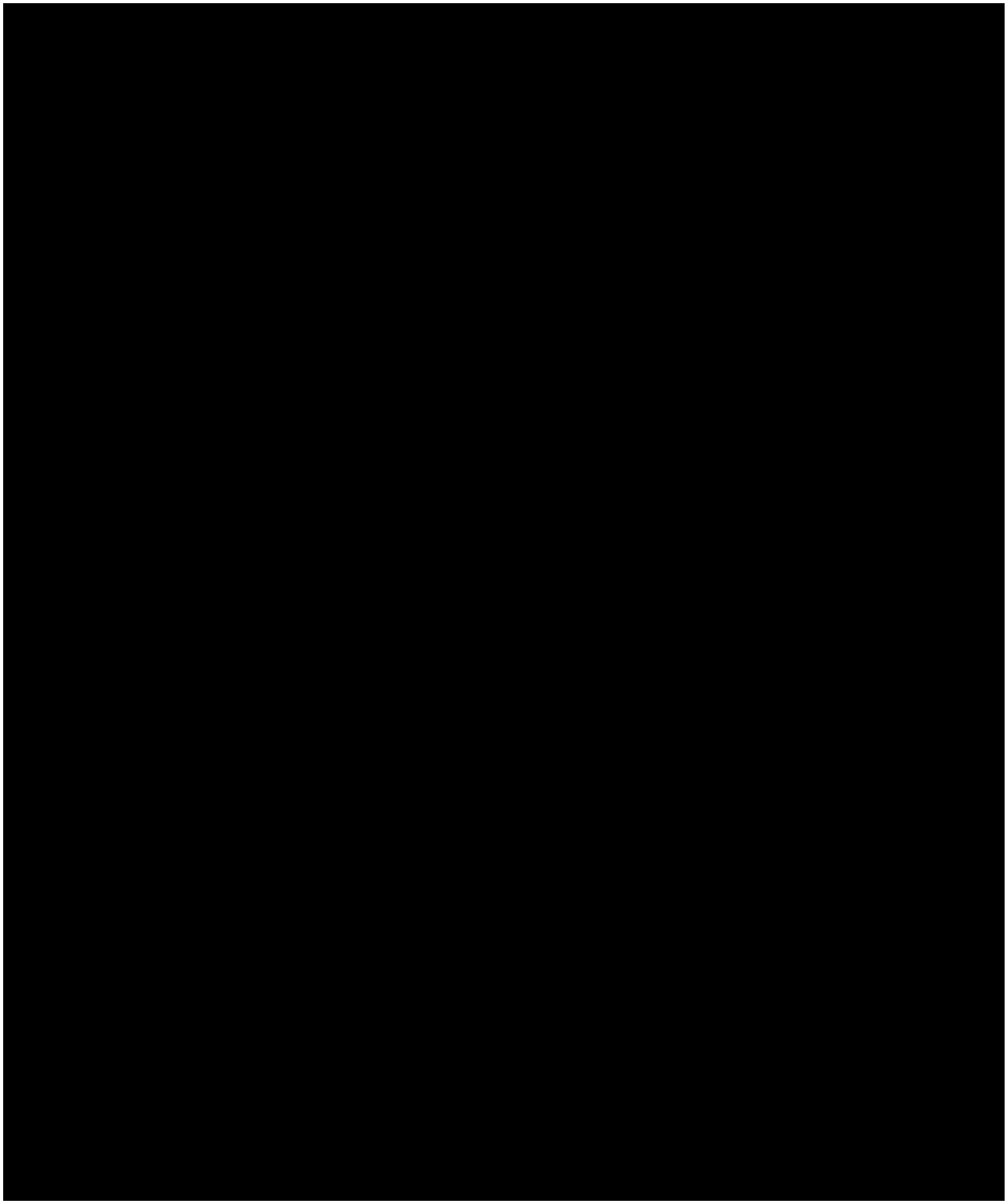
Clinical Site:	Dr. Rubén Velazquez Guerrero, Private Practice Consultorio Optométrico Queretaro # 238-604 Colonia Roma, Cuauhtémoc. Ciudad de México.

