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A new method to analyse the effect of multifocal contact lenses on visual function

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ABSTRACT

Purpose: Presbyopic contact lens (CL) fittings produce simultaneous vision, providing different retinal images that reduce visual quality and wearers' satisfaction. The purpose of this study was to develop a new method to isolate the multifocality effect of different CL options to manage presbyopia, analysing the impact on binocular visual acuity (VA), stereopsis and contrast sensitivity (CS) and determining the effect of the use of a yellow filter (YF) on visual function.
Methods: A prospective and double-masked randomized pilot study involving 20 healthy volunteers was conducted. Four multifocal CLs and monovision CLs without far prescription were fitted. All subjects wore their spectacles over the CLs to guarantee optimum VA at distance. Binocular VA, stereopsis and CS were assessed after 20 min of CL wear with or without a YF of 455 nm.
Results: Binocular VA decreased with all multifocal CLs ($P < 0.05$), as did stereopsis ($P < 0.01$). All presbyopia correction reduced CS compared with spectacles ($P < 0.05$), except aspheric designs, at a frequency of 3 cycles/° ($P > 0.06$). Using the YF, visual function improved; better binocular VA was found with all multifocal CLs (statistically significant ($P < 0.02$) with both low-addition designs), and better CS was observed at most spatial frequencies (statistically significant ($P < 0.02$) at low frequencies with all CLs).
Conclusions: This pilot study proposes a simple method to analyse the impact of multifocal CL wear on VA, stereopsis and CS while maintaining habitual spectacle correction to assess the patient's short-term opinion and help practitioners and patients make a decision during presbyopia correction with CL fitting.

1. Introduction

Contact lenses (CLs) are used by more than 125 million people worldwide to correct refractive errors [1]. Moreover, a study on CL prescriptions to compensate for presbyopia in 38 countries found approximately 16,500 presbyopic wearers (over 45 years old) and nearly 20,000 pre-presbyopic wearers (between 35 and 44 years old) among a total of 105,734 CL fittings [2]. With increases in life expectancy, presbyopic CL fittings are becoming more common and will continue to increase in frequency in the future [3].

Currently, different ways to achieve presbyopia compensation with CLs have been proposed [4]. Monovision involves fitting one eye for distance (usually the dominant eye) and the other eye for near distance, significantly reducing stereopsis [5]. Bifocal CLs are available with two basic designs: "alternating" vision and "simultaneous" vision [2]. Alternating vision lenses (usually rigid gas-permeable CLs) involve a translating bifocal design that relies on eyelid-lens interactions to position the appropriate optical portion of the lens in front of the pupil. Independent of the lens' material, simultaneous vision lenses are available with different designs: concentric, diffractive, aspheric and balanced optical [2,6]. Simultaneous vision lenses simultaneously position the distance and near portions of the lens over different parts of the pupil [2,6].

Currently, the most common CLs fitted for presbyopia management are soft CLs with aspheric or balanced progressive designs [7,8]. However, these designs may limit the wearer's visual function quality, inducing ghosting, halos, visual fluctuation or impaired facial recognition [8], in turn all reducing the wearer's satisfaction. The quality of vision

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is decreased because the retinal image is poor, which is related to different issues: increases in patient pupil diameter, ocular aberrations, ocular dominance, CL position (increasing with CL decentration) or a defocused CL power profile [8–13].

Because CLs with simultaneous vision design provide different retinal images (simultaneous images of far and near objects), neural adaptation is necessary for optimal visual performance. Multifocal CLs enable the partial recovery of binocular neural functions better than monovision CLs, which do not permit recovery of stereopsis [5,13,14].

However, the mechanism of neural adaptation to multifocality is not well known. One hypothesis regarding adaptation supposes that the brain suppresses the blurred component of the simultaneous image. Moreover, the neural adaptation mechanism may be similar to the mechanisms of pure defocus and multifocal defocus [14]. This process may be different between subjects because of differences in visual optics and the neural code for blurring. For these reasons, multifocal CL designs should produce the best retinal image possible to ensure optimal neural adaptation, with a minimal impact on binocular visual acuity (VA), stereopsis and contrast sensitivity (CS) [11,14]. This approach should reduce the multifocal fitting dropout rate and achieve comfortable fittings with satisfactory visual quality.

Currently, there is no accepted method for assessing the impact of presbyopia correction on visual function during the adaptation process. This type of method could be of great utility to guide presbyopic patients in the process of CL fitting, demonstrating vision through a multifocal CL in order to increase fitting success and the wearer's satisfaction.

The purpose of the present study was to develop a new method to isolate the addition effect of different alternatives to presbyopia correction with CLs, analysing the impact on binocular VA, stereopsis and CS after a short time of CL wear and determining the effect of the use of a yellow filter (YF) of 455 nm. This method could help practitioners and patients during the fitting procedure for presbyopia compensation with CLs.

