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Assessing a modified fitting approach for improved multifocal contact lens fitting

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ABSTRACT

Purpose: : To compare the effectiveness of a modified and previous fitting guide for multifocal (MF) contact lenses that share a common optical design, lotrafilcon B, nelfilcon A, and delefilcon A, in current soft contact lens (CL) wearers needing presbyopia correction.

Methods: : This international multicenter, prospective, randomized, subject-masked study assessed the superiority of the modified guide relative to the previous guide as determined by the number of MF CLs needed to successfully fit each eye at the screening/fitting visit.

Results: : A total of 183 presbyopic subjects were randomized to fitting using the modified (n = 99) and previous (n = 84) MF CL fitting guides. The mean ± SD numbers of lenses required to fit each eye at the screening/fitting visit using the modified and previous fitting guides were 1.2 ± 0.5 and 1.4 ± 0.5, respectively. The least-squares mean difference (0.2) met predetermined criteria for superiority of the modified fitting guide. At the screening/fitting visit, 82.8% (164/108) and 65.1% (105/166) of presbyopic eyes were fit with one pair of MF lenses using the modified and previous guides, respectively, and 98.0% (194/198) of eyes were fit with 1–2 pairs of MF lenses using the modified guide. A higher percentage of eye care practitioners gave the highest ratings for ease of fit for the modified than for the previous fitting guide (63.6% [7/11] vs 33.3% [3/9]).

Conclusions: : The modified fitting guide was superior at reducing the number of MF lenses required to successfully fit each presbyopic patient.

1. Introduction

Presbyopia is characterized by a slow and progressive loss of the ability to focus vision at a normal near reading distance and is caused by the inability of the crystalline lens to change shape in response to the ciliary muscle [1]. The changes in the crystalline lens that contribute to presbyopia are age-related, and the condition usually becomes evident during the early forties [2,3]. The worldwide prevalence of presbyopia is estimated to be 1.8 billion people and is expected to increase to more than 2 billion people by 2030 [4]. This trend is attributed to the growing size and aging of the world's population [5].

Presbyopia can be corrected by the use of single vision spectacles for correcting near vision, bifocal or progressive lens spectacles, progressive addition lenses, monovision contact lenses, or multifocal (MF) contact lenses [2,3]. The use of MF contact lenses has been increasing over the last two decades [6], and have been associated with greater patient satisfaction among presbyopes than monovision contact lenses [7].

Multifocal lenses manufactured in lotrafilcon B, nelfilcon A, and delefilcon A (Alcon, Fort Worth, TX, USA) all share the same center-near aspheric MF optical design [8–10]. Because of this common feature, eye care professionals (ECPs) can use the same fitting guide in each case, regardless of lens material or replacement schedule [11].

Because fitting time may be longer for MF than for monofocal lenses, some ECPs may hesitate to offer MF lenses to their presbyopic patients [12]. To address this, a modified fitting guideline was

