IRB Approved: 12 December 2023
Version: 1.0

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Protocol number: 2023W0119

NCT number: NCT06172881

20 November 2023

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Novel Multifocal Soft Contact Lens Study

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Purpose

The primary objective of this study is to evaluate the safety and quality of vision of a novel multifocal soft contact lens in habitual contact lens wearers.

Study Overview

A single site, open label protocol will be used to evaluate the safety and quality of vision of a novel soft contact lens. Habitual contact lens wearers will be asked to come to the study site for one visit. Ocular health assessments and visual acuity will be completed with both the study lens and without.

Background and Rationale

The United States population was estimated to have 40.9 million adult contact lens wearers in 2014, with 93% wearing soft contact lenses. [1] Soft contact lenses are manufactured of various materials, and are available in various designs with differing curvatures (base curve) and diameters in order to correct refractive error. Spherical lenses correct only for near-sightedness (myopia) and far-sightedness. Patients with regular astigmatism can wear soft lenses in a toric design which relies upon a lens shape that will not rotate on the eye during wear in order to keep vision stable.[2] Soft lens designs which create clear vision at more than one viewing distance are known as multifocal lenses.[3] Soft multifocal lenses are typically prescribed for patients who can no longer see at close distances due to age-related presbyopia. The optical design of these lenses is based upon "simultaneous vision," a design in which different portions, or zones, of the lens are created inside the viewing area centered over the pupil, with different zones corresponding to different viewing distances.[4] The design varies among lens brands, with some providing the near vision in the center of the lens and intermediate and distance vision in concentric rings outside of this near vision zone. Other lenses provide distance vision in the center of the lens, with concentric rings focusing upon intermediate and near vision just outside of the distance portion of the lens. Patient success with these lenses can vary depending upon the fit and centration of the lenses, since all of the zones necessarily must fall within the pupil of the wearer.

Purpose

In this study, a soft lens with a novel multifocal optical design, will be studied to evaluate the quality of vision of participants while wearing the lenses.

Study Material

The lens used in this study is made of Omafilcon A, a soft lens material already approved by the FDA as Proclear contact lenses in 2006 (K061948, Cooper Vision, Pleasanton, CA, USA). The Omafilcon A material is a polymer created with 2-hydroxy-ethylmethacylate and 2-metacryloloxyethyl phosphorylcholine cross linked with ethylmethacrylate, and is approved as a Group II, Non-Ionic, High

Water Content lens. (https://www.accessdata.fda.gov/cdrh_docs/pdf6/K061948.pdf) Proclear lenses were approved to be used for spherical, toric, and multifocal lens designs created by Cooper Vision.

The lens used in this study is a multifocal contact lens design which is different from previous multifocal lens designs. The lenses are manufactured in an FDA approved manufacturing site. The contact lens design is a patent-pending design licensed from The Ohio State University to Myoptechs, Inc (7720 Rivers Edge Drive Ste 101, Columbus, Ohio 43235). The study lenses will be manufactured by our manufacturing partners, CL Tech (United Kingdom) and Schalcon (Italy/Romania) as described in the attached Non-Significant Risk statement.

Study Visit

This study will enroll up to 15 participants ages 18-40 for a single study visit in order to have 10 participants complete the study visit. Participants will be current soft contact lens wearers with no active ocular health complications that may confound data collection. They will complete the informed consent process before completing any study procedures. The participant's medical and ocular history, demographics, and medications will be collected. Entering acuity will be collected, and biomicroscopic examination of the front surface of the eyes, as is performed in a typical eye examination, will be completed to evaluate the ocular health. A refraction will be completed to determine the Best Corrected Distance Visual Acuity (BCDVA) of each eye. High contrast and low contrast BCDVA will be completed using ETDRS visual acuity while wearing the manifest refraction. The scotopic, low mesopic, and high mesopic pupil size will be measured. Intraocular pressure and keratometry will also be measured. The study lenses will be inserted, and the fit of the lenses will be evaluated. An over-refraction will be completed while the participant is wearing the study lenses to determine Visual Acuity while wearing the lenses. High contrast and low contrast ETDRS visual acuity will be completed with the study lenses and over-refraction if necessary. A visual analog scale (VAS) survey of comfort will be completed using REDCap. The study lenses will be removed and the ease of removal will be documented. The scotopic, low mesopic, and high mesopic pupil sizes will be measured after study lens wear. Intraocular pressure and keratometry will be measured pre- and post- lens wear. A biomicroscopic examination of the front surface of the eyes will be complete post removal of the study lenses. Exit acuity using the participant's habitual correction will be completed and adverse events will be collected.

Statistical Analysis

Ten participants will be enrolled in the feasibility study to determine the vision of participants while wearing the study lenses. Statistical comparison of the best corrected visual acuity and the visual acuity with the study lenses and over-refraction will be conducted with a paired t-test for each eye.

Recruitment

Potential subjects may see posters placed on bulletin boards at The Ohio State University (OSU) or local eye care offices, emails to students, faculty and staff at OSU, online or paper ads, signs on the OSU buses, StudySearch, The College of Optometry website and the Innovation in Vision and Eye Care Research Group (iVERG) website. Word of mouth referrals by study team members to OSU employees and friends may occur.

