

Safety and Efficacy of a New Water Gradient Biomimetic Monthly Replacement Spherical Contact Lens Material (Lehfilcon A)

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Purpose: The objective of this study was to evaluate the safety and performance of the investigational lens, lehfilcon A, when worn in a daily wear modality and replaced monthly as compared to the commercially available comfilcon A contact lens.

Methods: This was a multicenter, prospective, controlled, double-masked, randomized, parallel-group clinical study with bilateral lens wear for 3 months. In all, 115 subjects completed the study (77 with test lehfilcon A and 38 with control comfilcon A contact lenses). Distance visual acuity (VA) was assessed using Snellen VA. Lens performance was assessed by examining lens fit/movement, centration, front surface wettability and front/back surface deposits using slit-lamp biomicroscopy.

Results: At the 3-month follow-up visit, all eyes had a distance VA of 20/20 or better. Further, lens fit/movement was assessed as optimal in 92.9% of the eyes with lehfilcon A and 89.2% with comfilcon A. There were no ratings of unacceptably tight or loose fits for either contact lens material. Lens centration was assessed as optimal in 98.7% of eyes with lehfilcon A and 94.6% with comfilcon A. For front and back surface deposits, both materials showed minimal lens surface deposits. Front surface wettability was assessed as grade 0 or 1 for most of the study lenses in both lens groups across all attended study visits. There were no ocular adverse events related to the study lenses.

Conclusion: Overall, lehfilcon A showed excellent VA, optimal lens fitting characteristics, a clean surface, high wettability, and low risk for adverse events after 3 months of lens wear.

Keywords: biomimetic, comfilcon A, lehfilcon A, visual acuity, water gradient, contact lens

Introduction

Contact lens wearers and their prescribing eye care practitioner today have many different contact lens materials, wear schedules, and replacement plans to choose from; however, no single lens, wear modality, or replacement schedule is suitable for all individuals. Survey results from the United States have shown that 39% to 50% of the wearers use daily disposable lenses, whereas 32% to 36% wear monthly reusable lenses.¹ Monthly replacement lenses may be preferred by some people due to cost considerations and concerns about the potential ecological consequences of daily lens disposal.² It has been shown that people fitted with monthly reusable lenses are more compliant with replacement schedules than those fitted with 2-week reusable lenses.^{3–5}

Recent advances in the technology for reusable daily wear contact lenses generally have been limited compared with those for daily disposable contact lenses.⁶ The most recent technological development in daily disposable silicone hydrogel contact lenses has been the development of “water gradient” delefilcon A lenses. These lenses have low water content in the core and then transition to higher water content (approaching 100%) at the surface, creating a hydrophilic layer aimed at producing superior on-eye performance in terms of comfort.^{7–10} Delefilcon A lenses have been shown to be comfortable and convenient to use.^{11,12} Recently, 2-methacryloyloxyethyl phosphorylcholine (MPC)—a substance designed using a biomimetic approach to match the structure of phospholipids on cellular membrane surface and which

has many properties that make it highly suitable for incorporation into a monthly replacement contact lens^{13,14}—has been included in the development of a new lehfilcon A monthly replacement daily wear water gradient contact lens. This substance was designed to have multiple properties with the potential to enhance the on-eye performance of contact lenses. These properties emerge from extreme hydrophilicity, electrical neutrality and a unique structure with hydrophilic phosphorylcholine groups in the side chain which decrease the surface tension of water.^{13–17} Further, MPC mimics the surface of the cornea with polymer nanofibers, similar to the gel-like layer of protection provided by the corneal glycocalyx and microvilli. Addition of MPC results in a lens surface that selectively attracts smaller water molecules while deflecting larger bacteria and lipids.¹⁴ Thus, inclusion of MPC in lehfilcon A contact lenses helps to provide a lubricious surface that has fewer deposits, helps resist bacterial adhesion, and is durable to last 30 days.^{14,15,18–24}

The purpose of the present study was to describe the clinical performance of lehfilcon A contact lenses with a daily wear monthly replacement schedule. This study was a registration study and thus the study design, endpoints, sample size, and descriptive analysis in this study adhered to ISO 11980:2012 and the US FDA 510(k) guidance document for daily wear contact lenses.

