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Visual function, ocular surface integrity and symptomatology of a new extended depth-of-focus and a conventional multifocal contact lens

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ABSTRACT

Purpose: To evaluate visual function, ocular surface integrity and dry eye symptoms with an extended depth-of-focus (EDOF) design and a conventional multifocal (MF) contact lens (CL) after 15 days of wear.
Methods: A crossover single mask randomised clinical trial was conducted including 30 presbyopes who used an EDOF and a conventional MF CL (Biofinity MF) for 15 days each. Defocus curves, depth-of-focus range, contrast sensitivity (CS) under photopic and mesopic conditions (with and without glare) and subjective perception of halos and glare were evaluated. The ocular surface was evaluated through non-invasive Keratograph tear breakup time (NIKBUT), averaged tear breakup time (NIKBUT-avg), tear meniscus height (TMH), bulbar and limbal redness, and conjunctival and corneal staining. Dry eye symptoms were assessed with the OSDI questionnaire.
Results: No statistically significant differences were found for defocus curves or depth-of-focus between the two CLs (both $p > 0.05$). Subjective perception of halos and glare was not significantly different between CLs. Statistically significant differences were observed for CS under mesopic conditions for low spatial frequencies ($p = 0.008$). None of the CL produced significant changes in NIKBUT, NIKBUT-avg, TMH or redness. No change in conjunctival staining was observed in 76.7 % and 73.3 % of participants for EDOF and Biofinity MF, respectively. No change in corneal staining was observed in 86.7 % and 83.3 % of participants for EDOF and Biofinity MF, respectively. No changes were observed in the symptomatology measured with OSDI questionnaire ($p > 0.05$).
Conclusions: Both CL for presbyopia offer good visual quality, preserve the ocular surface integrity and provide the patient with similar symptomatology levels after 15 days of lens wear.

1. Introduction

Over one billion people suffer from presbyopia [1]. Due to the increase in the presbyopic population associated with an ageing population, a rise in multifocal contact lens (CL) fitting will be expected in the next few years [2,3]. However, despite improvements in multifocal options and lens designs, it is estimated that approximately 63 % of presbyopes are fitted with non-presbyopic correction [2].

There are currently a wide variety of multifocal designs and it has been previously reported that the multifocality design directly affects the discontinuation rate [4]. Currently, simultaneous-image CLs are the most prescribed multifocal CLs [5]. However, these designs are often associated with dysphotopsias such as halos and glare perception, decreased contrast sensitivity [6] and ghosting [7]. Additionally, they are influenced by pupil variations and illumination levels [8,9], which might be detrimental for quality of vision.

To overcome these limitations, new designs for presbyopia are being developed varying high order spherical aberration terms to induce an extended depth-of-focus (EDOF) [10]. Based on theoretical modelling, these lenses are less susceptible to inherent ocular aberrations, pupil variations and CL decentration [11], which might alleviate visual disturbances associated with multifocal designs. EDOF provide significantly improved intermediate and near vision without compromising distance vision and are, theoretically, pupil-independent, which may significantly facilitate fitting process [10].

Additionally, an often hypothesised reason for the low multifocal CL

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Table 1
Inclusion criteria.

Inclusion criteria
Age between 45 and 65 years
Best corrected distance visual acuity 20/20 or better in both eyes
Near addition power ≥ 0.75 D
Astigmatism ≤ 0.75 D
No history of ocular surgery
No history of ocular or systemic disorder known to interfere with CL wear
Willing to provide informed consent and follow the protocol

Table 2
Contact lens parameters.

