PROTOCOL COVER PAGE

Sponsor	Visioneering Technologies, Inc. 4555 Mansell Rd., Suite 300 Alpharetta, GA 30022 USA
Protocol Title	Clinical Evaluation of VTI Lens Designs -Optimization and Comparative Clinical Trial (OPAC)
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Investigational Site
Principal Investigator Signature Page

Clinical Evaluation of VTI Lens Designs -Optimization and Comparative Clinical Trial (OPAC)

Protocol Number: VTI-2206
Version Number: V1.0
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Principal Investigator Acknowledgement Signature:
I have received and carefully read this version of the "Clinical Evaluation of VTI Lens Designs-Optimization and Comparative Clinical Trial (OPAC)" Version: 1.0. I will ensure that the study is conducted as described herein.

Principle Investigator:	**PI Signature:**	**Date:**
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1. INTRODUCTION

Visioneering Technologies, Inc. (VTI) currently has a market cleared multifocal contact lens NatrualVue Multifocal (NVMF), which is a Class II, non-significant risk (NSR) device. This contact lens product is designed for the correction of ametropia including myopia, myopia progression control (outside the US), hyperopia, and/or presbyopia. The optical design of the contact lens creates an enhanced depth of focus (EDOF), which provides clear distance, intermediate, and near vision. This unique optic while expands the depth of the focus, it also generates a significant amount of myopic defocus on the retina in a gentle and discrete way, therefore, it causes minimal visual disturbance.

A. Type of Research

Clinical study for NSR device refinement. This will be a single-masked trial. Subjects will be masked to the design or brand of lenses.

B. Purpose/Objective of the Study

Under this protocol, clinical trials will be undertaken to further optimize the current product design, and evaluate the design with different power or lens configurations including multifocal-toric lenses or other market approved lens materials. The goal of these Research and Development studies is to expand the product line in order to address and serve a larger population.

This protocol will serve as an umbrella protocol, as the clinical studies will be focusing on different aspects of lens performances during difference phase of product development and may conduct at different clinical sites. Minor optimization to the lens design will be made in Phase I, at this phase, shorter follow up evaluations will be made. Other available lenses or lens materials may be used for bench marking purposes. After optimization, the lenses may be dispensed for longer term performances (Phase II).

For each clinical site, the investigator required information (CV, license, site questionnaire, letter of submission) would be submitted to the IRB for review prior to that site recruiting or enrolling subjects. For the duration of the study during dispensing trials, subjects will be required to wear the study lenses for a minimum of 6 hours per day, 5 days per week. Subjects will not be allowed to keep the lenses.

C. Background of the Study

C.1 Normal Vision

For humans to see clearly, light rays entering the eye at various angles must be bent, sometimes referred to as ‘refracted’, to converge at a single point at the back of the eye. Light rays are first bent by the Cornea, which is the clear front surface of the eye. After the light rays pass through the Cornea, they are bent a second time by the Crystalline Lens, which lies just behind the Cornea. If the eye is focusing the light correctly, the Cornea and the Crystalline Lens bend the incoming light rays so that the light rays converge precisely on the back surface of the eye (the Retina), thereby producing a clear and unblurred image.

It is the ability of the Cornea and Crystalline Lens to bend and converge the incoming light rays precisely onto the Retina, which creates the clear image. If the Cornea and Crystalline Lens bend the light rays too much or too little, the light rays converge either in front of, or behind the Retina, respectively, resulting in a blurry image that requires visual correction.

C.2 Vision Deficiencies

Myopia (Also Known as 'Nearsightedness' or 'Shortsightedness')
Nearsightedness, or Myopia, occurs when the light rays converge in front of the Retina. Myopic people can generally see well for close-up tasks such as reading and computer use, but have difficulty seeing more distant objects clearly without eyeglasses or contact lenses, for example road signs. Other signs and symptoms of uncorrected Myopia include squinting, eye-strain, and headaches, and may also include feeling fatigued when driving or playing sports.

Myopia occurs when the eyeball is too elongated relative to the focusing power of the Cornea and Crystalline Lens of the eye. In Myopia, light rays entering the eye are over-bent (bent at too high an angle relative to the length of the eye) by the Cornea and Crystalline Lens, resulting in the light rays converging in front of the Retina instead of directly on the Retinal surface, thereby creating blur for distant objects. A patient with Myopia is prescribed a 'minus' powered corrective lens, which reduces the angle of the light rays entering the eye, thereby moving the convergence point of the light rays back to the Retina surface.