Materials and Methods

This was a prospective, randomized, controlled, double-masked, parallel-group, daily wear clinical trial (ClinicalTrials.gov number: NCT04178720; the trial started on January 28, 2020, and was completed on June 10, 2020). The study design, endpoints, and descriptive analysis in this registration study adhered to ISO 11980:2012 and the US FDA 510(k) guidance document for daily wear contact lenses. Eligible subjects requiring vision correction were randomized in a 2:1 ratio to wear in both eyes either lehfilcon A/test or comfilcon A/control contact lenses. Sample size is based upon ISO clinical standard and FDA 510(k) requirements with the recommendations of at least 50 subjects in the test group, in a 2:1 test-to-control ratio. Subjects and study personnel conducting evaluations were masked to treatment. There were 6 scheduled study visits: screening/baseline/dispense day 1, week 1 follow-up, week 2 follow-up, month 1 follow-up, month 2 follow-up, and month 3 follow-up/exit.

Ethical Considerations

The study was conducted in accordance with the ethical principles contained within the Declaration of Helsinki, and in compliance with the ICH E6 Good Clinical Practice Guideline, ISO 14155:2011, and US Food & Drug Administration Code of Federal Regulations Title 21. Before initiation of study-related procedures, the protocol and all amendments, the informed consent form, and any other written information given to subjects were approved by an institutional review board/independent ethics committee. The ethics committee included Sterling IRB, an independent institutional review board. Voluntary informed consent was obtained from every subject prior to the initiation of any study-specific procedures.

Contact Lenses

The contact lenses evaluated were lehfilcon A, an investigational new water gradient monthly replacement silicone hydrogel lens, and commercially available comfilcon A (Table 1).

Table 1 Characteristics of Contact Lenses

Lens Polymer (Brand)	Lehfilcon A (TOTAL30® Contact Lenses)	Comfilcon A (Biofinity® Contact Lenses)
Core water content, %	55	48
Base curve, mm	8.4	8.6
Diameter, mm	14.2	14.0
Power range, D	−1.00 to −6.00 (0.25 D steps)	−1.00 to −6.00 (0.25 D steps)

Subjects

Potential subjects were aged ≥ 18 years, with non-diseased eyes and manifest cylinder ≤ 0.75 D in each eye, were frequent replacement daily wear soft contact lens wearers, had ≥ 3 months of soft contact lens wearing experience, wore their habitual lenses ≥ 5 days/week and ≥ 8 hours/day, and required contact lens spherical correction from -1.00 D to -6.00 D, with a best corrected visual acuity (VA) of 20/25 or better in each eye. Potential subjects were excluded if they were wearing habitual contact lenses in an extended wear modality (routinely sleeping in lenses for ≥ 1 night/week) over the last 3 months prior to enrollment, monovision contact lens wearers, or habitually wearing comfilcon A contact lenses.

Lens Wear

Subjects were instructed to wear the study lenses during waking hours for ≥ 8 hours/day and ≥ 5 days/week. The total duration of study lens exposure was 3 months. Lenses were to be removed at the end of each day for cleaning, disinfection, and storage with CLEAR CARE® Cleaning & Disinfecting Solution (Alcon Vision LLC, Fort Worth, TX) prior to reinsertion the next day. Subjects were to replace the assigned study lenses with a fresh pair each month. Subjects were instructed to wear their study lenses for at least 4 hours prior to each follow-up visit.

Endpoints

The primary effectiveness endpoint was distance VA with study lenses collected by the Snellen method for each eye. Additional exploratory endpoints included lens fit/movement characteristics, lens surface characteristics, and lens wear time. A slit-lamp examination was performed at all study visits for lens fit/centration, lens surface evaluation, and safety. The contact lens characteristics were assessed with the lens on-eye and utilizing the biomicroscope with low magnification and white light with the scales provided per ISO 11980:2012. Safety endpoints included biomicroscopy and adverse events (AEs).

Assessments

Visual Acuity

Snellen distance VA assessments were performed using conventional methods.

Lens Fit/Movement

Lens fit/movement was evaluated immediately after blinking with the eye in the primary position and following digitally applied push-up of the lower lid margin. Lens fit/movement was assessed as follows: -2 , unacceptably tight (reduced movement, unacceptable fit); -1 , acceptably tight (reduced movement, acceptable fit); 0 , optimal fit/movement; $+1$, acceptably loose (excessive movement, acceptable fit); or $+2$, unacceptably loose (excessive movement, unacceptable fit).