	EDOF	BIOFINITY MF
Company	Mark'ennovy	Cooper Vision
Material	Filcon V3	Comfilcon A
Water content (%)	75	48
Base curve (mm)	7.10 – 9.80 (step 0.30)	8.60
Diameter (mm)	13.50 – 15.50 (step 0.50)	14.00
Spheres (D)	+18.00 to −18.00 (step 0.25)	+6.00 to −6.00 (step 0.25) −6.50 to −10.00 (step 0.50)
Addition power (D)	0.75, 1.50, 2.25	1.00–2.50 (step 0.50)
Dk	60	128
Oxygen Transmissibility (Dk/t)	75 (ct −3.00 0.08)	142 (ct 0.09)
Modulus (MPa)	0.29	0.75

EDOF: extended depth-of-focus; Dk: oxygen permeability; ct: central thickness.

prescription rate is the absence of a multifocal CL providing adequate comfort and satisfying visual demands. In fact, presbyopes graded comfort and visual quality as equally important regarding CL dropout [12] and prefer CL correction when both factors are successfully achieved [13].

However, the great majority of studies carried out with CLs for presbyopia have mainly focused on visual performance. This means there is a need to design and develop more satisfactory options to correct presbyopia and consider both comfort and vision as crucial factors for CL fitting success.

Therefore, the aim of this study was to objectively evaluate visual function, ocular surface integrity and dry eye symptomatology with an EDOF CL design and a conventional aspheric multifocal CL throughout 15 days of wear.

2. Methods

2.1. Design

A prospective, crossover, randomised, single-masked (participant) clinical trial was conducted at the Complutense University of Madrid. The study conformed to the principles of the Declaration of Helsinki and obtained ethical approval from the Ethics Committee of San Carlos University Hospital (Madrid, Spain). Participant-masking was achieved by using non-labelled lens packaging. Examiner masking was not feasible due to differences in visibility tints and contact lens diameter.

2.2. Participants

A total of 30 presbyopic participants were enrolled in the study. Inclusion criteria are summarised in Table 1. The enrolled participants included existing CL wearers and non-CL wearers. Signed informed consent was obtained from all participants prior to study procedures. A one-week washout period was required for habitual CL wearers.

Table 3
Subjective perception of halos and glare. Questionnaire score description.

Frequency (0−3)	Intensity(1−3)	Bothersome(0−3)
0: Never		0: Not at all
1: Occasionally	1: Mild	1: A little
2: Quite often	2: Moderate	2: Quite
3: Very often	3: Severe	3: Very

2.3. Contact lenses

The study was carried out using an investigational prototype of EDOF CL (Mark'ennovy) and the commercially available Biofinity Multifocal (MF) CL (CooperVision). Both simultaneous vision CLs were fitted according to the manufacturer's fitting guide. The EDOF CL was customised, and its parameters were obtained from the manufacturer's automatic calculator based on keratometry readings, anterior corneal eccentricity and horizontal visible iris diameter, measured with the Keratograph 5 M (K5 M; Oculus GmbH). Lens details are shown in Table 2.

The EDOF prototype alters spherical aberration terms to provide a non-monotonic, non-aspheric, aperiodic, non-diffractive, refractive power profile across the optic zone [10]. This means there are distinct zones for distance and near powers changing abruptly and non-equally separated across the optic zone. On the other hand, the Biofinity MF uses an aspheric, monotonic and aperiodic design [14], which provides a gradual change in power distribution from distance to near power (centre-distance, CD) or vice versa (centre-near, CN).

Low (≤1.25D), medium (1.50−1.75D) and high (≥2.00D) addition powers were used for the EDOF lenses, based on the manufacturer's fitting guide. For the Biofinity MF, a CD design was fitted in the dominant eye, whereas a CN design was fitted in the non-dominant eye for addition powers higher than +1.50D. For additions of +1.50D or less, a CD design was fitted in both eyes. The dominant eye was determined using the +1.50D blur test [15]. Biotrue® Multi-Purpose solution (Bauch&Lomb, New York, USA) was used for disinfecting, cleaning and storing both lenses.

2.4. Clinical assessments

2.4.1. Visual performance

Binocular defocus curves were measured under photopic conditions (85 cd/m^2) over the range +1.00 to −3.50D in 0.50D steps with randomised letter sequences in order to reduce memory effects, Afterwards, the depth-of-focus range was defined as the range of focusing errors for which the visual acuity (VA) did not decrease below 0.1 logMAR. All the visual acuity measurements for the defocus curves were assessed using a distance visual acuity retro-illuminated ETDRS chart. Near visual acuity was checked with a near optotype but was not considered for the analysis.