Myopia typically shows up in early childhood, and progressively worsens until it stabilizes in early adulthood (usually 18-25 years of age).[1,2] The worsening of Myopia throughout childhood and adolescence is known as Myopia Progression. [1,2,3] It is currently understood that one of the most significant optical risk factors for Myopia Progression is a condition known as Peripheral Hyperopia.[3-8]

In Peripheral Hyperopia, peripheral light rays converge behind the Retina, signaling the eye to grow in length.[3-8] Minus lenses are employed to correct the Myopia at the center of the Retina to provide clear distance vision, but a by-product of this central correction is that the peripheral light rays at the edge of the eye are now moved behind the Retina, which in turn re-establishes a growth signal and consequently, leads to the lengthening of the eyeball.[4,7] This cycle of central correction leading to eye growth repeats itself over and over, resulting in higher and higher amounts of Myopia.[4,6,7]

Two additional visual risk factors for Myopia Progression both deal with the amount and accuracy of the eye's ability to focus (called accommodation).[4,7] When the eye is tasked with focusing for extended periods of near work, which is common in Myopic school-age children, the eye can become stressed and not focus accurately.[10,15] This lack of accurate focusing can create additional Peripheral Hyperopia that is also thought to contribute to Myopia Progression.[4,7]

Hyperopia (Also Known as 'Farsightedness')
Hyperopia, or farsightedness, occurs when the light rays converge behind the Retina due to the length of the eye. Hyperopic people can generally see well for distance tasks (for example road signs), but have difficulty seeing close objects clearly without eyeglasses or contact lenses, for example reading books and computer use.

Hyperopia occurs when the eyeball is too short relative to the focusing power of the Cornea and Crystalline Lens of the eye. In Hyperopia, light rays entering the eye are under-bent (bent at too low an angle relative to the length of the eye) by the Cornea and Crystalline Lens, resulting in the light rays converging behind the Retina instead of directly on the Retinal surface, thereby creating blur for close objects. Farsightedness usually is present at birth and tends to run in families as an inherited condition. A patient with Hyperopia is prescribed a 'plus' powered corrective lens, which increases the angle of the light rays entering the eye, thereby moving the convergence point of the light rays forward to the Retina surface.

Presbyopia – Age Related Loss of Near Vision
Presbyopia is characterized by an age-related progressive loss of the ability to see things that are near. Presbyopia usually begins in a patient's 40s. Presbyopia affects close-up tasks such as reading or working at the computer. Most people become presbyopic around the age of 40, even if they have never had a vision problem previously. People who were previously wearing eyeglasses or contact lenses for their Myopia or Hyperopia will also start to notice that their near vision blurs when they wear their usual eyeglasses or contact lenses. Presbyopia typically continues to worsen until around the age of 60.

Presbyopia predominantly arises from a stiffening and weakening of the eye's Crystalline Lens with age. When a person is looking at something up close, light rays enter the eye at a high angle. In a younger person, the eye's Crystalline Lens is flexible and strong, rapidly changing shape to bend those high-angle light rays so that they converge precisely where they are supposed to: on the surface of the Retina (producing a clear image). However, with advancing age, the Crystalline Lens stiffens and weakens, and is unable to sufficiently bend the high-angle incoming light rays. As a result, the incoming light rays converge at a point behind the Retina, thereby creating a blurred image for near vision. A patient with Presbyopia is prescribed a 'relative plus' powered corrective lens (plus relative to their pre-Presbyopia prescription), which increases the angle of the bend, thereby moving the convergence of the light rays forward to the Retinal surface.

For a person who, prior to developing Presbyopia, already has Myopia or Hyperopia due to the length of the eye, Bifocal or Multifocal lenses will be prescribed, containing both an area of 'minus' power (to correct the Myopia) or 'plus' power (to correct the Hyperopia) as well as an area of 'relative plus' power to correct the presbyopia arising from age.

Astigmatism – Light Does Not Come to a Single Focus in the Eye
Astigmatism is another refractive condition that affects how the eye focuses incoming light.

