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CLINICAL TRIAL REPORT

Comparison of Clinical Performance and Fit Success of Lehfilcon A and Lotrafilcon B Daily Wear Monthly Replacement Silicone Hydrogel Multifocal Contact Lenses in Patients with Presbyopia

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Purpose: To compare and evaluate the clinical performance and fit success of lehfilcon A and lotrafilcon B multifocal soft contact lenses (MfSCLs).

Patients and Methods: This was a prospective, randomized, double-masked, crossover, dispensing clinical study. Eligible wearers were fitted and wore study MfSCLs bilaterally (≥8 hours/day, ≥5 days/week) over 30 days. Endpoints: binocular visual acuity (VA) at distance (4 m), intermediate (80 cm), and near (40 cm) at day 30; fit rate success; eye care professional (ECP) rating, study dispensed lens power at visit 1; lens fit, and surface characteristics at dispense and day 30; safety assessments.

Results: Overall, 101 subjects were enrolled. At day 30, lehfilcon A MfSCLs were noninferior to lotrafilcon B MfSCLs for distance, intermediate, and near VA (non-inferiority margin: 0.05; 95% UCL of LSM difference 0.00, 0.02, 0.04; mean VA, lehfilcon A: −0.10 ± 0.08, −0.10 ± 0.08, and 0.01 ± 0.12; lotrafilcon B: −0.09 ± 0.07, −0.11 ± 0.08, and −0.02 ± 0.11). At visit 1, ≥99.5% of both MfSCLs achieved successful fit with 1–2 lenses/eye. Mean ECP ratings for ease of fit: lehfilcon A 9.8 ± 0.6; lotrafilcon B: 9.7 ± 0.6. About 96.0% of subjects had same sphere (D) power and 100.0% had same ADD power in both eyes for both lenses. All MfSCLs had optimal/acceptable fit. Majority of MfSCLs (>96%) had grade 0/1 front surface wettability and front/back surface deposits. No serious AEs were reported, and all biomicroscopy findings were graded 2 (mild) or lower.

Conclusion: Lehfilcon A multifocal contact lenses combine excellent visual performance, high fit success, and a stable, comfortable wearing experience over 30 days of daily wear. With their water-gradient surface, favorable safety profile, and ease of fit, they represent a reliable and beneficial option for clinicians to consider when selecting multifocal lenses for presbyopic patients.

Keywords: fit success rate, multifocal soft contact lens, visual performance, water-gradient surface

Introduction

Presbyopia, an age-related refractive condition, is expected to reach 2.1 billion by 2030 globally.[1,2] Presbyopia negatively impacts the patient's quality of life, self-esteem, and work productivity.[3,4] Thus, clinicians have several opportunities to provide appropriate vision correction to these patients based on specific or unmet needs.[5,6]

Presbyopia can be corrected with single-vision or spectacles, progressive addition lenses, monovision or multifocal soft contact lenses (MfSCLs).[7,8] Most practitioners indicated a preference for multifocal lenses over monovision lenses and spectacles in patients with presbyopia; however, the percentage of multifocal fits has remained low over the past

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decade (18.0% in 2022 vs 15.0% in 2012).[9] The low usage of the multifocal lens can be attributed to issues with lens fitting, retention, or discomfort, and a lack of awareness about these lenses as an alternative for correcting presbyopia.[5,6,10,11]

Eye care professionals (ECPs) are hesitant as well to provide or fit MfSCL due to reduced success rates, longer chair time requiring multiple fitting trials,[12] and absence of an MfSCL with a good clinical performance or better comfort.[5,11] Therefore, an understanding of patients' visual needs, optical design features of MfSCLs, and the use of appropriate fitting guides could meet the needs of patients with presbyopia.[5]

Over the past decade, MfSCLs have seen significant advancement to accommodate the requirements of patients with presbyopia, with lens replacement schedules ranging from daily to yearly replacement. Globally, the most frequently prescribed contact lens wear modality in 2022 was daily disposables, followed by the monthly category among soft contact lens wearers.[9] In terms of patient compliance, monthly replacement lenses were preferred over bi-weekly replacement lenses.[13,14] Lehfilcon A, a new monthly replacement MfSCL made of a silicone hydrogel lens material, can address the growing needs of the presbyopia population.[15] These water gradient silicone hydrogel lenses comprise 55% water content at the core,[16,17] that gradually increases to >90% water on the outer surface and could lead to better comfort, wettability, and on-eye performance.[17–19,] The silicone hydrogel core allows for high oxygen permeability (Dk/t: 154) and a core modulus of 0.6 MPa for easy handling.[17] Lehfilcon A MfSCLs also feature the biomimetic Celligent® Technology that mimics the eye's corneal surface with polymer nanofibers (2-methacryloyloxyethyl phosphorylcholine [MPC])[20] and resists bacteria and lipid deposits.[17] Lehfilcon A MfSCLs use a center-near aspheric multifocal optical design (Precision Profile® Design, Alcon, Fort Worth, TX) that controls the spherical aberration with a smooth power profile. Lotrafilcon B is a monthly replacement MfSCLs with the same Precision Profile multifocal design, with 33% water and 67% lotrafilcon B. These lenses are indicated for correcting refractive errors (myopia and hyperopia) and presbyopia in both phakic and aphakic individuals with non-diseased eyes.[21] Precision Profile multifocal design offers several advantages, primarily focusing on enhanced vision clarity and uninterrupted vision for individuals with presbyopia. The lens design allows for a smooth transition between different viewing distances (near, intermediate, and far) with minimal distortion.[22]

Comparing modern multifocal lenses using consistent fitting methodologies (such as Precision Profile) is crucial for accurate assessment and optimal patient outcomes. Direct comparisons, with all other variables controlled, allow for a fair evaluation of lens performance and help determine the best fit for individual needs.[23] This approach minimizes the influence of variations in fitting techniques, ensuring that differences in visual performance are directly attributable to the lens design.[23] Despite these advancements, studies comparing the safety and efficacy of MfSCLs in patients with presbyopia are limited.