2. Materials and methods

2.1. Study design

A prospective and double-masked randomized pilot study involving 20 healthy volunteers between 18 and 30 years old was conducted. Complete optometric exploration was carried out to verify the inclusion criteria: corrected monocular and binocular VA better than 6/6.7 (Snellen scale), spherical refraction of ±6.00 D, cylinder lower than 2.00 D, stereopsis better than 60" and an absence of systemic or eye pathology. Informed consent was obtained from each subject after the Human Sciences Ethics Committee of the University of Valladolid granted approval of the study. All subjects were treated in accordance with the Declaration of Helsinki.

2.2. Materials and procedure

Binocular VA was measured under photopic conditions at 6 m of distance with the Snellen chart included in a projector ACP-7 (Topcon, Tokio, Japan) and recorded on the decimal scale to facilitate statistical analysis [11]. Stereopsis was measured with the TNO test (OOTECH Lameris, Nieuwegein, Holland) at 40 cm under photopic conditions with red-green spectacles. CS was measured with the CSV1000 test (VectorVision, USA) at frequencies of 3, 6, 12 and 18 cycles/degree at 2.4 m of distance under mesopic conditions [11]. A YF selectively transmitted 100% of light wavelengths greater than 500 nm and 80% between 455 nm and 500 nm and blocked the remainder (below 455 nm).

Binocular VA, stereopsis and CS were measured with each subject's best spectacle correction at baseline. Ocular dominance was determined with the "hole in the card" test [10,15]. Near binocular VA was not measured because accommodation was not paralysed and the VA could have been affected.

In the same session, 5 different types of CLs, with neutral power to far distance (except in monovision correction), were fitted to each subject with a crossover, randomized and double-masked design:

- Aspheric multifocal CL with low (+0.75 D to +1.50 D) and high (+1.75 D to +2.50 D) addition (PureVision 2, Bausch & Lomb) with neutral power to far distance (all with 8.6 mm back optic zone radius and 14.00 mm total diameter).
- Balanced progressive technology (BPT) with low (+1.50 D) and high (+2.50 D) addition (Biofinity Multifocal, Cooper Vision) with neutral power to far distance (all with 8.6 mm back optic zone radius and 14.00 mm total diameter). A CL with distance design in the centre for far distance was fitted in the dominant eye, and a CL with near design in the centre, which optimizes near vision, was fitted in the non-dominant eye.
- Monovision (MyDay, CooperVision) with far distance −0.25 D was fitted in the dominant eye and with +1.75 D to near distance was fitted in the non-dominant eye (all with 8.4 mm back optic zone radius and 14.20 mm total diameter). A −0.25 D CL was fitted in the dominant eye to guarantee the double-masked study design.

All subjects wore their spectacle corrections over the CLs to guarantee the correct ametropia correction, isolating the effect caused by the CL fitting (with a monovision or multifocal CL) for presbyopia correction. Binocular VA, stereopsis and CS were recorded 20 min after CL insertion with or without the YF (cut-off wavelength of 455 nm). The CLs were then removed, and the ocular surfaces were assessed with slit lamp biomicroscopy to evaluate any possible CL-related complications (ISO 11980 recommendations) [16]. A washout period of 15 min between CL removal and new CL insertion was used.

2.3. Data analysis

Statistical analysis was performed using the SPSS 15.0 (SPSS, Chicago, IL, USA) statistical package for Windows. The non-parametric data distribution was verified with the Kolmogorov-Smirnov test ($P < 0.05$ indicated that the data were non-parametrically distributed). The results are presented as the mean ± standard deviation (SD) and 95% confidence interval (CI). The Wilcoxon non-parametric paired test was used to compare the VA, CS and stereopsis achieved with each CL against the baseline value (with use of spectacles).

VA, CS and stereopsis differences for each CL fitted were compared with the Friedman test ($P < 0.05$ was considered significant). The effect of addition, and specifically low versus high power, was also assessed and compared using the Wilcoxon non-parametric paired test ($P < 0.05$ was considered significant).

Finally, VA and CS achieved with and without the YF were also compared using the Wilcoxon non-parametric paired test ($P < 0.05$ was considered significant).

3. Results

Twenty healthy subjects (12 women and 8 men) with an average age of 23.57 ± 3.08 years and an average spherical equivalent refraction of −1.37 ± 1.64 dioptres were enrolled in the study. No relevant clinical biomicroscopic signs (grade >1 according to ISO 11980) [16] of CL complications (corneal oedema, corneal staining, infiltrates, corneal vascularization, or other) were found during or following use of all CLs.