In an eye with Astigmatism, rather than the Cornea and Crystalline Lens causing incoming lights rays to converge on a single focal point on the surface of the Retina, the eye produces multiple focal points either in front of or behind the Retina, or both in front of and behind the Retina. Astigmatism is usually caused by an irregularly shaped Cornea. Instead of the Cornea having a uniformly round shape (like a tennis ball), it has a more oval shape in astigmatic patients (like a football), causing the incoming light to refract unevenly within the eye with no single point of convergence.

Astigmatism can be corrected with a prescription for 'cylindrical' or 'toric' vision correction lenses, which corrects the eye's refraction of incoming light to a single focal point.

C.3 Contact lenses

Contact lenses are widely used for vision correction in individuals who do not prefer to wear eyeglasses full time or undergo corrective surgery, such as LASIK. Worldwide use has been published as high as 125 million global contact wearers.[9] As published by the US Centers for Disease Control and Prevention (CDC), approximately 40.9 million Americans age 18 and older wore contact lenses in 2014. In particular, daily disposable contact lenses have gained traction and acceptance around the world since being introduced in the 1990s. As reported by Johnson & Johnson Vision Care Companies (2016), the United Kingdom has a larger market share of daily disposable contact lenses than reusable lenses at about 60%. Worldwide it is reported that one in every three lenses that were fitted in Y2015 were for daily disposable use.[10] The introduction of daily disposable lenses offers the lens wearing market an option for quality optics, but without the labor and responsibility of lens cleaning and care. It has been reported that common risk factors for inflammation and infection, such as infrequent storage case replacement, poor case hygiene, and bioburden on the lens and case, may be improved through daily disposable lenses.[11-13]

Over 30 years of daily disposable lens use is available demonstrating the acceptable performance and use of hydrogel lenses known as "Etafilcon A". Chalmers et al, reported the rates of adverse events with hydrogel and silicone hydrogel daily disposable lenses in a large postmarket surveillance data collection, known as the "TEMPO" registry.[14] Subjects were any new or experienced soft contact lens wearers age 8 and older who had recently been fit with either 1•DAY ACUVUE TruEye (narafilcon B = SiHyDD) or 1•DAY ACUVUE MOIST (Etafilcon A = HydDD) spherical lenses in both eyes. From these 1171 subjects (approximately half wearing Etafilcon A manufactured lenses and half wearing silicone hydrogel lenses) were assessed for the incidence of lenses related adverse events during a one year period. The rates of corneal infiltrative events were 0.4% and 0.0% for these groups which are significantly lower than the rates reported for reusable soft contact lenses.

C.4 NaturalVue Multifocal Contact lenses and Optimization Plan

VTI lenses are molded, hydrated and sterilized at an FDA inspected and audited facility (Pegavision Corporation, Taiwan). The VTI lens design has received FDA 510k clearance (K150385, 2015, Visioneering Technologies, Inc.). Minor optimization to the lens design will be made (phase I), to include base curves, power profiles, optical zone diameters, edge design, front surface design, toric design and contact lens material performance. None of these minor changes to the design are anticipated to impact the safety and efficacy of the product. After optimization, the lenses will be compared to other available multifocal contact lenses (Phase II).

VTI lenses are of an FDA approved etafilcon-A material, other materials to be evaluated will either been cleared by FDA or passed material safety evaluations per FDA contact lens guidance. The lenses will only be worn on a daily wear basis. All other brands of lenses used will be FDA approved/cleared and will also only be worn on a daily wear basis. If a comparative product is not FDA approved/cleared, separate IRB approval for the use of such product will be required. All lenses will be fitted according to the manufacturer recommended fitting guides, and only those subjects displaying the characteristics of an acceptable lens fit will be dispensed with the lenses.

Data collected under this protocol will include state-of-the-art evaluation methods in contact lens safety and performance testing, presbyopia performance testing and myopia progression control testing; including, but not limited to, vision performance under low-light, and low-contrast conditions, viewing distances or vergences, contrast sensitivity, stereopsis, lens fitting and surface assessments, ocular health and parameter assessments, refraction, and subjective evaluations.