[redacted]

Revision History

Document number	Date	Comments
EX-MKTG-157	02/01/2024	First draft (v 1.0)
EX-MKTG-157	02/06/2024	Final



Protocol Synopsis

Protocol Number	EX-MKTG-157
Title	Clinical Evaluation of Biomedics Monthly toric and Avaira Vitality toric
Name of Device(s) and (by USAN material)	Biomedics® monthly toric (ocufilcon D), Avaira Vitality™ toric (fanfilcon A) Note: Avaira Vitality brand is sold as Liberti™ in Mexico.
Indications for Use	**Approved for use:** • ocufilcon D. (Daily wear) • fanficlon 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 Biomedics® monthly toric when compared to the Avaira Vitality™ toric lenses after 15 minutes of daily wear each.
Study Duration	The anticipated timeline for this study is as follows: • Patient enrolment and completion: April 08 - May 6, 2024 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	Adapted soft contact lens wearers that provide written informed consent and meet protocol entry criteria.
Sample Size	Target enrollment and completion is **40** subjects.
Center Destination (Mexico)	Consultorio Optométrico Queretaro # 238-604 Colonia Roma, Cuauhtémoc. Ciudad de México. Código Postal 06760
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	Lens Fit Acceptance Ratings
[redacted]	

Table of Contents

1 Introduction

Toric soft contact lenses, (TSCL), work best for people with astigmatism and other refractive errors (e.g., nearsightedness, farsightedness). The use of toric soft contact lenses (TSCL) has increased significantly in recent years. Data from Contact Lens Spectrum's market research showed that across all contact lens designs, most of the reported fits and refits with soft toric lenses 21% in 2023 versus 16% in 2022).[1] Soft toric contact lens wearers demand two things from their contact lenses, great comfort and excellent vision. Contact lens manufacturers are continuously innovating in this area, with increased availability of soft toric contact lenses with novel designs in a range of replacement frequencies, from daily disposables to monthly replacement, and different materials, including silicone hydrogels. Therefore, CooperVision is interested in comparing the short-term clinical performance and subjective acceptance of Biomedics® monthly toric (**LENS A**), to Avaira Vitality™ toric (**LENS B**), 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 Biomedics® monthly toric when compared to the Avaira Vitality™ toric after 15 minutes of daily wear each.

The primary outcome variable is:

- Lens Fit Acceptance ratings (assessed by the investigator)

[redacted]

3 Study Hypothesis

3.1 Study Hypothesis

- Null hypothesis (Ho): There is no difference in clinical performance and subjective assessments between lens types.
- Alternative hypothesis (H1): There is a difference in clinical performance and subjective assessments between 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 the investigator's private practice located at: Consultorio Optométrico Queretaro # 238-604 Colonia Roma, Cuauhtémoc. Ciudad de México. Código Postal 06760 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, [redacted], shall be obtained in writing from the subject and the process shall be documented before any procedure specific to the clinical investigation is carried out.

7 Potential Risks and Benefits to Human Subjects

There may be direct benefits to the subjects in this study such as improved vision, comfort, convenience, and cosmetic advantage. Participation in a study may contribute to scientific research information that may be used in the development of new contact lens products. In addition, subjects will receive an examination of the front part of their eyes and may have the opportunity to try a different type of soft contact lenses and/or different lens care products at no cost to them. The contact lens materials used in this study are commercially available intended for daily wear (NOT extended wear) similar to the average wearing time of 10-16 hours for daily wear lenses.

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

Complications that may occur during the wearing of contact lenses include discomfort, dryness, aching or itching eyes, excessive tearing, discharge, hyperemia and variable or blurred vision. More serious risks may include photophobia, iritis, corneal edema or eye infection. Although contact lens-related infections are very infrequent, the possibility does exist. The incidence of infection due to day-wear soft lenses is 0.035%. Almost always an infection will occur only in one eye. This risk is assumed by 35-million Americans who currently wear contact lenses.