Lens Position/Centration

Lens position and centration were evaluated with the eye in the primary position (relaxed, looking straight ahead) and assessed as follows: 0 , optimal lens centration; 1 , acceptable decentration; or 2 , unacceptable decentration.

Contact Lens Surface Characteristics

Front surface wettability was recorded according to the following scale: 0 , smooth uniformly reflecting surface; 1 , coarse hazy surface that resolved momentarily with each blink and became exacerbated with staring; 2 , one stable dry (nonwetting) area of some magnitude; 3 , >1 stable dry area of some magnitude; and 4 , nonwetable lens surface. Front surface deposits were assessed according to the following scale: 0 , absent clean surface; 1 , very slight, only visible after tear film drying; 2 , slight visible deposits easily removable; 3 , moderate deposits adherent and not removable; and 4 , severe nonremovable deposits and comfort affected. Back surface deposits were recorded according to the following scale: 0 , absent (clean surface); 1 , very slight (≤ 3 spots of moving particles); 2 , slight (≤ 10 spots of moving particles); 3 , moderate (≤ 3 nonmoving deposits adherent to lens); or 4 , severe (≥ 4 deposits adherent to the lens or corneal indentation).

Study Lens Wear Time

At each post-baseline visit, subjects provided the approximate times of lens insertion and removal for each day. Subjects completed a daily diary indicating the total number of days the lenses were worn each month.

Safety

Safety was evaluated by recording ocular and nonocular AEs and biomicroscopic findings, all of which were collected at each study visit. Biomicroscopy findings included the following assessments: limbal hyperemia, bulbar hyperemia, corneal staining, conjunctival staining, palpebral conjunctival observations, corneal epithelial edema, corneal stromal edema, corneal vascularization, conjunctival compression/indentation, chemosis, corneal infiltrates, and other findings. The following scale was used to grade severity in accordance with the ISO11980:2012 scales: 0 = none, 1 = trace, 2 = mild, 3 = moderate, 4 = severe.

Data Analysis

Descriptive summary statistics were provided at each visit when applicable, using number and percentage for categorical variables; number of observations, mean, standard deviation, median; and range for continuous variables.

Results

Subjects

In all, 119 subjects (238 eyes) were enrolled (signed consent) in the study and 1 subject failed screening due to the exclusion criteria. A total of 118 subjects (236 eyes) were randomized and dispensed study lenses; 115 subjects completed the study and 3 discontinued early; 2 subjects from the comfilcon A group withdrew and 1 from the lehfilcon A group as a result of COVID-19-related circumstances. This study was conducted during the national health emergency response to the COVID-19 outbreak in March 2020. Study enrollment was completed at the time of the national emergency declaration and although most sites continued to see study subjects in-person in the study clinic, the COVID-19 emergency did impact the conduct of the study depending on the sites' unique features and local governances. Provisional contingency measures were implemented to ensure the safety of trial subjects and the integrity of the study conduct. Month 2 visits were the most impacted by COVID-19 and the implemented contingency measures, which can be seen in the data where there is a temporary decrease in available subject data for both lehfilcon A and comfilcon A. Subjects had an overall mean age of 33.9 years, with 74.6% women and 25.4% men. Subjects were generally white and not of Hispanic or Latino ethnicity (Table 2).

Table 2 Baseline Subject Characteristics

	Lehfilcon A (n=78)	Comfilcon A (n=40)
Age, years		
Mean (SD)	34.4 (7.6)	32.9 (7.3)
Median (range)	37 (21–52)	34 (18–50)
Sex, n (%)		
Men	21 (26.9)	9 (22.5)
Women	57 (73.1)	31 (77.5)
Race, n (%)		
White	65 (83.3)	36 (90.0)
Black or African-American	12 (15.4)	2 (5.0)
American Indian or Alaska Native	0 (0.0)	0 (0.0)
Asian	0 (0.0)	0 (0.0)
Native Hawaiian or other Pacific Islander	0 (0.0)	1 (2.5)
Other	0 (0.0)	1 (2.5)
Multiracial	1 (1.3)	0 (0.0)

(Continued)

Table 2 (Continued).