2. PARTICIPANT SELECTION

All subjects will be selected from the patient population at the investigational site. The investigator may review their records for subjects who meet the inclusion / exclusion criteria. Subjects may be qualified by telephone for their interest and availability for this trial. Subjects may be told that they will be trial fitted with a soft multifocal contact lens. If subject(s) can be successfully fitted and meet all inclusion / exclusion criteria, they may be dispensed to wear test lenses for daily wear, and return for a follow-up visits at approximately 2±1 days, and 5±3 days before being crossed over to the next lens.

The Informed Consent **MUST** be completed for each subject prior to enrollment.

A. Inclusion and Exclusion Criteria

Inclusion Criteria

Subjects must satisfy the following conditions for inclusion in the trial:

- Be of legal age, 18 years old or older
- Sign written Informed Consent.
- If a current contact lens wearer, usually wears their contact lenses for daily wear only.
- Have acceptable or optimal fit with test and control lenses and be willing to wear these lenses as directed for the duration of the study.
- Be correctable to high contrast Snellen distance VA to 20/25 in each eye.
- On examination, have ocular findings considered to be within normal limits.
- Normal binocularity (no amblyopia or strabismus, and no anisometropia of greater than 2.00D)
- Refractive astigmatism ≤ 1.00 diopters.
- Be willing and able to follow instructions and attend the schedule of follow-up visits.
- If not a current contact lens wearer, must have worn contact lenses previously and discontinued wear for reasons other than discomfort or dryness.
- For presbyopic performance study, need a reading add of +1.00 to +3.50 (inclusive).
- For presbyopic performance study, testing of EDOF curve, subject must have 20/50 or worse

distant corrected near visual acuity.

Exclusion Criteria

Any of the following will exclude a subject from this trial:

- Requires concurrent ocular medication contraindicating lens wear.
- Eye injury or surgery within twelve weeks immediately prior to enrollment for this trial.
- Pre-existing ocular condition that would contraindicating lens wear.
- Currently enrolled in an ophthalmic clinical trial.
- Pregnant, lactating or planning pregnancy (self-reported)
- Evidence of systemic or ocular abnormality, infection or disease likely to affect successful wear of contact lenses or use of their accessory solutions.
- Allergy or sensitivity to any product used in this trial.
- Any systemic disease including autoimmune disease, immunocompromising diseases, connective tissue disease, clinically significant atopic diseases, insulin dependent diabetes, use of medications including corticosteroids and antimetabolites that may affect the eye or be exaggerated by wearing contact lenses.
- Strabismus, amblyopia or habitually uncorrected anisometropia ≥ 2.00D Subjects who have undergone corneal refractive surgery
- Subjects with keratoconus or severe corneal irregularity contraindicating lens wear
- Inability to wear contact lenses, or an unacceptable contact lens fit
- Poor or unacceptable fit with any study lens
- Mesopic pupil size < 3.00 mm OU (measured at approx. 10 cd/m^2)
- Subjects who normally wear toric, GP, or hybrid contact lenses.
- Subjects who have never worn contact lenses will be excluded from this trial.
- Subjects who have previously worn contact lenses but discontinued wear due to discomfort or dryness related issues will be excluded from this trial.

B. Gender

Equal inclusion of both men and women in this study is desired but not necessary. There is no reported difference in contact lens safety or performance based on gender.

Pregnant women will be excluded from but women of childbearing potential, however, will not be excluded.

C. Racial/Ethnic Origin

There are no racial/ethnic enrollment restrictions. The racial/ethnic distribution of the participants will be likely reflecting the ethnic/racial population of the study site(s).

D. Vulnerable Populations

VTI employee may enroll in this study. Employees will be made aware that their decision of whether to participate will not affect their employment.

E. Age

The lens performance characteristics being tested during the study may results in age bias.
Example 1: Presbyopia typically occurs after 40 years old[15]. If we want to test the lens' Extended Depth of Focus performance, we will need to test it on moderate to mature presbyopic population, hence an older subject population.
Example 2: the Progressing Myopia typically shows up in early childhood, and progressively stabilizes in

early adulthood (usually 18-25 years of age).[1,2] If we want to test the lens' ability to improve accommodative lag (a risk factor for myopia progression), we will recruit a younger population as accommodation decrease drastically after 30 years old.[16]

F. Total Number of Participants to be Enrolled

Up to a maximum of 600 subjects will be seen under this protocol. No more than 100 subjects will be enrolled at each site.

