Evaluation of Wear Experience with Dailies TOTAL1 Multifocal® Contact lenses in Presbyopic Adults That Have Dropped out of Contact Lens Wear

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Purpose

The purpose of this study to explore the wear experience in Dailies TOTAL1 Multifocal® contact lenses (Alcon, Fort Worth, TX, USA) in presbyopic adults who have previously dropped out of contact lens wear.

Study Overview

This open-label study is of presbyopic adults that have dropped out of contact lens wear. Participants whose habitual vision correction device is spectacles will be fit into Dailies TOTAL1 Multifocal® contact lenses. Participants will be assessed after 1 week of wear at a follow-up visit (Visit 2) to confirm a successful contact lens fit. Refitting will occur if necessary. Participants will return for a final visit after 4 weeks of wear that will include an Overall Wear Experience Survey.

Background and Rationale

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 reduces 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]

Global contact lens prescribing for the first 20 years of this century show that the average age of contact lens wearers was 30.8 ± 13.9 years for males and 32.5 ± 14.3 years for females. Trend analysis for that

20 year period also revealed an increase in age of lens wearers and an incomplete provision of near contact lens corrections for contact lens wearing presbyopes.[4] The increasing age of lens wearers and the limited provision of corrections indicate an unmet need. In addition, many individuals discontinue contact lens wear once their eyes require presbyopic correction.[5] Reasons for this include dissatisfaction with comfort and/or vision[5].

Purpose

The purpose of this study is to evaluate the wear experience of people with presbyopia who previously dropped out of contact lens wear when fit with a Delefilcon A soft lens multifocal lens (Dailies TOTAL1 Multifocal, Alcon, Ft. Worth TX USA). We expect to enroll a relatively equal amount of former soft multifocal contact lens wearers who dropped out due to poor vision at distance or near and single vision wearers who dropped out due to poor near vision.

Key Endpoints

1. Visual Analog Scale survey of lens wear symptoms (comfort, dryness, vision) with contact lenses
2. Assessment of the participant's quality of life with the Dailies TOTAL1 Multifocal® contact lenses

Study Time Points

Visit 1 will occur to determine eligibility. The informed consent process will take place before the subject arrives on site via a phone call and REDCap e-consent. The participant will answer questions about their general and ocular health to further determine eligibility. Upon arriving, visual acuity and an assessment of ocular health will occur. Eligible subjects will complete a quality of life questionnaire via REDCap while wearing their progressive addition spectacles. A contact lens fitting will be completed to fit the participants in Dailies TOTAL1 Multifocal® contact lenses. The initial contact lens powers will be chosen following the manufacturer's fitting guide, and all subsequent changes will follow this guide, which is included in the appendix.

Visit 2 will occur 1 week (±3 days) after visit 1. Participants will return to the study site wearing the study provided contact lenses to complete distance and near visual acuity. Contact lens fit and movement will be assessed and the participants will be refit if necessary. If a refit is needed, an additional Visit 2 will be scheduled. This may be repeated until satisfactory fit is achieved.

Visit 3 will occur 1 month (±3 days) after the follow-up visit. Participants will return to the study site wearing the study provided contact lenses to complete distance and near visual acuity. Contact lens fit and ocular health will be assessed. The participants will complete the Overall Wear Experience Survey.

Surveys (which will be deployed in REDCap) will include:

Overall Wear Experience Survey
0-100 Scale:

- Quality of vision while watching television
- Quality of vision while using a smart phone
- Quality of vision while using the computer
- Quality of vision while dining out
- Quality of vision while playing sports
- Quality of vision while working out
- Quality of vision while reading a book/magazine/newspaper

- Overall quality of vision while wearing study lenses
- Overall comfort while wearing study lenses
- Overall satisfaction while wearing the study lenses

Exploratory endpoints

- How willing are you to continue wearing these contact lenses after the study?
- Would you recommend the study contact lenses to a friend?

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. A search of the electronic medical records of The Ohio State College of Optometry may be done to identify possible subjects who 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:

1. Ability to give informed consent.
2. Any gender.
3. Any racial or ethnic origin.
4. At least 38 years of age or older.
5. Willing to spend time for the study. Three visits are required to complete the study, and additional follow up visits could be scheduled if needed.
6. Subjects must have corrected distance visual acuity in both eyes equivalent to 20/25 or better at the screening visit.
7. Spectacle sphere power range between +6.00 to -10.00.
8. Subjects must have dropped out of contact lens wear due to vision or vision and discomfort.
9. 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)

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. Strabismus or binocular vision abnormalities that prevent completion of testing, at the discretion of the Investigator.
5. Demonstration or history of corneal ectasia or keratoconus.
6. 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 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 presbyopia. 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.

Statistical Analysis and Power Calculation

This monadic study will report outcomes with descriptive statistics, and as such, no power calculation is necessary. A previous multifocal study with 20 subjects was conducted recently at this site which successfully recruited and studied presbyopic patients who wore progressive addition spectacles and fit them with multifocal lenses.

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.

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. 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 a subject is not able to stand or move freely to utilize the equipment, to name a few possible causes. These issues are usually revealed at the screening assessment visit. Subjects who cannot provide analyzable data will 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.

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3. Ichijima, H.; Karino, S.; Sakata, H.; Cavanagh, H.D. 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*, 190-195, doi:10.1097/ICL.0000000000000167.
4. Morgan, P.B.; Efron, N. Global contact lens prescribing 2000-2020. *Clin Exp Optom* **2022**, *105*, 298-312, doi:10.1080/08164622.2022.2033604.
5. Rueff, E.M.; Varghese, R.J.; Brack, T.M.; Downard, D.E.; Bailey, M.D. A Survey of Presbyopic Contact Lens Wearers in a University Setting. *Optom Vis Sci* **2016**, *93*, 848-854, doi:10.1097/OPX.0000000000000881.