	Lehfilcon A (n=78)	Comfilcon A (n=40)
Ethnicity, n (%)		
Hispanic or Latino	4 (5.1)	2 (5.0)
Not Hispanic or Latino	74 (94.9)	38 (95.0)
Habitual Contact Lenses	Lehfilcon A (n=156 eyes)	Comfilcon A (n=80 eyes)
Visual acuity, n (%)		
20/15	72 (46.2)	41 (51.3)
20/20	82 (52.6)	35 (43.8)
20/25	2 (1.3)	3 (3.8)
20/30	0 (0.0)	1 (1.3)
Sphere, D		
Mean (SD)	-3.21 (1.23)	-3.14 (1.26)
Median (range)	-3.25 (-6.50 to -0.75)	-3.00 (-6.00 to -1.00)

Abbreviation: SD, standard deviation.

Effectiveness

Visual Acuity

All eyes had distance Snellen VA with study lenses of 20/30 or better at every visit, except 1 eye from the lehfilcon A group (Figure 1). Results at 3 months also showed that 99.4% of the eyes in the lehfilcon A and 100% in the comfilcon A group had VA 20/20 or better. For 1 eye in the lehfilcon A group, distance VA was worse than 20/30 (20/200) at month 3. It was discovered that the subject was wearing two lenses in the same eye. Once the contact lenses were removed and best corrected VA with manifest refraction was assessed, a distance VA of 20/20 was achieved. At each study visit, $\geq 98.6\%$ of the eyes wearing comfilcon A and $\geq 98.4\%$ wearing lehfilcon A lenses had distance VA with the study lenses of 20/20 or better.

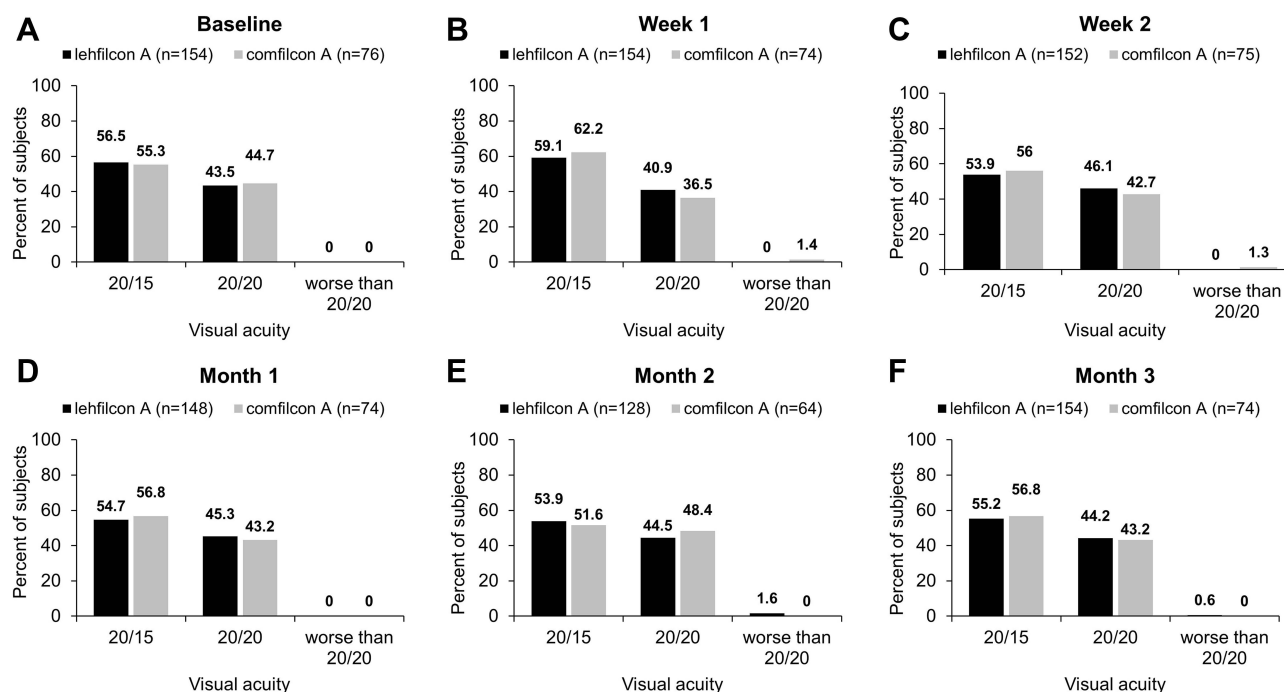


Figure 1 Snellen visual acuity at baseline (A) and at week 1 (B), week 2 (C), month 1 (D), month 2 (E), and month 3 (F).

