Evaluation of Wear Experience with PRECISION7® For Astigmatism Contact Lenses in Neophyte Lens Wearers

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Purpose

The purpose of this study is to explore the wear experience with PRECISION7® For Astigmatism lenses in adults who have not previously worn contact lenses.

Study Overview

This open-label study is of adults with astigmatism who have never worn contact lenses. Subjects will be fit into PRECISION7® For Astigmatism contact lenses and will wear lenses for approximately 3 weeks. Subjects will return for vision and lens fit assessments and will complete surveys about their wear experience.

Background

Soft daily wear contact lenses are used by an estimated 40.9 million adults in the United States.[1] Contact lenses which are worn for daily wear are considered minimal risk by the FDA, and risks to wearers are minimized by proper lens care and hygiene. The subjects in this study are adults with astigmatism that have never worn contact lenses who will be fit into PRECISION7® For Astigmatism, a 1-week replacement reusable contact lens.

Key Endpoints:

- Subjective assessment of P7 experience with CLDEQ-8, Visual Analog Scale survey of lens wear symptoms, and questionnaire about quality of life/preference of lens modality experiences.

Study Time Points:

After responding to recruitment material, potential participants will respond to pre-screening questions to determine initial eligibility. Those eligible will be scheduled for a screening visit and will complete the informed consent process. Manifest refraction, Best Corrected Visual acuity, and an evaluation of the participant's ocular health will occur. The OSDI questionnaire will also be complete to assess is the participant has dry eye. The fit of PRECISION7® For Astigmatism lenses will be analyzed and optimized before dispensing a pair of lenses for 1 week of wear (-3 days). The participant will be trained on insertion/removal and contact lens hygiene.

Visit 2: PRECISION7® For Astigmatism follow up visit. Vision, lens fit and ocular health will be assessed. If lens fit and eye health are acceptable, PRECISION7® for Astigmatism Contact Lenses will be dispensed and a contact lens follow-up visit scheduled for 2 weeks (-3 days). If an additional study visit is required because the lens power or fit must be changed at this visit, new lenses will be dispensed/ordered and Visit 2 will be repeated after 1 week of wear with the optimized lenses. (Participants will be compensated for a repeat visit.)

Visit 3: The contact lens follow up visit will occur approximately 2 weeks (-3 days) following the initial fitting. Subjects will have visual acuity, an assessment of ocular health, and lens fit completed. Subjects will then complete surveys about their lens wear experience.

All surveys at visit 3 will be completed in REDCap.[2,3]

Surveys will include:

CLDEQ-8
VAS survey of comfort/dryness/vision
0-100 scale:
- Overall vision throughout the week
- Overall vision while on digital device
- Stability of vision at end of day
- Stability of vision throughout the week
- Overall comfort throughout the week
- Overall comfort throughout the day
- Overall comfort while on digital device

End of Study Wear Experience
- Convenience of 1 week replacement lens
- Would you purchase PRECISION7 for Astigmatism?
- How easy is it to apply the lenses to your eye?
- How easy is it to remove lenses?

Recruitment

Potential participants may see posters placed on bulletin boards locally, at The Ohio State University, or local eye care offices, student dorms, emails to students, faculty and staff at OSU, online or paper ads, or signs on the OSU buses. Facebook advertising through the CCTS will occur. A search of the electronic medical records of The Ohio State College of Optometry may be done to identify possible subjects who then may be contacted by email or phone with information about the study. Word of mouth referrals by study team members to OSU employees and friends may occur. Emails to alumni of the OSU College of Optometry may be sent for local doctors to notify eligible potential subjects about the study.

Inclusion:

1. Subjects must be new to contact lenses and have astigmatism of -0.75 or greater (within the parameters available for the P7fA lenses)
2. Subjects must have 20/20 or better best corrected visual acuity.

3. 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 PI)
4. Ability to give informed consent
5. Willing to spend time for the study. Subjects will be required to attend three study visits and wear contact lenses on days between study visits.
6. Willing and able to wear contact lenses for at least 8 hours per day for 5 days per week during the study as daily wear.
7. Currently not using eye lubricating drops and willing to not use during study.
8. Either gender and 18-40 years of age.
9. Any racial or ethnic origin

Exclusion Criteria:

1. Any active ocular inflammation or infection.
2. Has a systemic condition that in the opinion of the investigator may affect a study outcome variable.
3. Are presbyopic and require or habitually uses reading glasses for near work
4. Is using any systemic or topical medications that in the opinion of the investigator may affect a study outcome variable
5. History of refractive surgery
6. Meets the diagnosis of dry eye disease with OSDI screening score ≥13.
7. Known history of allergy or sensitivity to contact lens solutions and/or sodium fluorescein
8. Is pregnant or lactating or planning a pregnancy during enrollment in the study
9. Is participating in another clinical research study that includes invasive ocular tests
10. An inability to perform contact lens application and removal after instruction.

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 investigator 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 a study for people with dry eyes. Privacy is protected by limiting information related to study recruitment only, and no other personal or medical information that should be private to the patients. The PHI needed is only for the purposes of this study. It is highly unlikely, indeed extremely remote that the dry eye symptoms or signs are related to private or personal information that should or would be preferred to be kept confidential to the patients. Risk factors for dry eye rarely relate to matters or conditions that would be personal to the patient such as personal relationships, behaviors or diseases that one prefers to keep private and confidential.

Statistical Analysis

This pilot study is investigating the wear experience of individuals who have not previously worn contact lenses. Sixty potential participants will be screened in order to complete 40 participants. This monadic study will report outcomes with descriptive statistics, and as such, no power calculation is necessary. This size of this study will enroll enough subjects to have robust responses to preference surveys.

Data Management and Security

During the active stages of the study (recruitment to last 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 locked cabinet 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 a locked cabinet 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

Visit procedures present no greater risk than would be experienced during a routine eye exam or routine contact lens fitting. Learning to apply and remove contact lenses may cause temporary redness or irritation of the eyes. Transient (less than one minute) blurring of vision, or transient (less than one minute) mild stinging may occur when inserting contact lenses. Although rare, contact lens wear is associated eye infection, abrasion, and discomfort, which can all be minimized with proper hygiene and contact lens care, which will be taught to study participants.

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. 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. Analyzable data is, for example, that which is obtained for the entire measurement interval and provides a readable eye image. Data may not be analyzable if patient isn't able to stand or move freely to utilize the equipment, to name just two causes issues. These issues are usually revealed at the screening assessment visit. Subjects who cannot provide analyzable data will be dismissed for 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.

References

1. Cope JR, Collier SA, Rao MM, 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):865-870.
2. Harris PA, Taylor R, Minor BL, et al. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform.* 2019;95:103208.
3. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)-A metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform.* 2009;42(2):377-381.