3. STUDY DESIGN / METHOD / PROCEDURES

A. Summary of the Research Design

The lens optimization trials (Phase I) will involve both non-dispense and dispensing clinical trials. These trials will be prospective and single masked (subject). After an optimized design is determined, the lenses will be dispensed in prospective, masked, cross over trials comparing the lenses to other optimized VTI lens designs and/or to other available contact lenses (Phase II). Phase II trials could be a dispensing study for a period of 1 week each. There will be a follow-up visit during the trial at approximately 2 ±1 days, and 5 ±3 days.

All lenses will be dispensed for **daily wear** in this trial.

All data for this trial will be collected using CRFs that will be supplied by the sponsor.

Non-Dispensing Visits	**Procedures**	**Data Collection**
Enrollment	• Biomicroscopic examination. • Baseline ocular health and visual performance evaluations.	• Subject reads and signs Informed Consent. • Baseline Form
Lens Fitting & performance evaluations (Lens 1)	• Biomicroscopic examination (if not on the same day of enrollment). • Trial fit lenses. • Visual performance evaluations with lens	• Lens Evaluation Form • Visual performance Form
Lens Fitting & performance evaluations (Lens 2)	• Biomicroscopic examination (if not on the same day of enrollment). • Trial fit lenses. • Visual performance evaluations with lens	• Lens Evaluation Form • Visual performance Form
Exit visit	• Collect data for End-of-day visit/Trial Exit.	• Lens End-of-day Visit Form/Trial Exit Form
Unscheduled Visit	• Clinical exam as necessary	• Unscheduled Follow-up Visit Form. • Trial Exit Form, as necessary. • Potential Adverse Event Form, as necessary.

Dispensing Visits	Procedures	Data Collection
Fitting / dispensing visit	• Biomicroscopic examination. • Trial fit lenses. • Dispense lenses.	• Subject reads and signs Informed Consent. • Baseline Form • Lens Dispense Evaluation
2-Day Follow-up Visit (2±1 days)	• Collect data for 2 Day visit.	• Lens 2-day Visit Form
1-Week Follow-up Visit (5±3 days)	• Collect data for 1-Week visit. • Collect data for Trial Exit.	• Lens 1-Week Visit Form • Trial Exit Form
Unscheduled Visit	• Clinical exam as necessary	• Unscheduled Follow-up Visit Form. • Trial Exit Form, as necessary. • Potential Adverse Event Form, as necessary.

Scheduled Visits

There are three scheduled visits per lens for a dispensing trial:

- Enrollment / dispensing
- Follow-up visit at 2±1 day
- Follow-up visit at 5±3 days.

Unscheduled Visits

Visits that are instigated by the subject or requested by the investigator for health or vision-related reasons that occur between scheduled trial visits as specified above are classified as unscheduled visits. In addition, every visit after the trial period that is required because of a finding during the trial is considered an unscheduled visit. For every unscheduled visit the Unscheduled Follow-Up Visit Form must be completed and the reason for the unscheduled visit must be documented.

Missed Visits

Although every effort should be made to comply with the proposed visit schedule, in the event of a missed trial visit, the visit will be documented as missed on the appropriate CRF for that visit.

Exit Visit / Completion of trial

A Trial Exit Form will be completed when each subject completes the trial or is permanently discontinued from the trial. The form will detail the reason(s) for discontinuation.

Study Outcomes:

Performance outcomes:

- Lens fit (biomicroscopy/slit lamp evaluation)
- Other visual acuity tests may include
    a. Best spherically corrected
    b. High and low contrast
    c. Photopic and mesopic
    d. Distance, intermediate and near
    e. Extended Depth of Focus (EDOF) curve (+2D to -4D)

- Contrast sensitivity (optional)
- Glare or visual distortion (optional)
- Accommodation performance (optional)
- Questionnaires (optional)

Safety outcomes:

- Best Corrected Visual acuity (High contrast),
- Corneal health as assessed by slit lamp biomicroscopy and other signs and symptoms
- Adverse events

Study Procedures:

Study Treatment

The study method is comprised of the placement of lens(es) on the eye.