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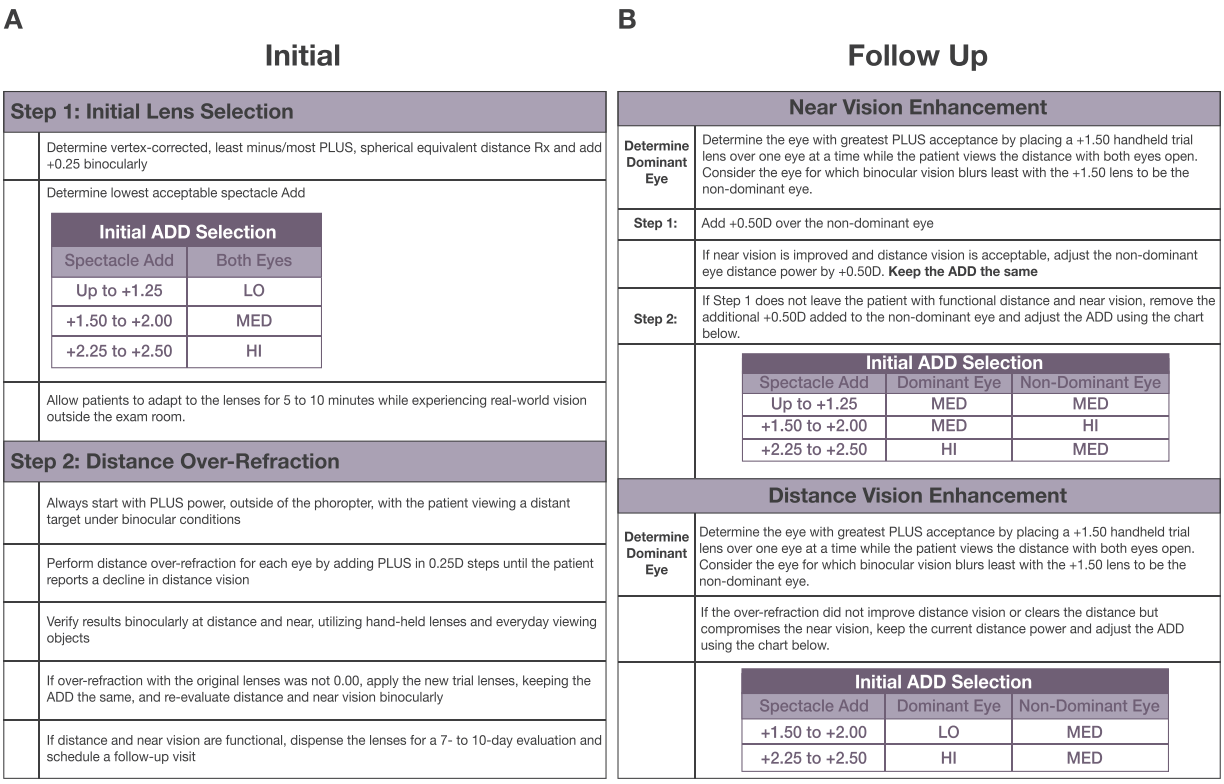


Fig. 1. Modified multifocal contact lens fitting guide, initial visit (A), follow up visit (B).

developed to improve the efficiency of lens fitting. This study therefore compared the efficiency of using the modified and previous fitting guides in a population of experienced soft contact lens wearers needing presbyopia correction.

2. Methods

2.1. Study design

This was an international multicenter, prospective, randomized, subject-masked, active-controlled, parallel-group, and stratified study comparing the fitting of lotrafilcon B, nelfilcon A, and delefilcon A MF contact lenses using either the modified or the previous MF fitting guides. The modified fitting guide directs the ECP to add +0.25D binocularly after determining the vertex-corrected, least minus/most PLUS, spherical equivalent distance prescription (Fig. 1). Twenty investigators, 14 in the United States, three in the United Kingdom, and three in Canada, participated in the study.

Randomization occurred in two parts. In the first, each site was randomized to use either the modified or the previous MF fitting guide, with all subjects at that site fitted using the same assigned guide. This strategy sought to reduce the likelihood of errors from confusion between fitting techniques made in fitting the study lenses by referencing the incorrect fitting guide, a likely error if two similar fitting guides were used at a given site. Fitting guide randomization was stratified by country. In the second part, randomization was based on habitual contact lens use: subjects who wore only monthly/weekly contact lenses were randomized 1:1 to either lotrafilcon B or nelfilcon A MF contact lenses, while those who currently wore daily disposable contact lenses were fitted with delefilcon A MF contact lenses.

At the screening visit (Visit 1), demographic characteristics of study subjects were recorded. Both eyes underwent ophthalmic examinations, including slit-lamp microscopy to assess limbal and bulbar hyperemia; measurement of pupil size under photopic and mesopic conditions; and determination of preferred reading distance, manifest refraction, and distance best-corrected visual acuity under manifest refraction. Subjects completed questionnaires addressing lifestyle and satisfaction with their habitual contact lenses. Lens parameters were optimized, prescription was recorded, and lens fitting was determined using the fitting guide assigned to that study site. Wearers of monthly/weekly lenses wore their lenses daily and cared for them with their habitual lens care solutions; wearers of daily disposable lenses removed and discarded their study lenses every night and inserted a new pair every morning.