Lens Fit/Movement and Position

At month 3, 89.2% of the eyes with comfilcon A and 92.9% with lehfilcon A lenses were assessed as having optimal fit/movement (Table 3). There were no reports of unacceptably tight or unacceptably loose-fitting lenses at any visit. Lens position at month 3 was assessed as having optimal centration for 94.6% of the eyes with comfilcon A and 98.7% with lehfilcon A lenses. There were no reports of unacceptable decentration at any visit. Despite the two study lens brands having different base curves and diameters, both study lenses fit well in the diverse range of subject corneal curvatures as randomized.

Lens Deposits/Wettability

For most worn lenses, front and back surface deposits were assessed as absent (grade 0) or very slight (grade 1) in both groups and across all study visits. At month 3, the respective percentages of lenses assessed as either grade 1 or 0 for front and back surface deposits were 95.9% and 100% with comfilcon A and 98.7% and 100% with lehfilcon A (Table 4). Front surface wettability was assessed as grade 0 or 1 for most of the study lenses in both lens groups across all attended study visits (Table 4). At month 3, 86.5% of comfilcon A and 82.5% of lehfilcon A lenses were assessed as grade 0, and each lens group had 1 lens assessed as grade 2.

Lens Wear Time

For subjects who completed the 3-month trial, mean daily wear time was 14.3 hours for the comfilcon A and 14.6 hours for the lehfilcon A group. Mean number of days the lenses were worn ranged from 28.0 to 32.9 for the comfilcon A and 28.8 to 33.8 for the lehfilcon A group.

Safety

There were no deaths or nonfatal serious AEs, adverse device effects, or discontinuations due to AEs. There were 8 nonserious ocular AEs reported by 6 subjects, all in the lehfilcon A group (hordeolum, OD; eye irritation, OU; eye irritation OD; conjunctival hyperemia, OU; conjunctival edema, OS; ocular discomfort, OD). In 6 out of the 8 nonserious ocular AEs, no action was taken, and no treatment was required. For conjunctival edema, the use of SYSTANE® eye drops prior to lens insertion was recommended. For ocular discomfort, the study device was temporarily discontinued. All of these AEs were mild in severity, resolved, and judged as unrelated to the study lens by the investigator. There were 4 nonocular AEs, all in 3 subjects in the comfilcon A group (bronchitis, influenza, and nasopharyngitis). All of these AEs were mild or moderate in severity, resolved, and judged as unrelated to the study lens.

No biomicroscopic findings of grade >2 (mild) were reported for subjects in either lens group. There were no reports of corneal edema or infiltrates in the study. Overall, there were no clinically relevant differences in biomicroscopic findings between the lens groups.

Discussion

The results of this registration clinical study indicate that the new lehfilcon A contact lens provided good VA over 3 months of follow-up, and that it also performed well with respect to fit/movement, position, and surface characteristics. There were no safety concerns for the lehfilcon A lens based on assessment of AEs, adverse device reactions, or biomicroscopy. No formal hypotheses were formulated for the primary effectiveness endpoint of VA; hence, no inferential testing was performed. Descriptive statistics were provided on the Snellen categories. Similarly, all supportive endpoints were summarized descriptively according to their measurement scale. There were no pre-specified safety hypotheses in this study. The focus of the safety analysis was a comprehensive descriptive assessment of occurrence of AEs and biomicroscopy findings. Although there are multiple in vitro publications highlighting the features and structure of the lehfilcon A contact lens material, this is the first clinical trial manuscript, as this is a brand-new contact lens material. Despite limitations of no inferential testing and limited subject numbers, this pivotal study did provide evidence that the lehfilcon A contact lens demonstrates good safety and efficacy.