Binocular contrast sensitivity (CS) function was measured using the CSV-1000 test (VectorVision, Greenville, Ohio) with a logarithmic scale for 3, 6, 12 and 18 cycles per degree (cpd) under photopic (85 cd/m^2) and mesopic (3 cd/m^2) illumination conditions. A glare source consisting of halogen lamps positioned in the middle of both vertical sides of the chart was used under mesopic conditions to measure CS function with the effect of glare. All CS measurements were taken at a recommended 2.5 m test distance. The results were expressed in logarithmic units for the statistical analysis.

Participants rated the frequency (0−3 scale) and intensity (1−3 scale) of halos and glare, and how bothersome (0−3 scale) these visual disturbances were. Questionnaire score description is explained in Table 3. A final score was calculated as follows: *Frequency x [(Intensity x Bothersome)/2],* on a scale of 0–9.

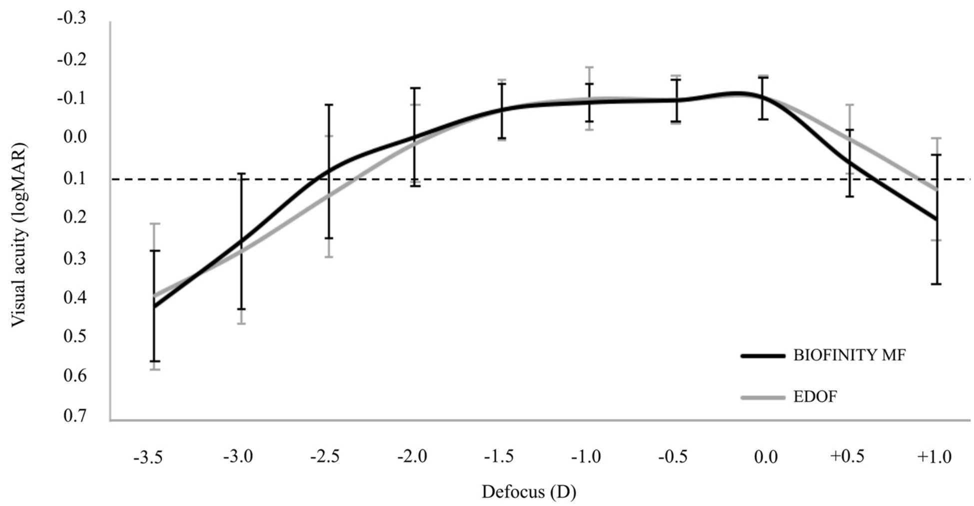

Fig. 1. Binocular defocus curves for EDOF CL and Biofinity MF on Day 15. Dash line indicates 0.1 logMAR visual acuity. Depth-of-focus range is defined as the range of vergences for which the visual acuity did not decrease below this line. $p > 0.05$ for all vergences. Data expressed as mean ± standard deviation.

2.4.2. Impact on ocular physiology

Ocular physiology was evaluated using the Keratograph 5 M. Measurements of tear meniscus height (TMH), objective non-invasive Keratograph first break-up time (NIKBUT), average of all break-up times (NIKBUT-avg), global ocular redness, bulbar temporal (BT), bulbar nasal (BN), limbal temporal (LT) and limbal nasal (LN) redness were obtained automatically from K5 M software. TMH values were measured perpendicularly to the lid margin in line with the pupil centre. For all redness parameters, the device generates a redness score based on the ratio between the blood vessels and the rest of the analysed area according to the JENVIS grading scale [16]. Corneal and conjunctival staining were measured using sodium fluorescein (FluoStrip, Contacare Ophthalmics and Diagnostics, Gujarat, India) and a cobalt blue filter. Images of staining were graded according to the Efron scale [17], range from 0 (normal) to 4 (severe).