During Visit 2, performed 0–7 days after Visit 1, study lenses were dispensed in an unmasked manner by a trained study staff member, but subjects were masked to the fitting guides used to fit each eye. After lens fitting, all subjects underwent slit lamp examination to measure lens movement (overall lens fit) and lens position (centration); if necessary, distance BCVA of each eye with manifest refraction was performed. After approximately 20 min of lens wear, subjects were asked to complete a series of subjective questionnaires regarding their inserted lenses, including vision quality at distance, intermediate, near, as well as overall. Responses were rated using a scale of 1–10, where 1 was poor and 10 was excellent.

Subjects wore their study lenses bilaterally on a daily wear basis for 10 ± 3 days, returning at Visit 3, during which they completed another series of subjective questionnaires based on their study lens, rating their functional quality of vision while driving and during digital device use (cell phone, tablet, and computer), where 1 is poor and 10 is excellent. Ophthalmic evaluations were repeated, including slit lamp measurements of overall lens fit and lens centration, and, if necessary, distance BCVA of each eye with manifest refraction. Optimal MF lens prescriptions was assessed, and subjects determined to have been fitted successfully exited the study. Those subjects determined not to have been fitted successfully were refitted according to the relevant fitting guide and dispensed new lenses for an additional 10 ± 3 days and the sequence described above was repeated. At final follow-up, subjects determined to have been fitted successfully exited the study, whereas those determined not to have been fitted successfully were re-assessed for optimal prescription, although no additional lenses were dispensed,

Table 1
Demographic characteristics of the presbyopic study subjects (Safety Analysis Set).

Characteristic	Modified Fitting Guide (n = 99)	Previous Fitting Guide (n = 83)	Overall (N = 182)
Age, y			
Mean (SD)	49.8 (6.7)	51.2 (6.8)	50.4 (6.7)
Range	(40, 65)	(41, 65)	(40, 65)
Age Group, n (%)			
40 – 65	99 (100)	83 (100)	182 (100)
Sex, n (%)			
Male	13 (13.1)	15 (18.1)	28 (15.4)
Female	86 (86.9)	68 (81.9)	154 (84.6)

SD, standard deviation.

and subjects exited from the study without being fitted successfully. The total duration of treatment was anticipated to be 10 ± 3 days per dispensed lens, with a minimum of 7 days and maximum of 26 days depending on the necessity of refit dispensing and follow-up visits.

This study was performed in compliance with the ethical principles of the Declaration of Helsinki, Good Clinical Practice, and International Organization for Standardization 14155:2011 and was approved by an independent Ethics Committee/Institutional Review Board. All subjects provided informed written consent. The clinicaltrial.gov identification number for this study is NCT 03118934.

2.2. Subjects

The study enrolled current soft contact lens wearers, defined as those who wore their lenses for 6 h/day on 5 days/week for the previous month, who were aged 40–65 years with otherwise normal eyes and not using any ocular medication. All subjects required presbyopia correction, with a near spectacle add of +0.50 D to +2.50 D (inclusive). Both emerging presbyopes (ADD power ≤ +1.25 D in both eyes) and established presbyopes (power of +1.50 to +2.50 D [inclusive] in either eye) were included.

2.3. Effectiveness assessments

This study evaluated the noninferiority and then the superiority of the modified MF fitting guide compared with the previous fitting guide as determined by the mean number of lenses needed to fit each eye at Visit 1, for all MF lenses combined. The corresponding endpoint was the number of MF lenses needed to fit each eye at Visit 1, derived from the number of on-eye lens prescriptions, for all MF lenses combined.

Several exploratory endpoints were also evaluated, including the proportions of subjects requiring one or more lenses to fit at Visit 1 and for a successful fit for both fitting guides for the overall study population and for emerging and established presbyopes. Ease of fit with the modified and previous fitting guides was rated by ECPs on a 10-point scale with 1 indicating difficult and 10 indicating easy. Subjective ratings of quality of vision included quality of vision at near, intermediate, and distance, measured at the dispensing visit, and functional vision while driving and during digital device use, measured after 10 ± 3 days of study lens wear.

2.4. Safety

Safety was assessed for all subjects/eyes exposed to the study lenses evaluated in this study, except for those used for the trial fit at Visit 1. Safety parameters included adverse event (AEs) and biomicroscopy findings.