The purpose of this study was to compare and evaluate the clinical performance and fitting characteristics of lehfilcon A, a new monthly replacement MfSCL, with lotrafilcon B, both with the Precision Profile multifocal design.

Materials and Methods

Study Design

This was a prospective, randomized, stratified, bilateral, crossover, double-masked dispensing study that compared the clinical performance of lehfilcon A and lotrafilcon B MfSCLs. Adult subjects were enrolled for approximately 30 days of bilateral lens wear at eight sites in the United States from May 2022 to September 2022. This study was conducted in accordance with the ethical principles of the Declaration of Helsinki, in compliance with Good Clinical Practices (GCP) guidelines ISO 14155:2020, international/national regulations, and applicable laws/guidelines. The study protocol/amendments, informed consent form, and any other written information given to subjects were reviewed and approved by an independent Institutional Review Board (IRB), Sterling IRB, before the commencement of the study. Voluntary informed consent was obtained from each subject before the initiation of any study-specific procedures. The study was registered at ClinicalTrials.gov with registration number: NCT05338333.

Subjects were aged ≥40 years, with non-diseased eyes; current wearers of daily disposable and biweekly/monthly replacement MfSCLs (including lotrafilcon B) in both eyes for ≥5 days/week and ≥8 hours/day during the past three

months; manifest cylinder ≤0.75 D in each eye; binocular corrected visual acuity (VA) distance 20/25 or better in each eye with a spherical refractive error between −1.00 and −4.00 D, and requiring a near ADD of LO, MED, or HI (ADD of +0.75 D to +2.50 D in each eye). Potential subjects were excluded if they had a history of amblyopia or other binocular vision abnormalities, were monovision contact lens wearers, were pregnant or breast-feeding, or were participating in a clinical trial or within the previous 30 days.

The eligible subjects were randomized in a 1:1 ratio to receive either lehfilcon A or lotrafilcon B as the first lens of the crossover sequence. Details of the study lenses are outlined in Table 1. The power range tested in this study for lehfilcon A and lotrafilcon B lenses was LO ADD with −1.25 to −4.00 D, MED ADD with −1.00 to −4.00 D, and HI ADD with −1.50 to −3.00 D (all in 0.25 D steps).

The subjects and investigators were masked to the assigned treatment sequence. During the study, the masked investigator designated an unmasked member to prepare the contact lenses for fitting and dispensing to the subjects as per their randomization assignment. The assessor and subject were masked in the study; subjects were masked to their lens assignment for the entire duration of the study, and the assessor remained masked about the lens and the assignment during the study.

Subjects attended four office visits: screening/baseline/lens fit, dispense lens 1, day 30 follow-up lens 1/dispense lens 2, and day 30 follow-up lens 2/exit (Supplementary Figure 1). Subjects were instructed to wear study lenses for ≥8 hours per day, ≥5 days per week, over a 30-day duration of bilateral wear each (total of approximately 60 days of lens wear), with a washout period of 3 to 5 days between baseline and visit 1. Lenses were cleaned with CLEAR CARE Cleaning and Disinfecting Solution (Alcon Vision LLC, Fort Worth, TX) and rinsed with LacriPure saline solution (Menicon, Japan) after removal/before insertion if needed.

Study Endpoints

The endpoints assessed were binocular high contrast/high illumination (HC/HI) VA logarithm of minimum angle of resolution (logMAR) at distance (4 m), intermediate (80 cm), and near (40 cm) on dispense and day 30 follow-up. Other endpoints were fit-rate success (as a number of lenses required to achieve final/successful fit) assessed for each eye at dispense/visit 1; the ECP rating on ease of fit rated on a 10-point scale (1 = difficult to 10 = easy) for each study lens individually at dispense/visit 1; study lens power dispensed (sphere [in diopter] and ADD [LOW, MEDIUM, HI] in accordance with Alcon's multifocal lens fitting guide) (Supplementary Figure 2) evaluated at dispense/visit 1; lens movement and lens position and lens surface characteristics at dispense and day 30 and safety.

Lens Fit or Movement

Lens fit or movement was assessed on a 5-point scale (−2 = unacceptably tight, −1 = acceptably tight, 0 = optimal fit/movement, +1 = acceptably loose, or +2 = unacceptably loose) immediately after a blink in primary gaze and peripheral gaze/forceful blinks.

Table 1 Study Lenses Characteristics

Lens Characteristics	Lehfilcon A	Lotrafilcon B
Core material	Lehfilcon A	Lotrafilcon B
Water content	55%	33%
Base curve	8.4 mm	8.6 mm
Diameter	14.2 mm	14.2 mm
Oxygen permeability	Dk/t: 154 @ −3.00D	Dk/t: 138 @ −3.00D
Optical design	Center-near aspheric	Center-near aspheric
Surface treatment	Surface Modification with MPC Polymer (Celligent Technology)	Plasma surface treatment (SmartShield® Technology)

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Lens Position or Centration

Lens position or centration was evaluated on a 3-point scale (0 = optimal lens centration, 1 = acceptable decentration, or 2 = unacceptable decentration).

