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Performance evaluation of delefilcon a water gradient daily disposable contact lenses in first-time contact lens wearers

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ABSTRACT

Purpose: To evaluate the tolerability of and subject and investigator satisfaction with delefilcon A (DAILIES TOTAL1®) daily disposable contact lenses in first-time contact lens wearers.

Methods: This European multicenter, open-label, single-arm, two-week trial enrolled first-time contact lens wearers and fitted them with delefilcon A contact lenses. Assessments were made at dispensing and at Weeks 1 and 2. Subject-reported outcomes included comfort, quality of vision, convenience, and intent to purchase, which were ranked by agreement responses. Investigator-reported outcomes included slit-lamp biomicroscopy findings and lens fit satisfaction.

Results: Ninety-two subjects were included in the per protocol dataset. Mean scores at Weeks 1 and 2 for subject-reported quality of vision and ocular comfort were significantly higher with delefilcon A contact lenses than with the subjects' habitual spectacles during the day, at the end of the day, and overall (all $p \leq 0.02$). Ninety-one percent of subjects reported that their study lenses were more comfortable than expected, 98% agreed that they were convenient to use, and 92% were interested in purchasing the lenses (all $p < 0.001$). Investigators reported that study lenses had an acceptable fit in at least 97% of subjects.

Conclusions: Practitioners can expect favorable outcomes when transitioning first-time contact lens wearers from spectacles to delefilcon A daily disposable contact lenses.

1. Introduction

Daily disposable contact lenses offer a number of advantages compared with conventional daily wear or frequent replacement (weekly/monthly) contact lenses. These include a reduced complication rate, such as those due to microbial contamination [1,2], and a reduced risk of lipid deposition, which has been linked to contact lens comfort [3,4]. Moreover, daily disposable lenses help address the issue of patient noncompliance with the lens replacement frequency associated with weekly/monthly lenses [5,6], as well as improving patient convenience, in that daily disposable lenses do not require cleaning, disinfecting, and storage every night.

First introduced in the mid-1990s, daily disposable contact lenses were initially made of conventional hydrophilic hydrogel materials with relatively low-oxygen transmissibility (Dk/t of 31×10^{-9} barrer/cm) [7] and low tensile modulus [3]. Although the hydrophilicity and low tensile modulus produce flexible and relatively comfortable lenses with good wettability that drape easily over the cornea, the associated low tensile and tear strength reduces durability and may make them more difficult to handle [3,8,9]. Oxygen transmissibility facilitates a number of biological processes, including inhibition of bacterial adhesion [10,11] and maintenance of corneal homeostasis [10]. The level of oxygen transmissibility with traditional hydrophilic materials is limited due to the relatively high water content of those lenses. Thus, although hydrophilic hydrogels are good for lens fit, comfort and wettability, they may be difficult to handle and allow limited oxygen transmission.

The introduction of silicone hydrogel lenses, which offer high oxygen transmissibility, therefore, represents a technological advance in daily disposable contact lenses. Compared with conventional hydrogel lenses, silicone hydrogel lenses have higher Dk/t levels [7] and a higher tensile modulus [3]. Higher Dk/t levels increase oxygen transmissibility, which facilitates the maintenance of corneal metabolism [7,10,12], and a higher tensile modulus makes the lenses easier to handle and less vulnerable to damage than conventional hydrogel lenses [3]. However, a high tensile modulus also makes lenses stiffer, which can lead to more unacceptable fittings [13]. The hydrophobic nature of silicone may also lead to poor wettability and surface lubricity. This, in turn, potentially increases the lens surface coefficient of

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friction, which may contribute to discomfort with silicone hydrogel lenses [3,4,14–16].

Delefilcon A daily disposable water gradient contact lenses (DAILIES TOTAL1®; Alcon Laboratories, Inc., Fort Worth, Texas, USA) are a unique type of lens, with characteristics of both conventional hydrogel and silicone hydrogel lenses. These water gradient lenses have a silicone hydrogel core, providing high oxygen transmissibility, and a high tensile modulus, promoting ease of handling. However, unlike silicone hydrogel lenses, they have a water gradient, transitioning from a low water content (33%) at the silicone hydrogel core to a high water content (> 80%) at the outermost hydrophilic gel layer, providing a lubricious surface [17] with a low surface compression modulus [18] and excellent comfort [19].

The aim of our clinical study was to evaluate subject tolerability and subject and investigator satisfaction with delefilcon A water gradient daily disposable contact lenses when dispensed to first-time contact lens wearers.

2. Methods

2.1. Subjects and study design

This was a multicenter, open-label, single-arm, two-week study of first-time contact lens wearers who were fitted with delefilcon A water gradient daily disposable contact lenses.