2.5. Sample size

The sample size calculation for the primary effectiveness hypothesis on fit success was based on an assumed common standard deviation of 0.06 and expected difference in means of 0.25, a sample size of 80 (160 eyes) in each group would provide 83% power for a noninferiority margin of 0.5 (one-sided $\alpha = 0.05$), based on a two-group t test.

2.6. Statistical analyses

The Full Analysis Set (FAS) consisted of subjects randomized or assigned to study lenses as applicable and exposed to study lenses including trial fit at Visit 1. Superiority was defined as achieving both noninferiority and a one-sided 95% upper confidence limit (UCL) for the least squares mean (LSM) of the difference in scores for the MF fitting guide difference (modified minus previous) of less than 0 at Visit 1. Noninferiority as the primary effectiveness endpoint was defined as a one-sided 95% UCL for the fitting guide difference (new minus old) of less than 0.5 at Visit 1. Inferential testing was also planned to address superiority. A sequential gatekeeping strategy was implemented to control multiplicity according to the following sequence: noninferiority followed by superiority. By doing this, the overall type I error was controlled at a P-value > 0.05. The remaining endpoints were summarized descriptively. Continuous variables were summarized using the number of observations (n), mean, standard deviation (SD; a quantification of the amount of variation in a set of data values), standard error (SE; the standard deviation of the distribution of values used to calculate a mean), median, minimum, and maximum, as well as confidence intervals/limits where applicable. Categorical variables were summarized with counts and percentages from each category.

3. Results

3.1. Subject demographics, disposition, and refraction

A total of 183 subjects were randomized to be fitted bilaterally with one of the three MF study lenses using either the modified (n = 99) or the previous (n = 84) MF fitting guides (Table 1). Of the 20 study sites, 11 fitted presbyopic subjects using the modified fitting guide and nine fitted presbyopic subjects with the previous MF fitting guide. All subjects were aged between 40 and 65 years and most were female (154/182; 84.6%). Subject demographic characteristics were similar at sites randomized to the modified and previous fitting guides. Of the 183 subjects, one randomized to the previous fitting guide was discontinued prior to trial lens fit because of viral pharyngitis), with 182 randomized to be fitted with the lotrafilcon B, nelfilcon A, and delefilcon A MF contact lenses. Two subjects randomized to the modified fitting guide and three randomized to the previous fitting guide were discontinued after fitting but prior to contact lens exposure for the following reasons: for the modified guide, physician decision and ineligibility not determined until after subject randomized; for the previous guide, screen failure, withdrawal by subject, and failed lens fitting. Thus, 177 subjects were exposed to study contact lenses, including 62 to lotrafilcon B, 57 to nelfilcon A, and 58 to delefilcon A MF lenses. Of these 177 subjects, two were discontinued prior to study exit, one due to an AE (foreign body in the eye), and one at the discretion of the investigator. A total of 175 subjects completed the study. Of the study population, 48% were successful MF contact lens wearers (established presbyopes); the remaining subjects were single vision (with uncorrected presbyopia) or monovision. Table 2 provides data on subjective refraction and pupil size for the subjects at baseline according to randomization to fitting guide and overall. Refractive range was broad overall (sphere of -9.75 to +5.25 diopters; cylinder of -0.75 to ≤ +0.75 diopters axis of 1 to 180). Subjects' ADD power ranged from +0.50 to +2.50 diopters.

Table 2
Baseline subjective refraction and pupil size* (Safety Analysis Set).

Subjective Refraction	Modified Fitting Guide	Previous Fitting Guide	Overall
Sphere, diopter			
n	198	166	364
Mean (SD)	−2.72 (3.29)	−2.51 (2.63)	−2.62 (3.00)
Range	−9.25, +5.25	−9.75, +4.50	−9.75, +5.25
Axis			
n	138	119	257
Mean (SD)	88.9 (49.1)	96.6 (43.4)	92.5 (46.6)
Range	1, 180	10, 180	1, 180
ADD power, diopter			
n	198	166	364
Mean (SD)	1.63 (0.56)	1.64 (0.56)	1.64 (0.56)
Range	0.50, 2.50	0.50, 2.50	0.50, 2.50
Pupil size			
Photopic			
n	198	166	364
Mean (SD)	3.60 (0.84)	3.95 (1.02)	3.76 (0.94)
Range	2.0, 6.5	2.0, 7.5	2.0, 7.5
Intermediate			
n	198	166	364
Mean (SD)	4.53 (1.06)	4.78 (1.18)	4.65 (1.12)
Range	2.5, 7.0	2.0, 8.0	2.0, 8.0
Mesopic			
n	198	166	364
Mean (SD)	5.44 (1.22)	5.50	5.47 (1.27)
Range	3.0, 8.0	(2.5, 8.5)	2.5, 8.5

* Cylinder magnitude in this population was low (≤ 0.75D).