Inclusion Criteria

1. Ability to give informed consent
2. Any gender
3. Any racial or ethnic origin
4. 18 – 40 years of age
5. Distance visual acuity with best corrected visual acuity of 20/25 with each eye
6. Habitual soft contact lens wearer with myopia
7. Good general health (defined by medication use that has not changed within the last month and the absence of medical conditions or treatments that are deemed confounding to the data as determined by the investigator).

Exclusion Criteria

1. Current or active ocular inflammation or infection as determined by the Investigator.
2. Astigmatism > 0.75 D in either eye
3. History of previous eye surgery
4. Demonstration or history of corneal ectasia or keratoconus.
5. Pregnant or lactating.

Consent and Confidentiality

A team member trained in the consent process will provide the consent document for the potential subject to read and will review the procedures with reference to the consent form. The individual is then provided with time to read the consent form and offered the opportunity to ask questions. The participant is explicitly told that they may stop participation at any time. All subjects will have the capacity to give informed consent. If there is any doubt as to the subject's ability to consent to the study, the subject will be excluded from the study. If the subject agrees to take part in the screening or measurement, he or she will sign and date the most recent IRB-stamped consent as will the team member. The subject will be provided with a copy of the consent form.

The study team is trained in privacy issues and will be reminded of the importance of patient privacy prior to study initiation. Potential study participants will contact us after seeing advertisements, emails or hearing about the study by word of mouth, giving them the choice of whether or not they wish to participate in the study. Privacy is protected by limiting information to that which is related to study recruitment only, excluding other personal or medical information that should be private to the patients. The PHI needed is only for the purposes of this study.

Data Management and Security

During the active stages of the study (recruitment to end of measurement visit), all paperwork (consents, questionnaires and data forms) for each subject will reside in a subject folder for easy access throughout the study. The folders will reside in the limited-access research area, in a locked file drawer or cupboard. At the completion of the study or disenrollment of a subject the paperwork in the subject's folders will be reorganized into a regulatory binder (consents, W-9s) and a data binder (questionnaire and data forms) and will reside in an office in the limited-access research area. When the data analysis is completed and the study is considered complete, the binders will be stored in the secure Department or Office Clinical Research Area. Paperwork (questionnaire and data forms) for individuals who participate

in the baseline visit but are not eligible to continue the study will be stored in the study regulatory binder in the office in the limited-access research area. An electronic file of potential subjects and a file of enrolled subjects with their contact information, as well as electronic files of collected data with the subject number, will reside on a limited-access shared drive with firewall and password protection and is restricted to individuals in the research team. Any electronic data files that contain PHI will be destroyed at the conclusion of the study.

Risks to Subjects and Mitigation

Although rare, a subject could experience eye pain, changes in vision, continued redness or irritation of the eye when inserting or learning to insert a contact lens. More likely transient blurring of vision (less than one minute) or mild, transient (less than a minute) stinging may occur.

Whenever wearing a contact lens, the possibility of eye pain due to scratching the eye or getting an infection is possible, but not common.

Adverse Events

All adverse events will be documented and reported under the guidelines of The Ohio State University Event Reporting guidelines, with any serious, unanticipated and related events being reported to the IRB, by the PI, within 10 days. Adverse Events information will be summarized in the annual report to the IRB at the end of the study. Adverse events will be assessed and determined by Dr. Jennifer Fogt.

Subject Dismissal

Subjects who, after study team member coaching, are not able to provide analyzable data may be dismissed from the study. Subjects who do not keep scheduled visits within the required time frame will be dismissed from the study. Study team members will make reasonable efforts to accommodate subjects' schedules.

Protocol Violations, Discontinuation

In the event that a member of the study team or a representative of sponsor becomes aware of a major protocol violation, the IRB shall be notified within 10 working days.

[1] Cope JR, Collier SA, Rao MM, Chalmers R, Mitchell GL, Richdale K, et al. Contact Lens Wearer Demographics and Risk Behaviors for Contact Lens-Related Eye Infections--United States, 2014. MMWR Morb Mortal Wkly Rep 2015;64(32):865-70. https://doi.org/10.15585/mmwr.mm6432a2.

[2] Morgan PB, Efron N. Prescribing soft contact lenses for astigmatism. Cont Lens Anterior Eye 2009;32(2):97-8. https://doi.org/10.1016/j.clae.2008.10.006.

[3] Morgan PB, Efron N, Woods CA, International Contact Lens Prescribing Survey C. An international survey of contact lens prescribing for presbyopia. Clin Exp Optom 2011;94(1):87-92. https://doi.org/10.1111/j.1444-0938.2010.00524.x.

[4] Molina-Martín A, Piñero DP, Martínez-Plaza E, Rodríguez-Vallejo M, Fernández J. Efficacy of Presbyopia-Correcting Contact Lenses: A Systematic Review. Eye Contact Lens 2023;49(8):319-28. https://doi.org/10.1097/icl.0000000000001013.