Contact lens fit is an important consideration for both ocular health and avoiding wearer dropout.^{25,26} Poor fitting soft lenses have negative effects on ocular physiology that may be reflected by increased fluorescein staining, and higher

Table 3 Fit and Movement Assessments

	Baseline		Week 1		Week 2		Month 1		Month 2		Month 3	
	leh A (n=154) %	com A (n=76) %	leh A (n=154) %	com A (n=74) %	leh A (n=152) %	com A (n=75) %	leh A (n=148) %	com A (n=74) %	leh A (n=126) %	com A (n=64) %	leh A (n=154) %	com A (n=74) %
Lens Movement												
Unacceptably tight	0	0	0	0	0	0	0	0	0	0	0	0
Acceptably tight	4.5	5.3	9.1	8.1	2.0	5.3	7.4	5.4	9.5	4.7	7.1	10.8
Optimal fit/ movement	90.3	93.4	87.0	89.2	96.1	93.3	91.2	94.6	85.7	95.3	92.9	89.2
Acceptably loose	5.2	1.3	3.9	2.7	2.0	1.3	1.4	0	4.8	0	0	0
Unacceptably loose	0	0	0	0	0	0	0	0	0	0	0	0
Lens Position												
Optimal lens centration	97.4	97.3	98.1	97.3	97.4	94.7	97.3	94.6	96.8	98.4	98.7	94.6
Acceptable decentration	2.6	2.7	1.9	2.7	2.6	5.3	2.7	5.4	3.2	1.6	1.3	5.4
Unacceptable decentration	0	0	0	0	0	0	0	0	0	0	0	0

Abbreviations: com A, comfilcon A; leh A, lehfilcon A.

Table 4 Lens Surface Assessments

	Baseline		Week 1		Week 2		Month 1		Month 2		Month 3	
	leh A (n=154) %	com A (n=76) %	leh A (n=154) %	com A (n=74) %	leh A (n=152) %	com A (n=75) %	leh A (n=148) %	com A (n=74) %	leh A (n=126) %	com A (n=64) %	leh A (n=154) %	com A (n=74) %
Front Surface Wettability												
Grade 0 or 1	100	100	100	100	99.3	98.6	98.6	100	96	95.3	99.4	98.6
Grade ≥2	0	0	0	0	0.7	1.3	1.4	0	4	4.7	0.6	1.4
Front Surface Deposits												
Grade 0 or 1	100	100	98.7	98.6	97.3	98.7	99.3	100	95.2	100	98.7%	95.9%
Grade ≥2	0	0	1.3	1.4	2.7	1.3	0.7	0	4.8	0	1.2	4.1
Back Surface Deposits												
Grade 0 or 1	100	100	100	100	99.3	100	100	100	100	98.4	100%	100%
Grade ≥2	0	0	0	0	0.7	0	0	0	0	1.6	0	0

Notes: Front surface wettability graded on a scale of 0 (a smooth uniformly reflecting surface) to 4 (nonwetttable lens surface). Front surface deposits and back surface deposits graded on a scale of 0 (absent) to 4 (severe).

Abbreviations: com A, comfilcon A; leh A, lehfilcon A.

levels of bulbar and limbal hyperemia.^{25,27} Results from two surveys indicated that poor fit is a frequent reason for discontinuation of contact lens wear.^{28,29}

Contact lenses and other biomaterials incorporating MPC have been evaluated in multiple nonclinical studies that demonstrated high resistance to protein absorption and bacterial adhesion, a low coefficient of friction and high wettability, and high oxygen permeability.^{14,21,30,31} Additional in vitro studies focusing on lehfilcon A contact lenses demonstrated properties that contribute to enhanced performance and compatibility with a monthly replacement schedule, including high hydrophilicity and lubricity, and a lower coefficient of friction compared with senofilcon C and comfilcon A lenses.^{22,23} The aqueous gel layers of lehfilcon A contact lenses are protective against friction,²² which can result in an increase in inflammatory biomarkers and lead to cell damage and death.^{32–34}