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

8 Materials and Methods

8.1 Participants

Habitual soft toric contact lens wearers who currently wear toric lenses for distance vision correction and provide written informed consent and meet the protocol entrance criteria. Subjects will be recruited from the investigator's private practice databases who agree to voluntarily participate in the study [redacted]. 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 contact lens wearer.
- Is not a habitual wearer of either study lens.
- Has a contact lens spherical prescription between +5.00 to - 9.00 (inclusive) best corrected visual acuity of 20/30 or better in either eye.
- Have contact lens prescription of no less than -0.75D of astigmatism and no more than -2.25 D in both eyes.
- Can achieve best corrected spectacle distance visual acuity of 20/25 (0.10 logMAR) or better in each eye.
- Can achieve a distance visual acuity of 20/30 (0.18 logMAR) or better in each eye with the study contact lenses.
- Has clear corneas and no active ocular disease.
- Has read, understood and signed the information consent letter.
- Patient contact lens refraction should fit within the available parameters of the study lenses.
- Is willing to comply with the wear schedule (at least 5 days per week, > 8 hours/day assuming there are no contraindications for doing so).
- Is willing to comply with the visit schedule.

Exclusion Criteria

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

- Has a CL prescription outside the range of the available parameters of the study lenses.
- Has a spectacle cylinder less than -0.75D or more than -2.50 D of cylinder in either eye.
- Slit lamp findings that would contraindicate contact lens wear such as:
    - Pathological dry eye or associated findings
    - Pterygium, pinguecula, or corneal scars within the visual axis
    - Neovascularization > 0.75 mm in from of the limbus
    - Giant papillary conjunctivitis (GCP) worse than grade 1

- Anterior uveitis or iritis (past or present)
- Seborrheic eczema, Seborrheic conjunctivitis
- History of corneal ulcers or fungal infections
- Poor personal hygiene
- Has a known history of corneal hypoesthesia (reduced corneal sensitivity)
- Has aphakia, keratoconus or a highly irregular cornea.
- Has Presbyopia or has dependence on spectacles for near work over the contact lenses.
- Has undergone corneal refractive surgery.
- Is participating in any other type of eye related clinical or research study.

8.2 Study Materials

8.2.1 Contact lens

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

All subjects will be trial fitted and, if suitable, dispensed the first pair of the assigned lens brand assigned per a determined table [redacted]. 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	Biomedics® monthly toric **(LENS A)**	Avaira Vitality™ toric **(LENS B)**
Manufacturer	CooperVision Inc.	CooperVision Inc.
Material	ocufilcon D	fanfilcon A
WC %	55	55
Base Curve (mm)	8.7	8.5
Lens Diameter (mm)	14.5	14.5
Sphere Power (D)	+ 5.00 to – 9.00 (0.50 steps after ± 6.00)	+ 5.00 to – 9.00 (0.50 steps after ± 6.00)
Cylinder Power (D)	-0.75, -1.25, -1.75, -2.25	-0.75, -1.25, -1.75, -2.25
Axis	10 to 180 (in 10 degree steps)	10 to 180 (in 10 degree steps)
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

- Subjects should attend this visit wearing their spectacle lenses.
- Explanation of the study.
- Sign informed consent form.
- Collect habitual toric lens brand information.
    - Brand
    - Power(s)
    - Replacement schedule (daily, 2-week, monthly)

- [redacted]
- Insert trial toric **LENS A**, evaluate the fit and optimize the prescription if needed.
- [redacted]
- Measure lens fitting characteristics ([redacted] overall fit acceptance).
- Order final **LENS A**.
- Remove **LENS A** and insert trial toric **LENS B**. Evaluate fit and optimize the prescription if needed.
- [redacted]
- Measure lens fitting characteristics ([redacted] overall fit acceptance).
- Order final **LENS B**.

8.3.2 [redacted]

- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- **Lens Fit Assessment**
  - ➢ [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

8.3.3 Visit 3: 15 minutes (Evaluate LENS A)

- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- **Lens Fit Assessment**
  - ➢ [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

- Overall fit acceptance‡ (0 – 4) and reason if Grade 2 or less.
- Remove **LENS A**

8.3.4 [redacted]

- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- **Lens Fit Assessment**
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

8.3.5 Visit 4: 15 minutes (Evaluate LENS B / Study Exit)

- [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- **Lens Fit Assessment**
  - [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
  - Overall fit acceptance‡ (0 – 4) and reason if Grade 2 or less.
  - [redacted]
  - [redacted]
  - [redacted]
  - Complete the study exit form.