Methods:

1. Following detailed explanation and signing an informed consent form, each subject will perform the following:
    a. Baseline measurements on visual acuity (Best Corrected Visual Acuity), corneal health, ocular surface topography and anterior segment examination. If the subject meets this study's enrollment criteria,
    b. The study lens will be placed on the eye.
    c. The subject will undergo the following evaluations:
        i. Lens evaluation
            1. Lens position and movement
            2. Surface wettability evaluation (as needed)
            3. Slit lamp fluorescence imaging (as needed)
            4. Tear Exchange evaluation (as needed)
        ii. Photography/videography from anterior segment examination or lens evaluation (as needed)
        iii. Vision and Comfort assessment (questionnaire)
        iv. Uncorrected distance visual acuity (UCVA)
        v. Habitual distance visual acuity (as needed)
        vi. Distance best corrected visual acuity (BCVA)
        vii. Other visual acuity tests may include
            1. Best spherically corrected
            2. Low contrast letters

3. Mesopic lighting conditions
4. Intermediate and near viewing distance
5. Extended Depth of Focus (EDOF) curve (+2D to -4D)

viii. Glare testing (as needed)
ix. Distortion test (as needed)
x. Contrast Sensitivity (optional)
xi. Add power determination (optional)
xii. Accommodation range (optional)
xiii. Accommodative lag (optional)

d. The lens will be removed at the end of evaluation. Biomicroscopy and BCVA will be conducted as safety monitoring procedures.

All above mentioned testing are either standard clinical test in a routine eye exam or typical clinical/vision research evaluation method.

B. Analysis of Study Results

Descriptive statistics will be calculated for the primary variables in this trial. Where data from control lenses are available, appropriate inferential comparisons will be made.

C. Monitoring

VTI may provide a monitor who will monitor according to Good Clinical Practices (GCPs) the administrative (enrollment, discontinuations, etc.) and safety aspects (incidence and severity of complications, etc.), verify data integrity and assure the continued protection of subjects' rights and welfare.

D. Storage of Data

Case Report Forms (CRFs) are provided separately from this clinical protocol document. CRFs will be filled out legibly and completely (black or blue ball point pen). The original and copy of CRFs will be kept by the investigator. The CRF and related clinical files should be stored at least two years after the study is completed.

The sponsor will store study data electronically. Only authorized personnel have access to the study data.

E. Confidentiality of Data

The anonymity of participating subjects must be maintained. Subjects are identified by their initials and assigned a subject identification number on CRFs and other documents. Documents not submitted that identify the subject (e.g., the signed informed consent document) must be maintained in strict confidence by the investigator.

4. RISK/BENEFIT ASSESSMENT

A. Risks

Due to the nature of the study and the study device is Non-Significant Risk, the risk and discomforts involved are minimal. The NaturalVue Multifocal are approved for sale and use in the US since 2015 (K150385).

All contact lens wear can carry a risk of serious injury to the eye. Complications of contact lens wear can include light sensitivity, swelling of the cornea (the front part of the eye), red eye, corneal vascularization (small blood vessels growing into the cornea) and, in extreme cases, corneal infection. Corneal infection (microbial keratitis) may rarely cause a permanent reduction, or even loss, of vision. It has been reported that common risk factors for inflammation and infection, such as infrequent storage case replacement, poor case hygiene, and bioburden on the lens and case, may be improved through daily disposable lenses.[17-19] There is over 30 years of daily disposable lens use, with an estimated upper limit of microbial keratitis incidence of 1 in 500 years of wear.[20]

There is risk that optical perimeter changes may impact visual performances and results in suboptimal vision.

B. Prevention of Risks

All study lenses will be fabricated under GMP guidance to ensure sterility, traceability and quality.

The performances of the lenses and subjects wearing these lenses will be under close supervision at the study site(s). Lenses will not be dispensed (subject leaves study site with their study lenses) if the visual outcome and fit with the study lens is not satisfactory/safe.

C. Adverse Events

An Adverse Event in a clinical trial includes any undesirable clinical occurrence in a subject whether it is considered to be device-related or not. Adverse events may be classified as Serious Adverse Events, Significant Adverse Events, or Non-Significant Adverse Events as defined below.