2.4.3. Dry eye symptomatology

The Ocular Surface Disease Index (OSDI) questionnaire [18] was used to evaluate symptoms of ocular discomfort associated with dry eye. The questionnaire was completed under baseline conditions prior to lens fitting (after one-week washout period if necessary) and on Day 15 with each lens, and before conducting any clinical tests in order to avoid any influence on patient's response. The final score was calculated by the online calculator on a scale of 0–100 based on the following formula: OSDI = [(sum of scores for all questions answered) × 100] / [(total number of questions answered) × 4]. The higher the score, the more severe the symptoms and the greater the disability.

2.5. Study protocol

Visual performance metrics (defocus curves, contrast sensitivity and subjective perception of halos and glare) were measured on Day 15 of each lens wear (during lens wear). Ocular surface measurements were taken at baseline condition (with no lens and after one-week lens washout period) and on Day 15 of each lens right after CL removal. Participants were required to wear the lenses a minimum of 8 h per day. A one-week washout period was required between Day 15 of the first CL design and the baseline visit of the second CL.

All participants wore both CLs and the order of lens wear was randomised using a randomisation software (Randomisation generator, www.randomization.com). In order to minimise the effect of each clinical test on subsequent measurements, following the questionnaires, non-invasive tests were performed first, and corneal and conjunctival staining were performed last.

All examinations were performed by the same experienced CL practitioner. For the statistical analysis, one eye per participant was selected randomly.

2.6. Statistical analysis

The sample size was determined using the Epidat 4.2 software (http://dxsp.sergas.es) considering an error probability (α) of 0.05 and a required power (1-β) of 0.80, which produced an overall sample size of 20. 30 participants were recruited considering potential drop out during the study.

Descriptive and inferential data analyses were carried out using SPSS statistical package version 24 (SPSS, Inc, Chicago, IL). The Kolmogorov-Smirnov test was used to assess the normality of each variable. A two tailed paired *t*-test was applied for defocus curves and CS data to compare between Day 15 of each lens. The Wilcoxon signed rank test was applied for all other variables to compare between baseline and Day 15 of each lens (ocular surface variables and OSDI questionnaire), and between Day 15 of each lens (OSDI questionnaire and halo and glare questionnaire). Differences were considered statistically significant for $p < 0.05$.

3. Results

Thirty presbyopic participants (20 women and 10 men) with a mean age of 53.7 ± 5.3 years (range 45–64 years), with a mean myopic refraction of −2.18 ± 1.83 D, a mean hyperopic refraction of +1.84 ± 1.14 D (overall refractive error range from −5.50 to +4.00 D) and a mean near spectacle addition of +1.83 ± 0.40 D (range from +1.00 to +2.50 D) were enrolled in the study. Among the 30 participants, 20 were classified as high add, 8 as medium add and 2 as low add. 60 % of the participants had previously worn CLs, but none of them had worn multifocal CLs before.

3.1. Visual performance

Binocular defocus curves and depth-of-focus range values were measured on Day 15 after 8 h of wear. Fig. 1 shows no statistically significant differences for defocus curves between both CLs at any of the vergences (from −3.50 to +1.00 D) ($p > 0.05$ for all vergences). Depth-of-focus range values were 3.32 ± 0.61 D for EDOF CL and 3.21 ± 0.46 D for Biofinity MF, not being significantly different ($p = 0.521$).

Contrast sensitivity curves were measured on Day 15 after 8 h of wear. Fig. 2 shows binocular distance $\log_{10}$ CS under photopic, mesopic