‡ **0**=Should not be worn, **1**=Borderline but unacceptable, **2**=Min. acceptable, early review, **3**=Not perfect but OK to dispense, **4**=Perfect

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.

Sponsor contact details are:

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.

10.1 Statistical analysis

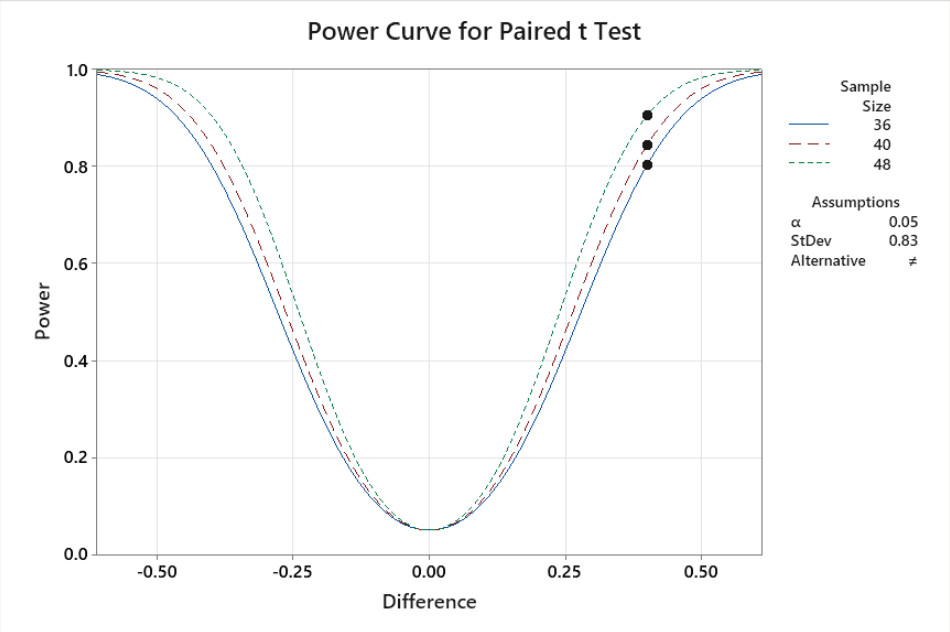
Summary statistics will be produced, (e.g., mean, standard deviation), by the principal investigator. Differences between lenses will be compared using Paired t-tests. Paired t-tests /analysis of variance for normal (interval/continuous) data, Wilcoxon's signed ranks test for non-normal (ordinal) data, chi-squares test for nominal data. Comments regarding the clinical relevance of differences in subjective ratings will be based on the conclusion by Navascues-Cornago et al.[2], Papas, et al.[3] that on a scale of 0-100, differences greater or equal to 7 points would generally represent a difference that a patient would notice. Equivalence testing will be conducted for ratings of comfort, using Mintab 20.2. A value of – 7 and + 7 will be used as the margins for equivalence.[2] Equivalence testing of visual acuity will be conducted using an equivalence margin of 0.10 logMAR.[4-9]

A Binomial 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

Using data from investigator's lens fit acceptance, collected in a previous study that evaluated soft contact lenses, a sample size was calculated (CooperVision data on file). Figure 1 shows the sample size calculation for a paired t-test in order to detect a difference between lenses in mean lens fit acceptance ratings. Assuming a standard deviation of 0.83, and an alpha level of 0.05, a sample size of 40 subjects provides 84% power to detect a difference of 0.4 points on a 0 - 4 scale. The study will enroll 44 subjects with the aim to complete 40 in total.

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



11 Data Quality Assurance

11.1 Study monitoring

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

11.2 Record keeping

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

11.3 Record retention

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

11.4 Data Entry / Data Management

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

11.7 References

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