Study site's contact information (including after hour) will be provided on the ICF to ensuring that medical or professional help is available in case an adverse event occurs.

All Serious Adverse Events (SAEs) that are unexpected and related or possibly related to participation in the research should be reported to Sterling IRB **within 10 business days** of when the site becomes aware of the event. All fatal or life threatening events should be reported immediately to Sterling IRB.

Serious Adverse Events

Events in which information suggests that the device has or may have caused or contributed to a death or serious injury. They include, but not limited to:

- Permanent decrease in best-corrected visual acuity (≥ two lines)
- Central corneal opacities - in the central 4 mm of the cornea
- Central corneal neovascularization - in the central 4 mm of the cornea
- Infectious corneal ulcers
- Uveitis
- Iritis
- Endophthalmitis
- Hypopyon
- Hyphema
- Penetration of Bowman's membrane
- Persistent epithelial defect
- Limbal cell damage leading to conjunctivalization

Significant Adverse Events

Events that require medical intervention and may warrant discontinuation (temporary or permanent) of contact lens wear (excluding serious adverse events noted above). These events are non-sight-threatening conditions that occur and are determined as device-related. They include:

- Peripheral and non-infectious corneal ulcer: inflammatory reaction of the cornea characterized by peripheral or mid peripheral corneal infiltrate with necrosis of the anterior stroma and excavation of the corneal epithelium. Bowman's layer is intact. Symptoms include moderate to severe pain, foreign body sensation, irritation, redness and tearing.
- Acute Red Eye: inflammatory reaction of the cornea characterized by small, focal and diffuse corneal infiltration with minimal or no epithelial involvement. Symptoms include irritation, pain, redness, tearing, and photophobia.
- Infiltrative keratitis: inflammatory reaction of the cornea characterized by anterior stromal infiltrates with or without epithelial involvement. Symptoms include mild to moderate irritation, and redness. Staining may be slight to moderate.
- Conjunctivitis: inflammatory reaction of the conjunctiva characterized by discharge, grittiness, redness and swelling.

Non-significant Adverse Events

Events that do not warrant discontinuation of contact lens wear, but may cause a reduction in wear time. Treatment, if needed, is usually with OTC products. They include:

- Asymptomatic infiltrative keratitis
- Blepharitis
- Meibomianitis
- Contact dermatitis
- Localized allergic reactions
- Severe solution-related ocular toxicity

D. Benefits

Depending on the subjects' age, they will have their refractive error corrected and even experience improved intermediate and near vision while wearing the lenses. In addition, valuable data will be collected in order to develop future products that could benefit a larger population.

E. Assessment of Potential Risks and Benefits

This is considered a non-significant risk study as study subjects will be wearing the lenses on a daily wear basis and the contact lens has been approved for sale in the United States since 2015. The risk is also reduced based on the results of biocompatibility testing and the history of safe wear of daily disposable contact lenses.

The following characteristics support the classification as a non-significant risk device. The study device is not intended as an implant and does not present a potential for serious risk to the health, safety or welfare of a subject. The device is not for use in supporting or sustaining human life, and the device does not represent a potential for serious risk to the health, safety or welfare of a subject. The device is for a use of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise preventing impairment of human health, but does not present a potential for serious risk to the health, safety or welfare of a subject. The device does not otherwise present a potential for serious risk to a subject.

The potential benefits of contact lens use for the control of myopia outweigh the potential nonsignificant risks to study subjects.

5. PARTICIPANT RECRUITMENT AND INFORMED CONSENT

A. Recruiting

Subjects will be recruited from participating clinic which provides contact lens services or within VTI. Employees will be made aware that their decision of whether to participate will not affect their employment.

B. Informed Consent / Assent

Written informed consent is required prior to enrollment in the study. It is the responsibility of the Investigator to obtain a valid Informed Consent.

C. Obtaining and Documenting Consent

The signed Consent is part of the study documents and will be kept by the investigator.

D. Participant Comprehension and Capacity

The investigator or the authorized study personnel will access the participant has clear understanding on all the information presented in the Consent prior to the document being signed.

E. Costs to Participants

There will be no study associated costs to the subjects.

F. Compensation to Participants

Subjects will be compensated for their time while participating in the study with gift certificates/checks.

