Evaluation of Wear Experience with Dailies TOTAL1® Contact lenses for Astigmatism and Biofinity® toric contact lenses

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Evaluation of Wear Experience with Dailies TOTAL1® Contact lenses for Astigmatism and Biofinity® toric contact lenses

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Purpose

The purpose of this study is to explore the wear experience of current soft toric contact lens wearers after they have been fit into Dailies TOTAL1® Contact Lenses for Astigmatism and Biofinity Toric contact lenses.

Study Overview

This cross-over study compares the wear experience with Biofinity® toric contact lenses (Cooper Vision, San Ramon, CA, USA) to that of Dailies Total1® for Astigmatism contact lenses (Alcon, Fort Worth, TX, USA). Each participant will wear each of the lenses for approximately 1 month. Surveys will be completed of wear experience with each contact lens, and comparison surveys will be given at the end of the study.

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 wearers of soft contact lenses for astigmatism. They will be fit with rewearable lenses (Biofinity®) and daily disposable lenses (Dailies TOTAL1 for Astigmatism). Is it hypothesized that the daily disposable contact lenses, will have higher ratings for comfort based on the replacement schedule and the type of soft contact lens material.

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Key Endpoints:

- Subjective assessment of Biofinity Toric and Dailies TOTAL1 for astigmatism with CLDEQ-8
- Visual Analog Scale survey of lens wear symptoms (comfort, dryness, vision) with both lenses
- 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 soft contact lens prescription to ensure that their prescription falls in the prescription range available for both study lenses, and to make sure that the patient requires lenses for astigmatism in both eyes. The participant will answer questions about ocular health to further determine eligibility. Upon reporting to the in-person portion of the visit, visual acuity and an evaluation of the subject's ocular health will occur. Following a randomization table, either the Biofinity Toric or the Dailies TOTAL1 for Astigmatism will be fit at this visit. A survey of initial impression of the lens will be completed. Enough lenses will be dispensed to last 1 month (until the next visit).

Visit 2: The participant will wear the study lenses to Visit 2, and will complete a VAS survey and the CLDEQ-8 survey to assess their wear experience. Visual acuity and lens fit, including lens rotation, will be assessed. Participants will then be fit with the other study lens. After a successful fit, the participant will complete an initial impressions survey.

Visit 3: The participant will wear the study lenses to Visit 2, and will complete a VAS survey and the CLDEQ-8 survey to assess their wear experience. Visual acuity and lens fit, including lens rotation, will be assessed. Subjects will then complete surveys about their lens wear experience and preference between the two study lenses.

In the unlikely event that additional contact lenses are needed to properly optimize a contact lens fit, and additional follow-up visit may be scheduled after Visit 1 or Visit 2.

Surveys will include:

CLDEQ-8
VAS survey of comfort/dryness/vision
0-100 scale:
- Overall Quality of vision
- End of Day Quality of vision
- Overall comfort
- End of Day comfort
- Overall Satisfaction
- End of Day Satisfaction
- Overall dryness
- End of Day dryness

Quality of life/preference, lens modality experience

Convenience of daily disposable, preference for daily disposable, ease of use
Which lenses do you prefer based upon comfort?
Which lenses do you prefer based upon vision?
Which lenses do you prefer based on over-all performance?

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 or a data base/records at the two off-campus sites may be done to identify possible subjects who then may be contacted by email or phone with information about the study. A search of The OSU College of Optometry Research Database (2017H0032) will also be completed. 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 soft lens wearers in both eyes.
- Subjects must have 20/25 or better distance visual acuity with current lenses (entering acuity).
- 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 two study visits and wear contact lenses on days between study visits.
- Either gender
- Any racial or ethnic origin

Exclusion criteria:

- Participants cannot be pregnant or lactating.
- Participants cannot be current Biofinity Toric or Dailies TOTAL1 for Astigmatism wearers
- No current ocular inflammation or infection as assessed by the study investigator

Consent and Confidentiality

A team member trained in the consent process will provide the consent document for the potential subject to review in REDCap and will review the procedures with reference to the consent form by telephone if the potential participant has further 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 consent form in REDCap. 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 70 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 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 and a data binder 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 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. Any electronic data files that contain PHI, which is only needed for recruitment purposes, will be destroyed at the conclusion of the study. PHI will not be accessed or created after participants are recruited and collected data will be used for research purposes only. All data must be kept for a minimum of five years per the OSU Office of Research's data retention policy.

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 a participant is unable able to utilize the examination room equipment, for example. 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.