Lens Surface Characteristics

The lens surface characteristics such as lens front surface wettability were assessed using a 5-point scale (0 = smooth uniformly reflecting surface, 1 = a coarse hazy surface which seems resolved momentarily with each blink and becomes exacerbated with staring, 2 = one stable dry [non-wetting] area, 3 = more than one stable dry [non-wetting] area, 4 = non-wettable lens surface) at dispense and day 30.

Front and back surface deposits were assessed using a 5-point scale (0 = absent, 4 = severe) at dispense and day 30 (For front surface: 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; 4 = severe, non-removable deposits and comfort affected.

For back surface: 0 = absent, clean surface; 1 = very slight, 3 spots or less of moving particles; 2 = slight, up to 10 spots of moving particles; 3 = moderate, 3 or less non-moving deposits adherent to lens; 4 = severe, 4 or more deposits adherent to the lens and/or corneal indentation).

Safety

The safety endpoints were adverse events (AEs, ocular/non-ocular), device deficiencies reported throughout the study, and biomicroscopy findings assessed in each eye (by slit lamp biomicroscopy) at dispense and day 30.

Each clinical evaluation was conducted by a qualified eye care professional designated for that purpose. To ensure consistency across assessments, standardized evaluation protocols and a uniform fitting guide were applied consistently for all participants.

Statistical Analysis

All statistical analyses were performed using SAS software (SAS Institute Inc., Cary, NC).

Data were summarized as categorical variables (frequencies and percentages) or continuous variables (mean, number of observations, median, minimum, maximum, standard deviation [SD], and standard error [SE]). For the endpoints, a mixed effects repeated measures model was used to test the hypotheses at day 30 with a 1-sided 95% upper confidence limit (UCL) and noninferiority (NI) margin of 0.05 for the difference between the study lenses. Noninferiority (lehfilcon A vs lotrafilcon B) for distance, intermediate, and near VA was reported if UCL was less than 0.05. There were no prespecified safety hypotheses in this study. The study lens power and ADD were assessed through a post hoc analysis. The study sample size was based on two prior clinical studies (data on file), which evaluated the performance of several marketed MfSCLs with Precision Profile design. For VA at near, based on SD of difference of 0.154, with an expected difference of 0, a sample size of 84 was needed to attain 90% power to demonstrate NI (margin = 0.05), at one-sided alpha = 0.05. Similarly, for VA at distance (SD = 0.0845) and VA at intermediate (SD = 0.1034), required sample sizes were 26 and 40.

Results

A total of 101 subjects were enrolled and dispensed to study lenses in this study. Of these, 100 subjects completed the study, and one subject discontinued due to an AE of conjunctivitis (in both eyes), which was mild in severity, resolved/recovered, and not related to the study lenses (Supplementary Figure 3). Overall, the mean ± SD age of subjects was 50.8 ± 6.5 years, with the majority being female (79.2%), of white race (97.0%), and not Hispanic or Latino ethnicity (97.0%) (Table 2).

Binocular HC/HI Distance, Intermediate, and Near VA

At day 30, lehfilcon A MfSCLs were noninferior to lotrafilcon B MfSCLs for distance VA (least square mean [LSM] difference [SE]: −0.01 [0.006], 95% UCL of LSM difference 0.00; mean ± SD logMAR: lehfilcon A, −0.10 ± 0.08; lotrafilcon B, −0.09 ± 0.07; Figure 1).

Table 2 Demographic Characteristics of Study Subjects at Baseline

Characteristics	Overall (n = 101)
Age, years	
Mean ± SD	50.8 ± 6.5
Sex, n (%)	
Male	21 (20.8)
Female	80 (79.2)
Age Group, n (%)	
18–64	98 (97.0)
≥65	3 (3.0)
Race, n (%)	
White	98 (97.0)
Black or African American	3 (3.0)
Ethnicity, n (%)	
Hispanic or Latino	3 (3.0)
Not Hispanic or Latino	98 (97.0)

Abbreviation: SD, standard deviation.

Similarly, lehfilcon A MfSCLs were noninferior to lotrafilcon B MfSCLs for intermediate (LSM difference [SE] intermediate VA: 0.00 [0.008], 95% UCL of LSM difference 0.02; mean ± SD logMAR: lehfilcon A, −0.10 ± 0.08; lotrafilcon B, −0.11 ± 0.08; Figure 2) and near VA (LSM difference [SE] near VA: 0.03 [0.008], 95% UCL of LSM difference 0.04; mean ± SD logMAR: lehfilcon A, 0.01 ± 0.12; lotrafilcon B, −0.02 ± 0.11; Figure 3) at day 30.