3.2. Effectiveness assessments

The primary objective of this study was to demonstrate the superiority of the modified MF fitting guide compared to the previous fitting guide, as determined by the mean number of trial lenses needed to fit each eye at the Screening/Fitting Visit for all MF lenses combined. The corresponding endpoint was the number of study lenses needed to fit each eye at the Screening/Fitting Visit, derived from number of on-eye lens prescriptions. Noninferiority was to be concluded if the one-sided 95% UCL for the fitting guide difference (modified minus previous) was less than 0.5 at the Screening/Fitting Visit.

The mean ± SD numbers of MF study lenses needed to fit each eye with the modified and previous MF fitting guides at Visit 1 were 1.2 ± 0.5 and 1.4 ± 0.5, respectively, with least squares means (LSM) ± SE of 1.2 ± 0.05 and 1.4 ± 0.06, respectively. The LSM difference was 0.2, and the 95% UCL was -0.1. As this UCL was less than 0.5, the modified fitting guide was noninferior to the previous fitting guide. Moreover, because this UCL was less than 0, the modified fitting guide was superior to the previous fitting guide.

At Visit 1, the percentage of eyes successfully fitted with one set of lenses was higher using the modified (82.8% [164/198]) than the previous (65.1% [108/166]) MF fitting guide (Fig. 2). The mean number of lenses required per eye for the modified and previous guide was 1.2 ± 0.6 and 1.4 ± 0.5, respectively. The percentage of subjects successfully fitted with one-to-two set of lenses was also higher using the modified (94.8%) than the previous (90.7% [164/166]) fitting guide, and the mean number of lenses required per eye for a successful fit was 1.4 ± 0.7 and 1.5 ± 0.7, respectively. The number of lenses used at Visit 1 for emerging (n = 140) and established presbyopes (n = 224) are shown in Fig. 3A–B. Among both emerging and established presbyopes, a greater proportion of subjects required only one set of lenses using the modified MF fitting guide compared with the previous fitting guide. For emerging presbyopes, 88.2% (67/76) and 78.1% (60/64) of eyes required one set of lenses for fitting with the modified and previous fitting guides, respectively. For established presbyopes, 79.5% (97/122) and 56.9% (58/102) of eyes required one set of lenses, respectively. Assessments by ECPs regarding ease of fit showed that a

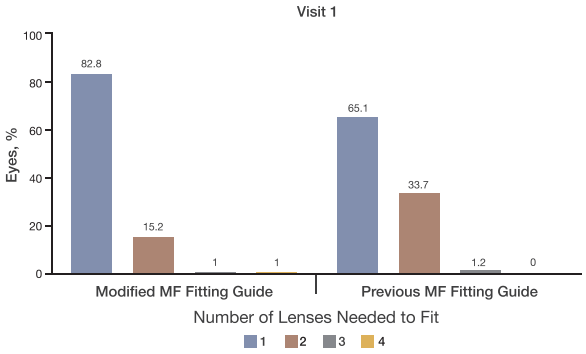
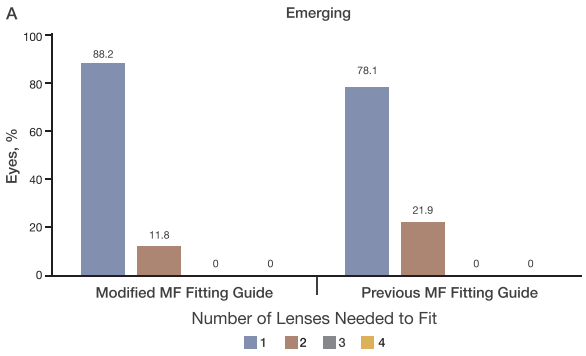


Fig. 2. Percentage of eyes requiring one, two, or three MF lenses for a successful fit at Visit 1 (screening/fitting visit) using the modified and previous MF Fitting Guides. MF, multifocal.