3.1. Binocular visual acuity

Binocular VA decreased with all multifocal CLs assessed ($P < 0.05$), showing a worsening when addition increased ($P < 0.01$), as shown in Table 1. Binocular VA with monovision was similar ($P = 0.13$) to that achieved with spectacles.

3.2. Stereopsis

Monovision showed the greatest decrease in the stereopsis value ($P < 0.01$), but all multifocal CLs reduced stereopsis ($P \leq 0.01$) as well. Table 1 summarizes the stereopsis outcomes.

Pairwise comparison (Wilcoxon test) of the stereopsis achieved wearing each multifocal CL showed non-statistically significant differences between CL designs ($P > 0.28$) and power additions ($P > 0.05$).

3.3. Contrast sensitivity

All multifocal CLs reduced CS compared with spectacles ($P < 0.05$), except aspheric designs (with both high and low addition) at a frequency of 3 cycles/degree ($P = 0.58$ and 0.78, respectively) (Table 2 and Fig. 1). CS was statistically significantly worse with BPT designs than with aspheric CL designs ($P < 0.01$), except with low addition at 12 or 18 cycles/degree frequencies, with non-statistically significant differences found ($P > 0.13$). When addition increased, CS showed a statistically significant ($P < 0.02$) greater reduction with BPT designs at all frequencies; however, with aspheric designs, this reduction was statistically significant ($P < 0.01$) only at a frequency of 6 cycles/degree.

3.4. Yellow filter

Improvement of the binocular VA was found with habitual spectacle correction and with all multifocal CLs using the YF (Table 1), but this change was statistically significant ($P < 0.02$) only with low-addition CLs for both tested designs (aspheric and BPT). CS outcomes increased using the YF at most spatial frequencies, as shown in Table 2, but this change was statistically significant ($P < 0.02$) only at low frequencies (3 cycles/degree) for all CLs tested and at high frequencies (18 cycles/degree) for high-addition aspheric CL design ($P = 0.04$). High CS frequencies showed a non-statistically significant ($P > 0.71$) small decrease with the YF.

4. Discussion

Presbyopia correction with multifocal or monovision CLs combines different lens designs (spherical and aspheric optics) to be respectively fitted on the dominant and non-dominant eyes [2,6]. It is difficult to make strict comparisons between studies because the factors that both directly and indirectly influence visual function (VA, stereopsis and CS) are not controlled across all studies with respect to differences in the methodology used to measure VA, reading addition, pupil size, and other parameters. Moreover, visual performance is also affected by other factors, such as the CL power profile, the CL design and the refractive error to be corrected [12,17]. Ocular ageing produces degradation of ocular optics, with loss of ocular transparency and the balance between corneal aberrations and the internal surfaces [18–20]. Over time, these changes could influence the adaptation process for the blurred image [14]. Other factors, such as ocular dominance, aberrations and pupillary diameter, seem to have little importance in neural adaptation to presbyopia correction [11,13].

The differences in visual function with multifocal CLs [21] could be related to the process of neural adaptation to the blurred image. For this reason, the subjective perception of patients can be an important measure [11,22] in addition to the clinical measurements of visual function. In practice, there are methods to evaluate each subject's opinion, but new methods are needed to understand the wearer's process of adaptation to multifocal CL fitting. Woods et al. [23] reported a rate of subjective dissatisfaction of 12% (n = 50) among multifocal CL and monovision CL wearers after two weeks of adaptation (measured at the third, seventh and twelfth days), declaring that both designs provided unacceptable visual quality. Studies with one week or more of adaptation did not show differences in visual function or reported small differences that usually affected the stereopsis value [3,24]. An increase in the wearing time of more than one week could not reduce the initial decrease in patients' quality of vision. Monovision CL fitting appears to result in more differences in the retinal image between the two eyes and may need more time for neural adaptation than multifocal CLs do (which require less than two weeks) [3,23].

The study aim was to analyse the initial state of vision, before neural adaptation starts. To develop a new method to isolate the im-

Table 1
Outcomes for binocular visual acuity (average ± standard deviation and 95% confidence interval) with and without yellow filter and stereopsis.