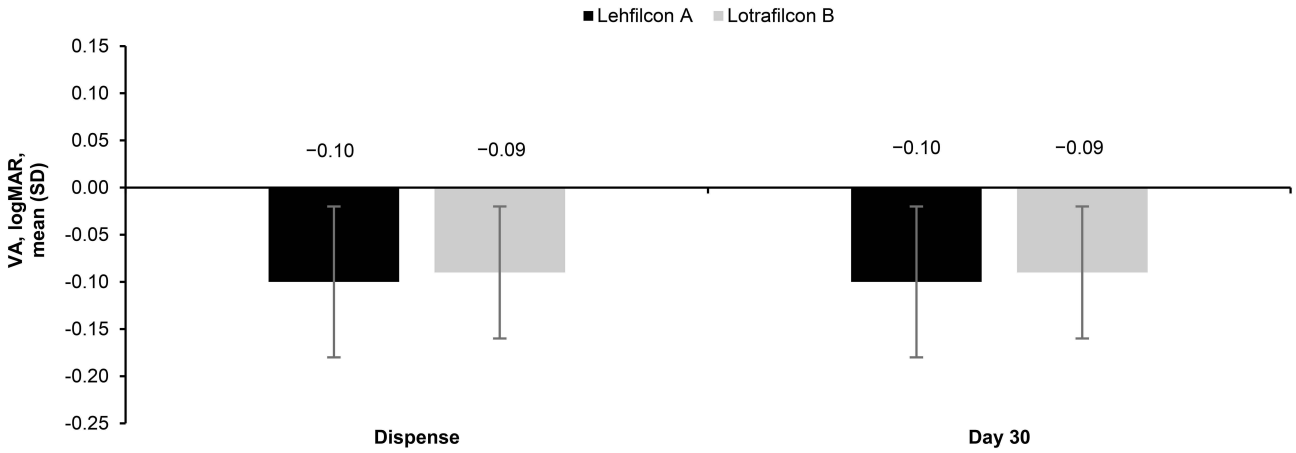

Figure 1 Binocular HC/HI distance visual acuity (logMAR) at dispense and day 30. Lehfilcon A (n = 101 [dispense], n = 100 [day 30]); Lotrafilcon B (n = 100 [dispense], n = 100 [day 30]). Error bars represent standard deviation.
Abbreviations: HC/HI, high contrast/high illumination; logMAR, logarithm of minimum angle of resolution; n, number of subjects; SD, standard deviation; VA, visual acuity.

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Figure 2 Binocular HC/HI intermediate visual acuity (logMAR) at dispense and day 30. Lehfilcon A (n=101 [dispense], n=100 [day 30]); Lotrafilcon B (n=100 [dispense], n=100 [day 30]). Error bars represent standard deviation.
Abbreviations: HC/HI, high contrast/high illumination; logMAR, logarithm of minimum angle of resolution; n, number of subjects; SD, standard deviation; VA, visual acuity.

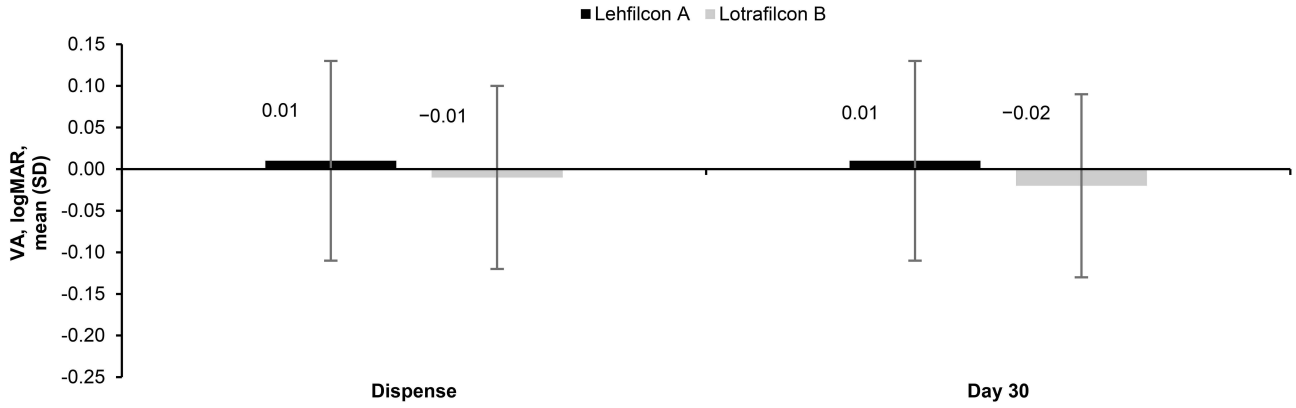

Figure 3 Binocular HC/HI near visual acuity (logMAR) at dispense and day 30. Lehfilcon A (n = 101 [dispense], n = 100 [day 30]); Lotrafilcon B (n = 100 [dispense], n = 100 [day 30]). Error bars represent standard deviation.
Abbreviations: HC/HI, high contrast/high illumination; logMAR, logarithm of minimum angle of resolution; n, number of subjects; SD, standard deviation; VA, visual acuity.

Fit-Rate Success and ECP Rating on Ease of Fit

At visit 1 (screening/fitting), 90.1% of the eyes with lehfilcon A MfSCLs and 91.1% of eyes with lotrafilcon B MfSCLs achieved a successful fit with 1 lens per eye. Moreover, 99.5% of the eyes with lehfilcon A MfSCLs and 100% of eyes with lotrafilcon B were successfully fit with 1–2 lenses/eye (Figure 4A).

The means ± SD ECP rating on ease of fit for lehfilcon A and lotrafilcon B MfSCLs was 9.8 ± 0.6 and 9.7 ± 0.6 at visit 1. The majority of subjects (95.0%) were rated on a scale of 9–10 for ease of fit for both MfSCLs (Figure 4B).

Lens Power and ADD

The majority of subjects (96%, n = 97) had the same sphere (D) power in both eyes, and all subjects (100%, n = 101) had the same ADD power in both eyes for both lehfilcon A and lotrafilcon B MfSCLs.