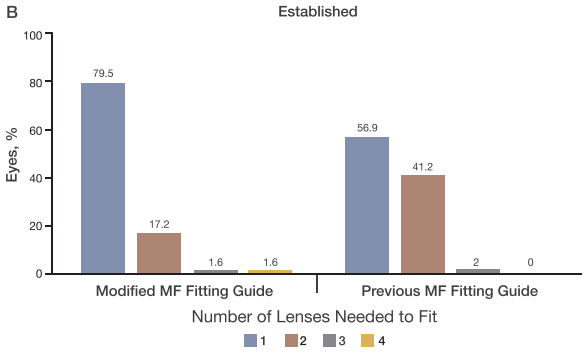


Fig. 3. Percentage of eyes requiring one or two MF lenses for a successful fit at Visit 1 (screening/fitting visit) in emerging and established presbyopes using the modified and previous MF Fitting Guides. MF, multifocal.

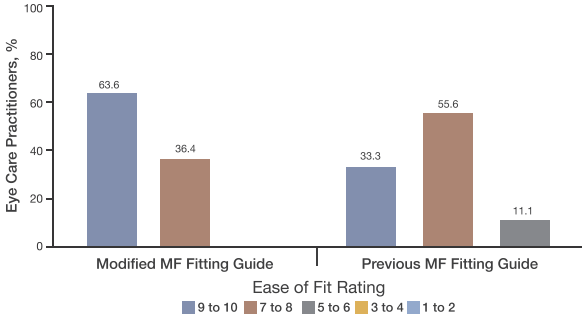


Fig. 4. Ease of fit ratings by eye care practitioners using a 10-point scale ranging from 1 (difficult) to 10 (easy) with the modified and previous MF Fitting Guides. MF, multifocal.

Table 3
Subjective ratings of vision quality for the successful fit.

Vision Quality*	Fitting	Modified Fitting Guide	Previous Fitting Guide
Near	Initial		
n		97	80
Mean (SD)		8.2 (1.8)	7.7 (2.3)
95% CI		7.9, 8.6	7.1, 8.2
Intermediate	Initial		
n		97	80
Mean (SD)		8.6 (1.4)	8.3 (1.5)
95% CI		8.3, 8.8	8.0, 8.6
Distance	Initial		
n		97	80
Mean (SD)		8.5 (1.2)	8.5 (1.3)
95% CI		8.3, 8.8	8.2, 8.8
Near	Successful		
n		96	75
Mean (SD)		7.8 (2.1)	7.4 (2.1)
95% CI		7.9, 8.6	6.9, 7.9
Intermediate	Successful		
n		96	75
Mean (SD)		8.4 (1.3)	8.2 (1.5)
95% CI		8.3, 8.8	7.9, 8.6
Distance	Successful		
n		96	75
Mean (SD)		8.4 (1.6)	8.5 (1.5)
95% CI		8.1, 8.8	8.2, 8.9
While driving			
n	Successful	96	75
Mean (SD)		8.3 (1.6)	8.3 (1.5)
95% CI		7.9, 8.6	8.0, 8.6
During computer use	Successful		
n		96	75
Mean (SD)		8.2 (1.7)	8.0 (1.6)
95% CI		7.8, 8.5	7.6, 8.4
During table/mobile phone use	Successful		
n		96	75
Mean (SD)		8.0 (2.0)	7.7 (1.8)
95% CI		7.5, 8.4	7.3, 8.1

* Scores are based on a scale of 9–10, with 0 being the worst and 10 being the best.

higher proportion rated ease of fit highest (9–10) with the modified (63.6% [7/11]) than the previous fitting guide (33.3% [3/9]) (Fig. 4).

3.3. Subjective ratings of vision quality

Subjects' ratings for vision quality are shown in Table 3. At both the initial and successful fittings, mean scores for near vision were comparable for lenses fitted using the modified and previous fitting guides. Comparisons between the fitting guides for intermediate and distance vision show a similar pattern. Mean scores for vision quality during activities reported at the successful fit visit included 8.3 ± 1.6 and 8.3 ± 1.5 for the modified and previous guides, respectively, during driving; 8.2 ± 1.7 (modified guide) and 8.0 ± 1.6 (previous guide) during computer use; and 8.0 ± 2.0 (modified guide) and 7.7 ± 1.8 during tablet/mobile phone use.

