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Evaluation of Wear Experience with Water Surface Toric Contact lenses on long lens-wear days

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Evaluation of Wear Experience with PRECISION1® Toric Contact lenses on long lens-wear days

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Purpose

The purpose of this study is to explore the performance of PRECISION1® Toric lenses on long days of lens wear.

Study Overview

This open-label study is of current soft contact lens wearers who wear their contact lenses for longer than a typical workday. Participants who regularly wear contact lenses for long days will be fit into PRECISION1® Toric contact lenses. Participants will be assessed after 1-2 weeks of wear with a follow up visit (Visit 2) to ensure a successful lens fit. Refitting will occur if necessary. After final completion of Visit 2, the five survey days will be determined. On 5 days between Visit 2 and Visit 3, the participant will respond to a survey sent to their smart phone to report the time they insert their lenses each morning. Each evening, the participant will be sent a survey for immediate response about their current comfort and vision with lens wear. The surveys will be sent at 10, 12, 14 and 16 hours of lens wear. Participants will return for a final follow-up visit including a VAS survey and the CLDEQ8 survey of their lens 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. Daily disposable contact lenses do not require daily cleaning and overnight storage, which lessens the required amount of time to care for contact lenses. In addition, daily disposable contact lenses are associated with less lens deposits, which decreases associated comfort issues in lens wearers, including decreasing the risk of triggering Giant papillary conjunctivitis (GPC) and/or ocular allergic responses in patients.[2] Additionally, daily disposable contact lens wearers are not likely to expose their lenses to water and tend to have better lens hygiene since these lenses do not require daily cleaning. This is reflected in a study which found less superficial punctate staining and symptoms of dryness when comparing daily disposable contact lens wear with planned replacement lenses.[3] The subjects in this study will be fit into PRECISION1 toric daily disposable contact lenses, which are less likely to be associated with the already minimal risks of daily contact lens wear. Because of these benefits of

daily disposable lenses, and the accompanying improvement in comfort, it is likely that these lenses will provide long lasting comfort and vision throughout the day. As many people wish to wear their contact lenses to work and then throughout the evening, it is of interest to know how a lens performs over the course of a day into evening.

Key Endpoints:

- Subjective assessment of comfort and vision at time points of extended contact lens wear (Scale of 1 -10) at evening time points on 5 days.
- Visual Analog Scale survey of lens wear symptoms (comfort, dryness, vision) at study end.

Study Time Points:

Visit 1 will be conducted to consent the subject and determine eligibility. Consenting will be conducted via phone call and REDCap and will occur before the subject arrives on site if possible. After consenting, the visit will begin with visual acuity and an evaluation of the subject's ocular health will occur to determine eligibility including positively responding to the question, "Do you currently wear contact lenses over a long day?" This will ensure that subjects are able and willing to participate in the study since long contact lens wear will be needed. Subjects will be asked their normal morning time for inserting lenses and evening time for lens removal. Eligible subjects can be habitual wearers of soft toric contact lenses and will be fit into PRECISION1®Toric Contact Lenses at this visit and will have a fit assessment and over-refraction completed in order to obtain the best fit and vision. Surveys of impressions of lenses will be completed. For any participant who is an existing PRECISION1® Toric wearer, the lenses will be evaluated and the prescription will be refined if necessary. Any existing PRECISION1® Toric wearer who does not require any changes in prescription at Visit 1 can immediately advance to Visit 2. Otherwise, all participants deemed eligible will be dispensed study lenses and Visit 2 will be scheduled.

Visit 2: Precision 1 Toric follow-up visit will occur approximately 1 week (±5 days) following Visit 1. Visual acuity and contact lenses fit assessment and over-refraction will be completed. If changes to the lens are necessary, those changes will be made and an additional follow up visit will be scheduled. Subjects will be asked their normal morning time for inserting lenses and evening time for lens removal. Subjects who are new to PRECISION1® Contact Lenses will be dispensed additional lenses to wear until Visit 3.

Five evening survey days: On the morning of each survey study day, the the participant will respond to a survey with the time when they inserted their contact lenses that day.. Participants will later be deployed a brief survey at 10, 12, 14 and 16 hours of lens wear that day via REDCap. The surveys will be deployed electronically on 5 days between Visit 2 and Visit 3 that are determined at the time of Visit 2. Every attempt will be made to complete the surveys on business days if possible.

Final visit: The contact lens follow up visit will occur approximately 1 week (±5 days) following the follow up visit. Subjects will have visual acuity, an assessment of ocular health. Subjects will then complete surveys about their lens wear experience.

Evening Surveys will include 1-10 forced choice grading of comfort and vision.

End of study surveys will include a lens experience survey, the CLDEQ-8 survey, and VAS scales assessing:

Overall Quality of vision
End of Day Quality of vision
Overall comfort
End of Day comfort
Overall dryness
End of Day dryness

Recruitment

Potential subjects may see posters placed on bulletin boards at The Ohio State University or local eye care offices, emails to students, faculty and staff at OSU, online or paper ads, or signs on the OSU buses. 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 criteria:

- Ages 18-40
- Subjects must be current soft toric contact lens wearers with longs days of lens wear within the parameters of P1 lenses available.
- Subjects must have 20/25 or better distance visual acuity with current lenses.
- Subjects should have had an eye exam in the past two years (self report).
- 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).
- Ability to give informed consent.
- Subjects must have a working smart phone or device and be willing to receive and respond to texts and or emails.
- Willing to spend time for the study. Subjects will be required to attend three study visits (with a possible fourth visit if needed), wear contact lenses on days between study visits, and must respond to communications on a smart phone or other electronic device on 5 weekdays between visits 2 and 3.
- Either gender.
- Any racial or ethnic origin.

Exclusion criteria:

- No current ocular inflammation or infection as assessed by the study investigator.
- Females who are currently pregnant or lactating or plan to become pregnant during the course of the study.

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 and Power Calculation

This small sample size was chosen for convenience as this study as enrollment for evening participation may be difficult.

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 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 an 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.

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. 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. Arita R, Mori N, Shirakawa R, et al. Meibum Color and Free Fatty Acid Composition in Patients With Meibomian Gland Dysfunction. *Invest Ophthalmol Vis Sci.* 2015;56(8):4403-4412.

2. Hickson-Curran S, Spyridon M, Hunt C, Young G. The use of daily disposable lenses in problematic reusable contact lens wearers. *Cont Lens Anterior Eye.* 2014;37(4):285-291.
3. Ichijima H, Karino S, Sakata H, Cavanagh HD. Improvement of Subjective Symptoms and Eye Complications When Changing From 2-Week Frequent Replacement to Daily Disposable Contact Lenses in a Subscriber Membership System. *Eye Contact Lens.* 2016;42(3):190-195.