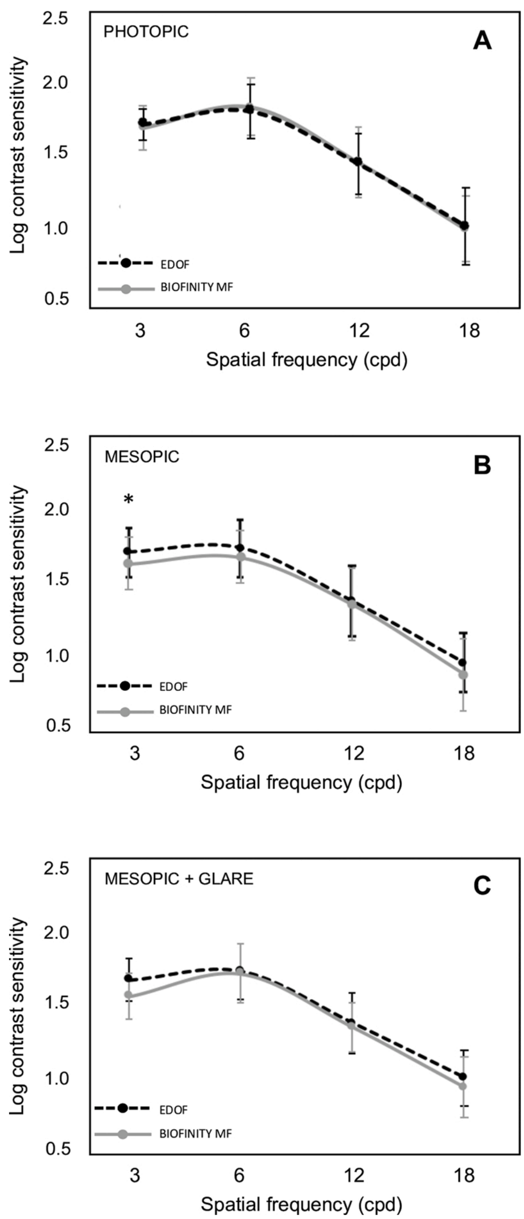

Fig. 2. Distance contrast sensitivity (CS) function on Day 15 with both multifocal CLs under photopic (A), mesopic (B) and mesopic with glare conditions (C). Data expressed in logarithmic units as mean ± standard deviation. Asterisk indicates statistical significance.

Table 4
Ocular surface parameters measured with the K5 M device. Results expressed as mean ± standard deviation.

	Baseline	Day 15	P-value
TMH (mm)			
EDOF	0.29 ± 0.11	0.28 ± 0.13	0.509
Biofinity MF	0.28 ± 0.10	0.27 ± 0.09	0.855
NIKBUT (sec)			
EDOF	9.31 ± 7.17	7.83 ± 5.75	0.648
Biofinity MF	8.32 ± 6.15	8.02 ± 5.87	0.776
NIKBUT-avg (sec)			
EDOF	12.36 ± 6.43	10.16 ± 5.86	0.191
Biofinity MF	11.34 ± 5.99	11.07 ± 6.26	0.650

EDOF: extended depth-of-focus; MF: multifocal; TMH: Tear meniscus Height; NIKBUT: Non-Invasive Keratograph Break-Up Time; NIKBUT-avg: average of all Break-Up Times.

and mesopic with glare conditions. Small statistically significant differences were observed for CS only under mesopic conditions for low spatial frequencies (3 cpd) ($p = 0.008$), being better for EDOF CL. The rest of the measurements remained similar between CLs ($p > 0.05$).

Both CLs induced a statistically similar perception of halos and glare visual phenomenon after 15 days of wear. Halo results were 1.36 ± 1.88 and 1.30 ± 1.42 units ($p = 0.687$) for EDOF and Biofinity MF, respectively, and glare results were 1.05 ± 1.29 and 1.20 ± 1.48 units ($p = 0.550$) for EDOF and Biofinity MF, respectively.

3.2. *Ocular physiology*

Regarding ocular surface parameters, Table 4 and Fig. 3 show the results of the variables measured with Keratograph 5 M (TMH, NIKBUT, NIKBUT-avg and ocular redness) at baseline and after 15 days of wear after CL removal. No statistically significant differences were found between both visits for any of the CL designs for TMH, NIKBUT, NIKBUT-avg and redness (all $p > 0.05$).