Lens Fit Characteristics

All study lenses (100%) had optimal/acceptable movement in primary gazes and peripheral gazes at dispense and day 30 (Figure 5A and B). None of the study lenses were unacceptably tight or unacceptably loose at dispense and day 30.

Both lehfilcon A and lotrafilcon B MfSCLs were assessed as having 100% optimal centration/acceptable decentration at dispense and day 30 (Figure 5C). Also, there were no reports of unacceptable decentration at both dispense and day 30.

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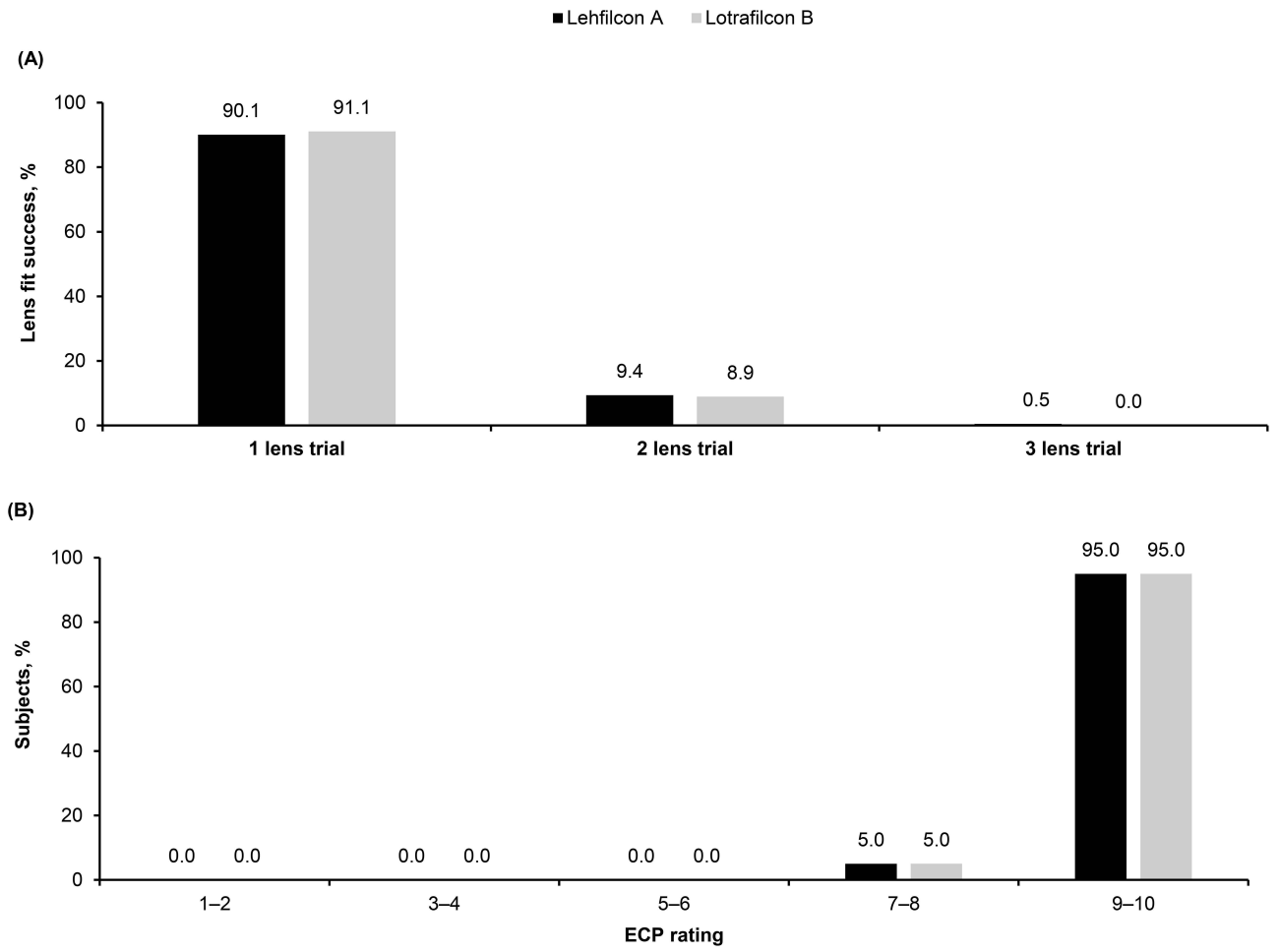

Figure 4 (**A**) Lens fit success rate 4 (**B**) Eye care professional (ECP) rating on ease of fit. For lens fit success: Lehfilcon A (n = 202 eyes); Lotrafilcon B (n = 202 eyes). For ECP rating: Lehfilcon A (n = 101 subjects); Lotrafilcon B (n = 101 subjects).
Abbreviation: ECP, eye care professional.

Lens Surface Characteristics

Most of the lehfilcon A and lotrafilcon B MfSCLs were graded as 0 for front surface wettability at dispense (lehfilcon A: dispense, 97.0%; day 30, 77.5%; lotrafilcon B: dispense, 98.0%; day 30, 73.0%; Figure 6A). Most of the lehfilcon A and lotrafilcon B MfSCLs were graded as 0 for front surface deposits (lehfilcon A: dispense, 98.5%; day 30, 84.5%; lotrafilcon B: dispense, 97.5%; day 30, 77.0%; Figure 6B) and back surface deposits (lehfilcon A: dispense, 97.0%; day 30, 94.0%; lotrafilcon B: dispense, 97.5%; day 30, 89.5%) at dispense and day 30 (Figure 6C).