In vitro data also demonstrate that lehfilcon A contact lenses have similar wettability after 30 days of daily wear compared with lenses evaluated immediately after removal from packaging.²² Nanoindentation testing of lehfilcon A indicated high degrees of softness and durability after 30 days of daily wear. Comparison with five other commercial lenses indicated that lehfilcon A was ~5 times softer than all other lenses tested.³⁵ Class 1 ultraviolet blocking with lehfilcon A contact lenses is comparable to that achieved with existing class 1 ultraviolet-blocking contact lenses (ie, senofilcon A and C). In addition, lehfilcon A lenses provide a level of high-energy visible light filtration similar to that for spectacle lenses marketed as providing this attribute.³⁶ The water gradient lehfilcon A contact lens has high in vitro oxygen transmissibility³⁷; it should be noted that addition of MPC does not compromise this property, which is important for corneal health.³⁸ MPC shows high oxygen permeability due to high water content, similar to the case of corneal surface.³⁹

Protein adsorption is also an important consideration for a contact lens with a monthly replacement schedule, and the MPC polymer can effectively prevent protein adsorption at the surface.²¹ In vitro adhesion of *microorganisms* *Escherichia coli* to lehfilcon A lenses is lower than for samfilcon A and comfilcon A lenses, and this is also the case for adherence of *Pseudomonas aeruginosa* to lehfilcon A vs samfilcon A, senofilcon C, and comfilcon A lenses.¹⁴ These differences are potentially important for maintenance of ocular health, particularly for contact lenses with a monthly replacement schedule.

Use of contact lenses with a monthly replacement schedule may be limited by discomfort and discontinuation in a high percentage of patients.⁴⁰ Results from several studies have indicated that use of daily disposable contact lenses provides greater comfort, decreased signs of eye irritation, and fewer complaints for tired eyes, irritated eyes, blurred vision, redness, discomfort, deposits, and dryness vs use of lenses with longer replacement schedules.^{41–43} Results from one comparison, however, indicated no significant differences in signs and patient complaints between monthly and daily disposable lenses.⁴⁴ Results from a 2-year study of 242 subjects (naïve contact lens wearers) wearing lotrafilcon B silicone hydrogel contact lenses with a monthly replacement schedule indicated a dropout rate of 29.2%, with 10.8% of subjects discontinuing in the first month,⁴⁵ and it has been repeatedly shown that the most common reason for contact lens discontinuation is discomfort.^{29,40,44,45,47} Other reasons cited for contact lens discontinuation include poor vision and problems with insertion or handling.^{28,46,47} All of these results indicate there is a significant unmet need for advancement in the technology of contact lens materials with a monthly replacement schedule. The on-eye and in vitro characteristics of the lehfilcon A lens, including excellent fit/movement and vision, high lubricity, oxygen transmissibility, low risk for adherence of proteins and ocular microorganisms, and protection against transmission of high-energy light, suggest that it may fulfill these needs.

Conclusions

Overall, lehfilcon A, a new biomimetic water gradient monthly replacement daily wear silicone hydrogel contact lens, showed excellent VA, optimal lens fitting/movement characteristics, a clean surface, high wettability, and seemingly low risk for AEs after 3 months of daily wear.

Abbreviations

AE, adverse event; MPC, 2-methacryloyloxyethyl phosphorylcholine; VA, visual acuity.

Data Sharing Statement

The data used to support the primary findings of this study are available at ClinicalTrials.gov (NCT04178720).

Ethics Approval and Informed Consent

This study was conducted in accordance with the principles of Declaration of Helsinki and in compliance with the ICH E6 GCP Consolidated Guideline, ISO 14155:2011, and the applicable US FDA 21 CFR Regulations. Before clinical study initiation, the protocol and all amendments, the informed consent form, any other written information given to subjects, and any advertisements planned for subject recruitment was approved by an IRB/IEC.

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Disclosure

Gina Wesley is a consultant for Bausch + Lomb Incorporated, Orasis and Lumenis and runs clinical trials for Alcon, Bausch + Lomb, CooperVision and Johnson & Johnson Vision Care. Brad Giedd conducts clinical trials for Alcon, Johnson & Johnson and Oculos Development Services, LLC. Bradley Hines is a study investigator for Alcon and Johnson & Johnson Vision Care. Katherine Bickle is a study investigator for Alcon, Johnson & Johnson, and CooperVision. Christopher Pearson is a study investigator for Alcon, Bausch + Lomb, CooperVision, Johnson & Johnson, and Ocuphire Pharma, Inc. Holly Lorentz is an employee of Alcon.

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