Changes in the conjunctival and corneal sodium fluorescein staining from baseline to Day 15 were evaluated for each lens. 76.7 % of participants exhibited no change in conjunctival staining after wearing the EDOF lens and 23.3 % increased by 1 point. For the Biofinity MF lens, 73.3 % of participants exhibited no change in conjunctival staining and 26.6 % increased by 1 point.

Regarding corneal staining, 86.7 % of participants exhibited no change after wearing the EDOF lens, while 13.3 % increased by 1 point. After wearing the Biofinity MF lens 83.3 % of participants exhibited no change while 16.6 % increased by 1 point.

3.3. *Subjective ocular symptoms*

Fig. 4 shows no statistically significant differences between baseline and after 15 days of lens wear for either design ($p = 0.073$ for EDOF, $p = 0.094$ for Biofinity MF) nor between Day 15 of each CL ($p = 0.110$).

4. Discussion

This crossover, randomised, single-masked clinical trial was performed to compared visual quality and performance, ocular physiological integrity and symptomatology of a novel extended depth-of-focus CL and a conventional aspheric multifocal design.

Defocus curves, depth-of-focus range, and contrast sensitivity function were measured to evaluate visual performance of two multifocal CL designs. Biofinity MF was considered as a representative of current multifocal CL designs, and was selected to participate in the study on account of a recent research [19], in which outperformed three other multifocal designs in terms of visual performance and impact on ocular physiology. Additionally, Biofinity MF is one of the most fitted multifocal contact lenses in the current market, which was an argument to choose these lenses. However, different contact lens design may have yielded different results.

The results of the current study supported that both simultaneous-image multifocal CLs provide good VA values for all vergences under photopic conditions, with no significant differences between designs. Biofinity MF obtained similar values in comparison to some studies [20] and slight variations compared to others [21], probably due to the difference in sample size. Additionally, defocus curve outcomes for EDOF were in accordance with a study conducted by Sha et al. [22] and slightly better compared to another study [23] conducted over 1 day, where multifocality adaptation played its role [20].

In regard to depth-of-focus range values, both multifocal designs performed similarly. Depth-of-focus, whether designed through manipulation of high order aberrations (EDOF) [10] or through the variation in the power profile across the lens (Biofinity MF) [24], provides comparable levels of depth-of-focus range between lenses.

To properly assess the visual function, CS was measured under

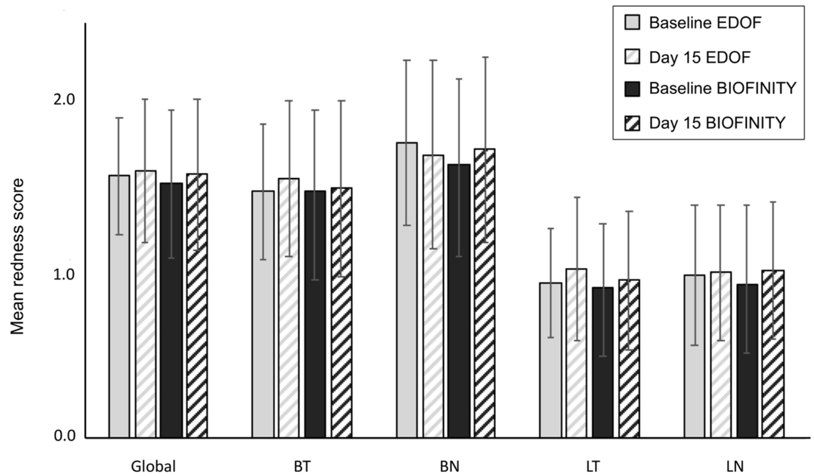

Fig. 3. Ocular redness measured with the K5 M device according to JENVIS grading scale for baseline and Day 15 of each CL. BN: bulbar temporal; BN: bulbar nasal; LT: limbal temporal; and LN: limbal nasal redness. Data expressed as mean ± standard deviation.