6. REFERENCES

1. American Optometric Association. Care of the Patient with Myopia. 2006.
2. American Academy of Ophthalmology. Refractive Errors & Refractive Surgery Preferred Practice Pattern. 2017.
3. Sakaridurg P. Contact lenses to slow progression of myopia. Clinical & Experimental Optometry 2017; 100:432-437.
4. Cooper J, Schulman E, Jamal N. Current status on the development and treatment of myopia. Optometry. 2012 May 31;83(5):179-99. Review. PubMed PMID: 23249121.
5. Cooper J, O'Connor B, Watanabe R, Fuerst R, Berger S, Eisenberg N, Dillehay S. Case Series Analysis of Myopic Progression Control With A Unique Extended Depth of Focus Multifocal Contact Lens. Eye & Contact Lens 2018; 44(5): e16-e24.
6. Flitcroft DI. Thee complex interactions of retinal, optical and environmental factors in myopia aetiology. Prog Retin Eye Res. 2012 Nov;31(6):622-60. doi: 10.1016/j.preteyeres.2012.06.004. Epub 2012 Jul 4.
7. Gifford P, Gifford KL. The Future of Myopia Control Contact Lenses. Optom Vis Sci. 2016 Apr;93(4):336-43. doi: 10.1097/OPX.0000000000000762. Review.
8. Huang J, Wen D, Wang Q, McAlinden C, Flitcroft I, Chen H, Saw SM, Chen H, Bao F, Zhao Y, Hu L, Li X, Gao R, Lu W, Du Y, Jinag Z, Yu A, Lian H, Jiang Q, Yu Y, Qu J. Efficacy Comparison of 16 Interventions for Myopia Control in Children: A Network Meta-analysis. Ophthalmology. 2016 Apr;123(4):697-708. doi: 10.1016/j.ophtha.2015.11.010. Epub 2016 Jan 27.
9. Key, JE. Development of Contact Lenses and their Worldwide Use. Eye Contact Lens. 2007; 33 (6 Pt 2): 343-5.
10. Morgan P B, Woods C, *et al*. International contact lens prescribing in 2015. *Contact Lens*

Spectrum (2016);31(1): 28-33.

11. Guillon M. Are silicone hydrogel contact lenses more comfortable than hydrogel contact lenses? *Eye and Contact Lens*, 2013, 39:1 86-92.
12. Burnham GW, Cavanagh HD and Robertson DM. The impact of cellular debris on Pseudomonas aeruginosa adherence to silicone hydrogel contact lenses and contact lens storage cases. *Eye Contact Lens* 2012, 38:7-15.
13. Kilvington S I, Shovlin J and Nikolic M. Identification and susceptibility to multipurpose disinfectant solutions of bacteria isolated from contact lens storage cases of patients with corneal infiltrative events. *Cont Lens Anterior Eye* 2013, 36:294-298.
14. Chalmers RL, Hickson-curran SB, Keay L, Gleason WJ, Albright R. Rates of adverse events with hydrogel and silicone hydrogel daily disposable lenses in a large postmarket surveillance registry: The TEMPO Registry. *Invest Ophthalmol Vls. Sci. 2015. Jan 8; 56(1): 654-63.*
15. American Optometric Association. Care of the Patient with Presbyopia. 2010.
16. Sun FC, Stark L, Nguyen et al. Changes in accommodation with age: static and dynamic. *Am J Optom Physiol Opt. 1988 Jun;65(6):492-8.*
17. Guillon M. Are silicone hydrogel contact lenses more comfortable than hydrogel contact lenses? *Eye and Contact Lens, 2013, 39:1 86-92.*
18. Burnham GW, Cavanagh HD and Robertson DM. The impact of cellular debris on Pseudomonas aeruginosa adherence to silicone hydrogel contact lenses and contact lens storage cases. *Eye Contact Lens 2012, 38:7-15.*
19. Kilvington S I, Shovlin J and Nikolic M. Identification and susceptibility to multipurpose disinfectant solutions of bacteria isolated from contact lens storage cases of patients with corneal infiltrative events. *Cont Lens Anterior Eye 2013, 36:294-298.*
20. Bullimore MA, & Richdale K. Myopia Control 2020: Where are we and where are we heading?. *Ophthalmic Physiol Opt 2020;40: 254–270.*