Safety

There were no deaths, ocular serious adverse events (SAEs), or serious adverse device effects (SADEs) reported in the study. There were two adverse device effects (ADEs) of blurred vision in both eyes (mild in severity and recovered/resolved) in the lehfilcon A MfSCLs; 2 ADEs of eye irritation in both eyes (mild severity and recovered/resolved) were reported with lotrafilcon B MfSCLs. No ocular significant nonserious treatment-emergent AEs were reported. Four non-ocular nonserious AEs were reported (3 reported with lehfilcon A [bronchitis, COVID-19, and oropharyngeal pain];1 reported with lotrafilcon B [COVID-19]).

No biomicroscopy findings of grade >2 were reported for either of the study lenses. Palpebral conjunctival observations were most frequently reported for both lenses at similar rates at dispense and day 30. There were two reports of grade 2 increase in conjunctival or corneal staining in one eye for both the study lenses between dispense and day 30. No corneal edema or infiltrates were reported in the study.

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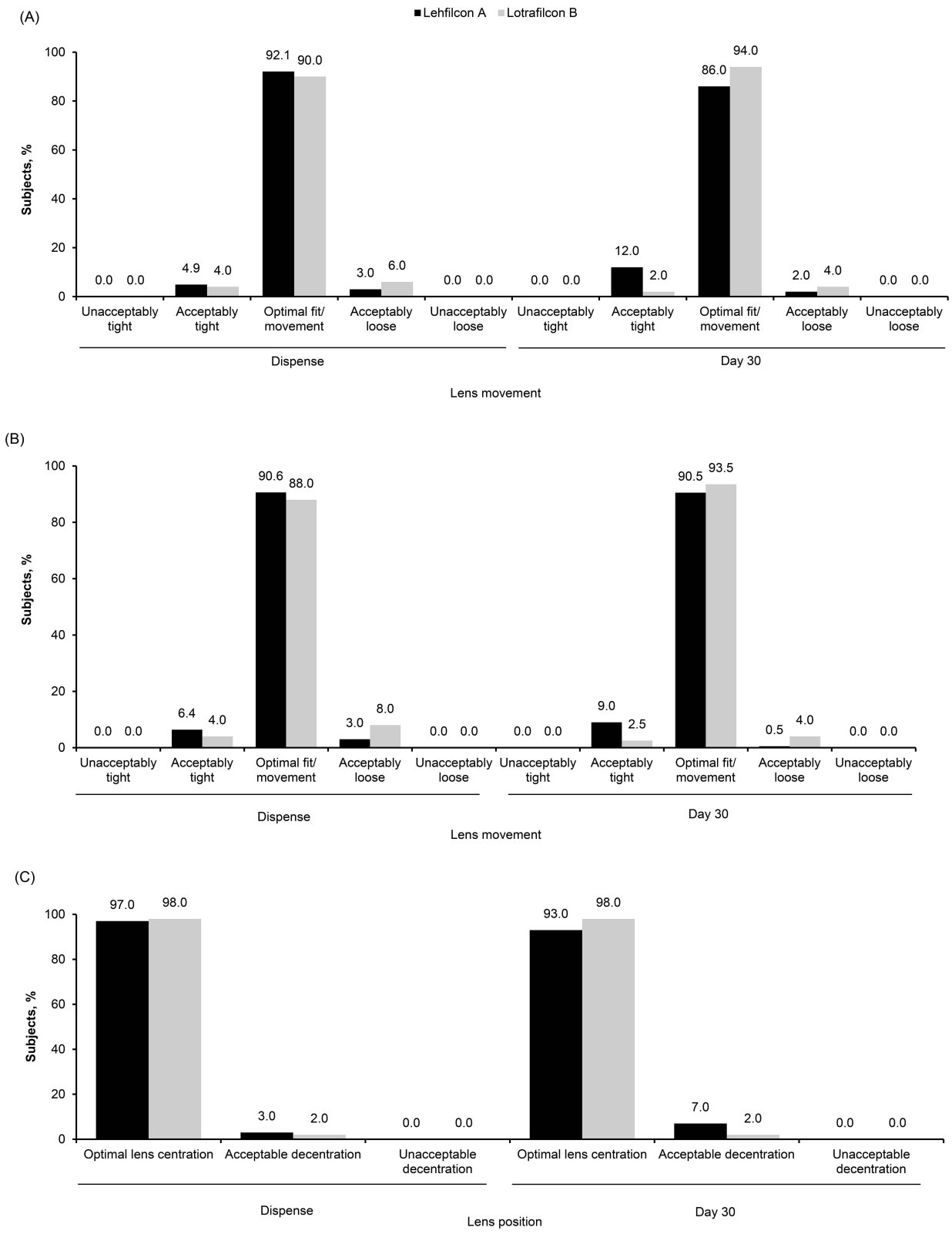

Figure 5 Lens fit characteristics at dispense and day 30 (**A**) Lens movement – primary gaze (**B**) Lens movement – peripheral gaze (**C**) Lens position. Lehfilcon A (n = 202 eyes [dispense], n = 200 eyes [day 30]); Lotrafilcon B (n = 200 eyes [dispense], n = 200 eyes [day 30]).