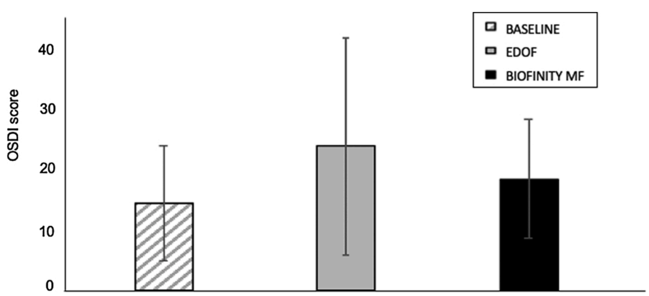

Fig. 4. OSDI values for baseline visit and after 15 days wearing EDOF and Biofinity MF CLs. Data expressed as mean ± standard deviation.

photopic, mesopic and mesopic with glare conditions. Previous studies have demonstrated that simultaneous-image multifocal CLs induce a deterioration of CS under photopic, mesopic and glare conditions when compared to monofocal or monovision [14,25]. Only statistically significant differences were found under mesopic conditions for low spatial frequencies, with EDOF obtaining better results. All other measurements were statistically similar between lenses, showing a comparable visual performance. CS function under photopic conditions for Biofinity MF is consistent with the literature for all spatial frequencies [21,26] and similar to another study [20] measured under glare conditions. However, these last results are not fully comparable because measurements with glare were taken under photopic conditions and not under mesopic conditions, as the current study.

EDOF results are also consistent with the literature for photopic CS for 18 cpd [23]. However, Bakaraju et al. [27] found slightly worse results for EDOF compared to the current study, mostly for 6 and 12 cpd under photopic conditions, probably due to multifocality adaptation (one more week of CL wear in the current study). Overall visual performance outcomes showed that EDOF provided comparable results to Biofinity MF with the added value of less pupil-dependence [11].

Beyond objective measurements, subjective measurements should be taken into consideration when it comes to evaluating patient satisfaction and visual performance with multifocal CLs [22,28]. Multifocality is known to induce deterioration in halometry [29]. However, no differences were found between CLs for subjective halo and glare perception, showing comparable results as well as being in accordance with a study conducted with EDOF CL and an aspheric design [22]. It should be noted that the questionnaire used was not validated, which can be considered as a potential limitation.

To the best of our knowledge, most multifocal CL studies focus on visual performance rather than on presbyopic ocular physiology. Accordingly, different ocular surface parameters were measured in this study to evaluate the interaction between the CLs and the ocular surface of presbyopes. Ocular physiology variables are in accordance with a study evaluating multifocal CL wear in presbyopes after 4 weeks, where no differences were found after lens removal for corneal staining, bulbar and limbal redness for Biofinity MF [19]. Overall ocular physiology outcomes showed no significant changes after each CL wear, as expected due to the same wearing modality and material similarities.

Regarding OSDI findings, no significant changes were observed between the baseline visit and 15 days after lens wear, despite the increase in the values after wearing time. This means that the severity of dry eye symptoms does not seem to be clearly affected by CL type. Several studies supported these results, showing no differences in OSDI values between three different silicone hydrogel CLs in first time CL users [30], and in ocular comfort in presbyopic patients after wearing two different multifocal CLs with different material [22,31]. However, it should be noted that multifocal CLs are manufactured in the same material as monofocal CLs. That is, the presbyopic population wear the same material as the young population, despite the increase in dry eye symptoms with age [32]. A recent study indicated that CLs do not behave the same way in the young population as in presbyopes, who reported more discomfort levels after 8 h than non-presbyopes [33]. The question arises whether a longer wearing period would have affected differently the ocular surface, which would allow researchers to determine if presbyopes require new or improved CL materials.

Although OSDI questionnaire is a validated and reliable questionnaire in assessing dry eye symptoms, different surveys, especially contact lens-specific surveys, may have yielded different results.

Thus, the conclusions of this study are that both CLs for presbyopia offer good visual quality and perform similarly in all visual performance variables, despite different optical designs. Additionally, they keep stable the ocular surface integrity as well as provide the patient with similar levels of symptomatology after 15 days of wear.

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Declaration of Competing Interest

The authors report no declarations of interest.

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