Evaluation of Wear Experience with Daily Disposable Water Surface Contact lenses in habitual Comfilcon A contact lens wearers

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Purpose

The purpose of this study is to explore the wear experience of current Comfilcon A (Biofinity®) contact lens wearers after they have been fit into Verofilcon A (PRECISION1®) Contact Lenses.

Study Overview

This open-label study is of current Biofinity® (Cooper Vision, San Ramon, CA, USA) contact lens wearers who are satisfied with their lenses. Subjects will be refit into PRECISION1® contact lenses and will wear lenses for approximately 2 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. Daily disposable contact lenses do not require daily cleaning and overnight storage, which improves 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 are current satisfied wearers of 1 month planned replacement lenses (Biofinity®) and will be fit into PRECISION1 daily disposable contact lenses, which are less likely to be associated with the already minimal risks of daily contact lens wear.

Key Endpoints:

- Subjective assessment of P1 with CLDEQ-8

- Visual Analog Scale survey of lens wear symptoms (comfort, dryness, vision)
- Assessment via questionnaire about quality of life, preference, and lens modality experience

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. The participant will verify their current prescription with Biofinity lenses and answer questions about ocular health to further determine eligibility. Participants will also verify that they are happy with their current lenses. Upon reporting to the in-person portion of the visit, visual acuity and an evaluation of the subject's ocular health will occur. Biofinity® lenses will be evaluated and optimized before dispensing a new pair of lenses for approximately 1 week of wear.

Visit 2: Biofinity® contact lens follow up and Precision 1 fitting visit. Patients will verify that they are still satisfied with their current Biofinity® contact lenses in order to proceed and vision, lens fit and ocular health will be assessed. Subjects will then be fit with PRECISION1® Contact Lenses and will complete assessments of initial satisfaction, initial comfort, and initial vision using REDCap. Lenses will be dispensed and a contact lens follow-up visit will be scheduled.

Visit 3: The contact lens follow up visit will occur approximately 2 weeks (±3 days) following the PRECISION1 lens 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.

Surveys will be completed using REDCap and include:

- CLDEQ-8
- VAS survey of comfort/dryness/vision on a 0 to-100 scale:
    - Overall Quality of vision
    - End of Day Quality of vision
    - Overall comfort
    - End of Day comfort
    - Overall dryness
    - End of Day dryness
- Quality of life/preference, lens modality experience
- Convenience of daily disposable, preference for daily disposable, ease of use
- Satisfaction with P1

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:

- Subjects must be current Biofinity® spherical lens wearers.
- Subjects must have 20/25 or better distance visual acuity with current lenses.
- 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
- 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.
- Either gender
- Any racial or ethnic origin
- 18 to 40 years of age.

Exclusion criteria:

- No current ocular inflammation or infection as assessed by the study investigator
- Pregnant or lactating females

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 will be given provided time to read the consent form and offered the opportunity to ask questions. Participants will be 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 of 30 was chosen for convenience, as this study is not intending to prove superiority, but to study the acceptability of the study lens in previous successful Biofinity® wearers.

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. 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.

Timeline

IRB submission and approval →	Recruitment and Data collection →	Data processing and analysis →	Final report
6-8 weeks	Months 3-4	Month 5	Month 6

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.