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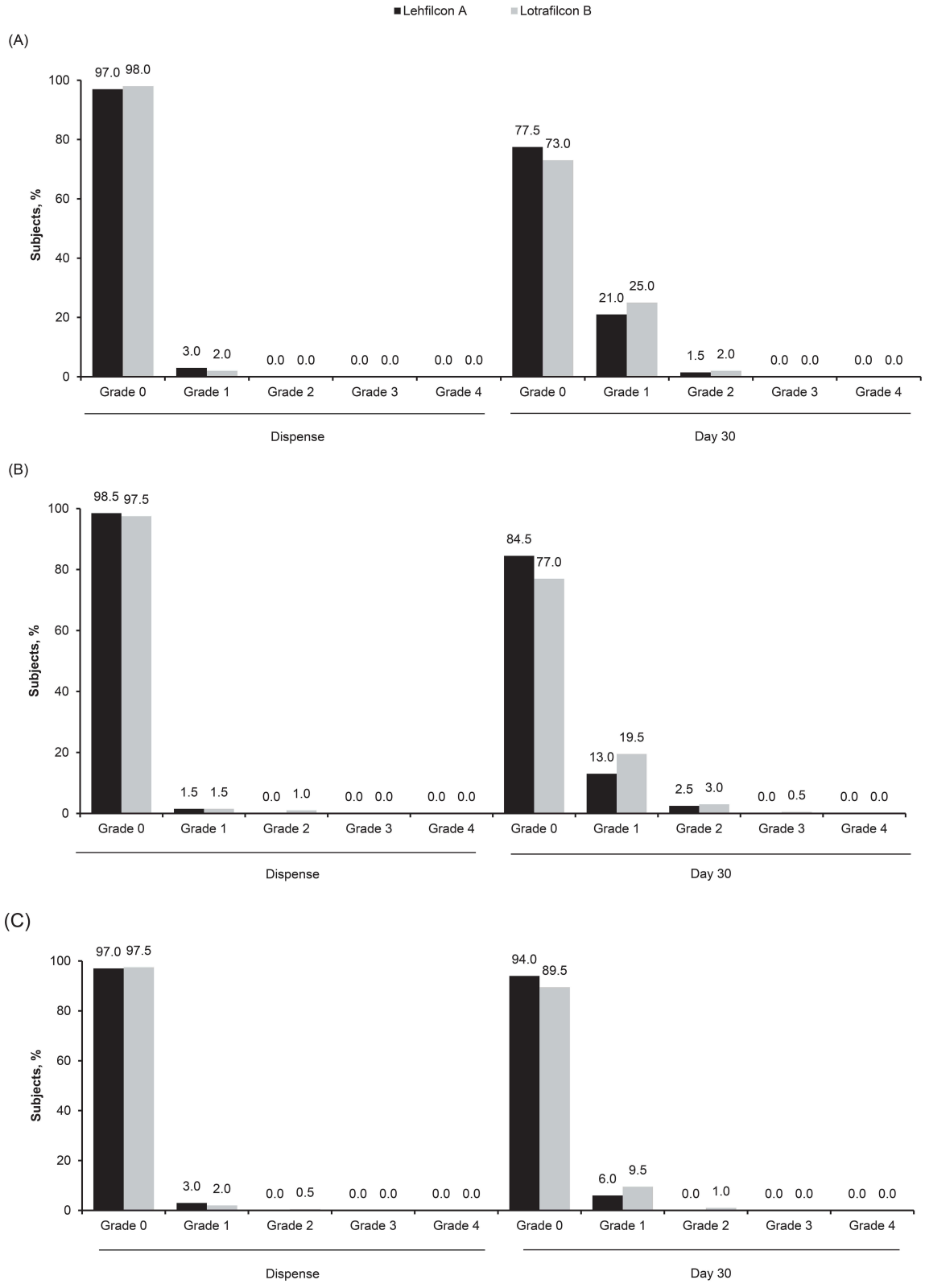

Figure 6 Lens surface characteristics at dispense and day 30 (**A**) Front surface wettability (**B**) Front surface deposits (**C**) Back surface deposits. Lehfilcon A (n = 202 eyes [dispense], n = 200 eyes [day 30]); Lotrafilcon B (n = 200 eyes [dispense], n = 200 eyes [day 30]).

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Five device deficiencies were reported for lehfilcon A MfSCLs and 4 for lotrafilcon B MfSCLs (lehfilcon A lenses: edge defect [n = 1], non-wetting area [n = 2], torn lens during handling/pack [n = 2]; lotrafilcon B lenses: surface defect [n = 1], torn lens during handling/pack [n = 1], and other [n = 2]).

Discussion

This prospective, randomized bilateral dispensing study evaluated the clinical performance of a new monthly replacement MfSCLs, lehfilcon A and lotrafilcon B MfSCLs, through 30 days of wear. The results from this study showed that lehfilcon A was noninferior to lotrafilcon B MfSCLs for VA (at all distances) based on the NI margin of 0.05 logMAR units. The VA was excellent at all distances for both lehfilcon A and lotrafilcon B MfSCLs. The findings also demonstrated good fit-rate success, ease of fit, optimal fit (movement and centration), and surface characteristics, with both lehfilcon A and lotrafilcon B MfSCLs. There were no safety concerns for both MfSCLs based on the assessment of AEs, ocular reactions, or device deficiencies.