Eight investigators recruited subjects from eight private practices in Germany, Spain, Norway, Sweden, and Denmark. All eligible subjects were aged 14–44 years and used eyeglasses for vision correction, with a prescription between −0.5 diopters (D) and −6.0 D, with cylinder ≤0.75 D in both eyes and no ADD power correction. Subjects must have had no previous contact lens wearing experience nor had previously attempted to wear contact lenses, although they could have attended a contact lens fitting in the past without being dispensed lenses. Subjects had to have answered “very interested” or “quite interested” in response to a screening question regarding their interest in wearing contact lenses, and they had to be willing to wear the contact lenses for at least eight hours per day for at least five days per week. Subjects were required to achieve a visual acuity of at least 20/25 Snellen in each eye with the study lenses. They also had to be willing to discontinue any mechanical eyelid therapy or eyelid scrubs within 14 days of enrollment and for the duration of the study.

Subjects were excluded from the study if they had any systemic or ocular disease or disorder (refractive disorder and dry eye were permitted), complicating factors, or structural abnormality that would negatively affect the conduct or outcome of the study. Other exclusion criteria included a history of ocular surgery/trauma within six months of enrollment, use of any topical or systemic antibiotic or corticosteroid, use of any immunomodulatory medication, pregnancy, or lactation.

At the screening/baseline visit, subjects were assessed for eligibility. The dispensing visit was scheduled within one month of the screening/baseline visit and could have occurred on the same day. At the dispensing visit, subjects received a two-week supply of delefilcon A lenses and completed a questionnaire regarding their initial ocular comfort and quality of vision with the contact lenses, using a scale of 1 (poor) to 10 (excellent). Subjects received training on the insertion and removal of the lenses, and training times for initial insertion and removal were recorded. Investigators performed slit-lamp biomicroscopy and evaluated lens fit. Subjects were instructed that the lenses were intended for daily disposable use and should be discarded after wearing each day and new lenses inserted the following day.

Subjects returned for visits at one week (± three days) and two weeks (± three days) after the dispensing visit. Subjects completed a paper questionnaire at both visits, including questions on contact lens comfort and quality of vision, using a scale of 1 (poor) to 10 (excellent), and collecting lens wearing time. At the two-week visit, enrolled subjects evaluated lens performance by completing a paper questionnaire that asked them to rate their agreement to statements, with responses varying from strongly agree to strongly disagree. Investigators performed slit-lamp biomicroscopy and evaluated lens fit at both the one-week and two-week visits. Lens fit was evaluated as a numerical score from 1 (not at all satisfied) to 10 (very satisfied), based on relevant observations, including centration, adequate movement, and complete corneal coverage.

The protocol was approved by Institutional Review Boards of all participating institutions, and the study was performed in compliance with the ethical principles of the Declaration of Helsinki and Good Clinical Practice. All participating subjects provided written informed consent. This study was registered with ClinicalTrials.gov (NCT01494545).

2.2. Objectives and outcomes

The primary objective was to evaluate delefilcon A contact lenses in first-time contact lens wearers. The assessments included subject- and investigator-reported outcomes. Subject-reported outcomes were quality of vision and contact lens comfort, convenience, and satisfaction, including average wearing time, average comfortable wearing time, ease of insertion and removal, vision satisfaction, intent to purchase, and comparison with eyeglasses. The investigator-reported outcomes were lens fit satisfaction, duration of overall training time, and ease of fit.

Related and unrelated adverse events (AEs), encoded using the Medical Dictionary for Regulatory Activities system, were recorded, monitored, and evaluated throughout the study. Possible AEs evaluated by slit-lamp biomicroscopy included corneal epithelial edema, stromal edema, corneal staining with fluorescein, conjunctival staining with fluorescein, limbal redness, bulbar redness, tarsal abnormalities, and other abnormal ocular findings.

2.3. Statistical methods

The safety population consisted of all subjects who were dispensed study contact lenses; factors evaluated in this population included demographic characteristics, AEs, and slit-lamp biomicroscopy results. The per-protocol (PP) population consisted of all subjects who were dispensed contact lenses and did not have a major protocol violation. Due to the potentially high drop-out rate in this trial of first-time contact lens wearers, a sample size of 100 subjects was proposed to achieve the goal of 80 evaluable subjects, providing an 80% power to detect a difference of 16% from the null hypothesis between subjects agreeing and disagreeing with the Likert-style subjective statements regarding vision and comfort. The null hypothesis stated that the percentage of subjects agreeing and disagreeing with the Likert-style statements would be the same (i.e., 50% each).

The subjective agreement questionnaire responses, overall satisfaction, purchase interest, ease of fit, and overall lens fit were expressed as frequencies and percentages. The comfort and quality of vision of the study lenses and the overall subjective satisfaction level and purchase intent were summarized using descriptive statistics. A one-sample Wilcoxon Signed Rank test was used to compare the median score of the sample (with 2 = strongly agree, 1 = agree, −2 = strongly disagree and −1 = disagree) with a median score of 0 (which represents a neutral response or no preference). If the median of the sample is greater than 0, it is concluded that significantly more subjects agreed with the statement. Comfort and quality of vision (rated on a quantitative scale) were compared with the subject’s baseline value with spectacles using a mixed model for repeated measures. Comfort and quality of vision upon insertion after two weeks of wear were compared with the values recorded at the dispensing visit. *P*-values were calculated for comparisons of the one-week and two-week visits with baseline. Descriptive statistics were calculated for all outcomes. A two-sided