3.4. Safety

No serious AEs were reported during this study. Overall, 19 eyes in 13 subjects experienced 22 ocular non-serious AEs during the study, nine while wearing lotrafilcon B, 11 while wearing nelfilcon A, and two while wearing delefilcon A MF lenses. The most common ocular AEs were eye allergy (6 subjects; 6 eyes), eye irritation (5 subjects; 5 eyes), and ocular discomfort (5 subjects; 5 eyes). All ocular non-serious AEs were assessed as mild in severity and resolved. One subject wearing delefilcon A MF lenses was discontinued prior to study exit due to an ocular non-serious AE, a foreign body in the right eye, which was assessed as not related to the MF contact lens. Most biomicroscopy parameters were graded 0 (none) and 1 (trace) in all eyes and at all visits.

4. Discussion

This study demonstrated the superiority of a modified MF fitting guide over the previous fitting guide based on the number of sets of lenses required for fitting after establishing the noninferiority of the modified guide to the previous guide. This finding is supported by the 82.8% fitting success rate for one set of lenses using the modified MF guide, which is 18 percentage points higher than that with the previous fitting guide (65.1%), and the 98% fit success rate for up to two lenses. A previous study regarding lens fitting with lotrafilcon B, nelfilcon A, and delefilcon A lenses using the modified fitting guide showed successful fit rates of 96% or higher with up to 2 lenses [13], which is similar to the rates for fitting with up to 2 lenses seen for the modified MF fitting guide in this study. This rate for the modified guide was also higher than the 74% fit success rate with one set of lenses observed in a study of fitting of senofilcon A (Johnson & Johnson Vision Care, Jacksonville, FL, USA) MF lenses [14].

The high rates of successful fitting with one set of lenses using the modified guide are consistent with the data on ease of fit. ECPs gave higher ratings for ease of fit with the modified than with the previous MF fitting guide. In addition, subject-rated mean quality of vision for near and intermediate was numerically higher using the modified guide compared with the previous guide, as was mean functional quality of vision for computer and tablet/mobile device use. However, mean quality of vision at distance and mean functional quality of vision while driving was not affected. These results suggest that changes as small as 0.25 DS in the fitting guide can impact patient acceptance of MF contact lenses.

The population in this study had a broad refractive range, ADD power, and pupil sizes. The proportion of emerging and established presbyopes fitted with 1 set of lenses at Visit 1 with the modified fitting guide were similarly high, indicating that the modified fitting guide would be appropriate for a wide range of presbyopic patients. Subjects gave similarly high ratings for quality of vision at near, intermediate, and distance with lenses fitted using either the modified or previous fitting guides. Functional vision ratings during driving, using a computer, and using a cell phone/tablet were also comparably high for MF lenses fitted with the two guides.

These findings indicate that use of the modified fitting guide improves the efficiency of fitting presbyopic contact lens wearers with all the MF lenses used in this study. This increased efficiency will benefit ECPs, possibly by reducing chair time and potentially reducing the costs of fitting MF lenses. Furthermore, the need for fewer trial lenses may enhance subject confidence in their ECPs and in the performance of their MF contact lenses.

5. Conclusions

The modified fitting guideline developed for lotrafilcon B, nelfilcon A, and delefilcon A MF soft contact lenses is superior to the previous fitting guideline, as shown by the reduced number of MF lenses required to fit each eye at screening. Subjective assessments of vision showed that the modified and previous fitting guides both provide clear vision at near, intermediate, and far distances and during driving and while using a computer or a tablet or mobile phone. These findings were obtained in a subject population with a large range of refraction, ADD power, and pupil sizes, supporting the use of the modified fitting guide for a wide range of presbyopic patients.

Submission declaration

Portions of the study results have been presented previously at the

British Contact Lens Association 40th Clinical Conference & Exhibition, held June 9–11, 2017, in Liverpool, UK, and the American Optometric Association 121st annual meeting, June 20–24, 2018, in Denver, Colorado.

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Appendix A. Supplementary data

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