The success of contact lens wear depends on its ability to coexist on the eye without any AEs.[24] Findings from studies spanning over a decade demonstrated that improper fit, poor vision (at all distances), and discomfort were common reasons for contact lens wear discontinuation.[24–28] Similarly, current treatment (lens/glasses) options for presbyopia require patients to compromise on quality and vision flexibility at all distances.[29,30] Thus, on-eye performance and contact lens fit are of prime importance for ocular health and preventing contact lens dropout.[11,31,32] In this study, lehfilcon A MfSCLs demonstrated noninferiority in comparison with lotrafilcon B MfSCLs for binocular HC/HI VA (logMAR) at distance (4 or 3 m), intermediate (80 cm), and near (40 cm) through 30 days of wear; along with excellent VA at all distances.

Fit success, specifically for multifocal lenses, is affected by factors such as noncompliance with the fitting guide, nonusage of updated refraction, and selection of non-optimal refractions during lens try and fit.[6] Therefore, it is essential to understand and optimize the multifocal lens fitting guide for its success upon wear.[33] As a result, fitting guides for a multifocal lens are tailored based on evidence from clinical studies, considering the potential drawbacks of a specific multifocal lens.[5] Several studies have reported that, for a successful multifocal lens fit, only 1 or 2 trials per eye are required when fitting guides or online calculators are used.[5,6,34,35] Studies have shown that the use of a fitting guide along with ocular information such as distance spectacle refraction, near ADD power, and ocular dominance has demonstrated first lens fit success in 75% of cases.[5,6] In this study, lehfilcon A MfSCLs and lotrafilcon B MfSCLs (fitted using Alcon's multifocal fitting guide) achieved a final/successful lens fit after only one trial lens fit for most eyes, which is in concordance with a previous study reporting high fit success with multifocal lenses.[36] In addition, the ease of fit for lehfilcon A MfSCLs was comparable and rated as high (on 9–10), similar to lotrafilcon B MfSCLs, both fitted with unique Precision Profile Design and designed for a high first-lens fit success rate based on centration, movement, and rotation at the initial fitting.[36]

Lens movement and centration are vital measurements to determine proper lens fit and are closely related to ocular health, lens comfort,[31] and successful simultaneous vision.[37,38] Both lehfilcon A and lotrafilcon B MfSCLs lens fit (movement and centration) was similar and assessed as acceptable/optimal through 30 days of wear. In this study, both MfSCLs had optimal lens surface assessments with good wettability and lesser surface deposits at dispense and day 30. Lehfilcon A contact lenses have been demonstrated to maintain in vitro wettability following 30 days of on-eye daily wear comparable with lenses evaluated immediately after removal from packaging.[39] Additionally, a clinical study showed good surface characteristics (front/back surface deposits [grade 0 or 1]: 98.7%/100%) with lehfilcon A lenses through 3 months of daily wear.[32]

Contact lens power profiles provide information on the distribution or magnitude of relative plus power in MfSCLs that can be used to correlate lens design features with visual performance.[40] Descriptors, such as low/medium/high ADD power, correspond to the equivalent spectacle ADD power in the fitting guide.[40] In this study, the mean study lens power dispensed was similar between both study MfSCLs, regardless of habitual lens wear or ADD power. Overall, both the study MfSCLs demonstrated comparable safety profiles. Lehfilcon A MfSCLs showed no serious/ocular AEs, which is consistent with the known safety profile of these lenses.[15]

The study had a few limitations. Although multifocal soft contact lenses have demonstrated clinical benefits in our study, real-world compliance with multifocal soft contact lens wear involves several key considerations, such as appropriate lens fitting and adaptation, patients' satisfaction and adherence, lens cost, and accessibility which could be explored further in future studies. The results of subgroup analysis based on the type of habitual lens and ADD power were not included due to the low sample size, which may be considered for future clinical studies. However, this does not impact the overall study results or the validity of the primary results. To enhance applicability to clinical practice, future studies should consider longer lens wear periods to depict real-world dynamics, taking into consideration factors such as sustained comfort, adaptation, and compliance. Only myopic presbyopes were included in this evaluation due to the availability of minus-power lenses. Nonetheless, the Precision Profile multifocal design has previously been evaluated in both myopic and hyperopic presbyopes across various lens materials and modalities, supporting its broader clinical applicability.[36] The predominance of female participants and individuals identifying as White in our study cohort may limit the generalizability of these findings to more diverse patient populations. Future studies with broader demographic representation are warranted to further validate these results.

Conclusion

The new lehfilcon A MfSCLs (TOTAL30® Multifocal) demonstrated excellent VA at all distances with optimal movement and centration through 30 days of daily wear. Lehfilcon A MfSCLs with Alcon's Precision Profile multifocal design was shown to have an easy and predictable fit with a high lens fit success rate (99.5% success with two lenses or less using Alcon's multifocal fitting guide), similar to lotrafilcon B MfSCLs. There was a 96.0% exact fit between lehfilcon A MfSCLs and lotrafilcon B MfSCLs, based on lens sphere and ADD power, centration, and movement at the initial visit, which indicates that ECPs can confidently and easily switch patients from lotrafilcon B MfSCLs lenses to new monthly replacement water gradient lehfilcon A MfSCLs.

Data Sharing Statement

The data used to support the primary findings of this study are not available separately; individual patient data are not available.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in critically reviewing and revising the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

Vidhya Subramanian is an employee of Alcon. Katherine Bickle, Stephen Montaquila, Bradley Giedd, Gina Wesley, and Mark Perry are independent clinical investigators conducting research for Alcon. The authors report no other conflicts of interest in this work.

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