	Binocular visual acuity			Stereopsis
	Without YF Mean ± SD (95% CI)	With YF Mean ± SD (95% CI)	P-value*	Mean ± SD (95% CI)
Spc	1.44 ± 0.25 (1.32, 1.55)	1.50 ± 0.31 (1.38, 1.62)	0.07	51.75 ± 14.98 (43.96, 58.67)
MV	1.35 ± 0.29 (1.21, 1.48)	1.39 ± 0.26 (1.27, 1.51)	0.24	312.63 ± 155.66 (237.60, 387.66)
P-value**	0.25	0.13	–	< 0.01
Asph Low	1.11 ± 0.20 (1.01, 1.20)	1.19 ± 0.21 (1.09, 1.29)	0.01	115.15 ± 111.76 (63.08, 173.02)
P-value**	< 0.01	< 0.01	–	0.01
Asph High	0.96 ± 0.24 (0.85, 1.08)	1.00 ± 0.22 (0.90, 1.11)	0.25	137.25 ± 135.33 (74.91, 207.72)
P-value**	< 0.01	< 0.01	–	< 0.01
BPT +1.50	1.11 ± 0.28 (0.98, 1.24)	1.21 ± 0.25 (1.09, 1.32)	0.01	124.50 ± 111.09 (73.40, 182.39)
P-value**	< 0.01	< 0.01	–	< 0.01
BPT +2.50	0.89 ± 0.25 (0.77, 1.01)	0.95 ± 0.21 (0.85, 1.04)	0.06	164.25 ± 112.19 (115.52, 223.95)
P-value**	< 0.01	< 0.01	–	< 0.01
P-value***	< 0.01	< 0.01	–	< 0.01

P-value* = Difference with yellow filter compared with without yellow filter (Wilcoxon test); P-value** = Difference with spectacles (Wilcoxon test); P-value*** = Difference achieved with all CLs (Friedman test); Spc: Spectacles; MV: Monovision; Asph Low: Aspheric with low addition; Asph high: Aspheric with high addition; BPT +1.50: Balanced progressive technology with addition of +1.50 D; BPT +2.50: Balanced progressive technology with addition of +2.50 D; and YF: Yellow filter

Table 2
Outcomes for binocular contrast sensitivity (average ± standard deviation and 95% confidence interval) with and without yellow filter at four spatial frequencies in CSV1000 test.

	Contrast sensitivity											
	3 c/d			6 c/d			12 c/d			18 c/d		
	Without YF Mean ± SD (95% CI)	With YF Mean ± SD (95% CI)	P-value*	Without YF Mean ± SD (95% CI)	With YF Mean ± SD (95% CI)	P-value*	Without YF Mean ± SD (95% CI)	With YF Mean ± SD (95% CI)	P-value*	Without YF Mean ± SD (95% CI)	With YF Mean ± SD (95% CI)	P-value*
Spc	5.75 ± 0.64 (5.45, 6.05)	6.30 ± 1.22 (5.73, 6.87)	0.06	7.00 ± 0.86 (6.60, 7.40)	7.15 ± 0.81 (6.77, 7.53)	0.05	7.35 ± 0.75 (7.00, 7.70)	7.30 ± 0.98 (6.84, 7.76)	0.80	7.50 ± 0.83 (7.11, 7.89)	7.55 ± 0.76 (7.20, 7.91)	0.78
MV	5.30 ± 0.98 (4.84, 5.76)	5.85 ± 0.99 (5.39, 6.31)	0.02	5.60 ± 0.99 (5.13, 6.07)	6.10 ± 1.41 (5.44, 6.76)	0.06	5.95 ± 1.36 (5.32, 6.59)	6.10 ± 1.55 (5.37, 6.83)	0.58	6.50 ± 1.50 (5.80, 7.20)	6.25 ± 1.65 (5.48, 7.02)	0.27
P-value**	0.04	0.22	–	<0.01	0.01	–	<0.01	0.01	–	0.03	<0.01	–
Asph Low	5.70 ± 0.80 (5.33, 6.08)	6.25 ± 0.85 (5.85, 6.65)	0.01	6.35 ± 1.09 (5.84, 6.86)	6.45 ± 0.89 (6.04, 6.87)	0.05	5.95 ± 0.94 (5.51, 6.39)	6.00 ± 1.08 (5.50, 6.50)	1.00	6.50 ± 1.24 (5.92, 7.08)	6.25 ± 1.59 (5.51, 6.99)	0.33
P-value**	0.78	0.87	–	0.04	0.01	–	<0.01	<0.01	–	0.01	<0.01	–
Asph High	5.45 ± 0.89 (5.04, 5.87)	5.95 ± 0.83 (5.56, 6.34)	0.02	5.15 ± 1.35 (4.52, 5.78)	5.50 ± 1.28 (4.90, 6.10)	0.12	5.75 ± 0.85 (5.35, 6.15)	6.00 ± 1.34 (5.37, 6.63)	0.28	5.90 ± 0.91 (5.47, 6.33)	6.50 ± 1.36 (5.87, 7.14)	0.04
P-value**	0.58	0.28	–	<0.01	<0.01	–	<0.01	<0.01	–	<0.01	0.01	–
BPT +1.50	5.05 ± 1.00 (4.58, 5.52)	5.50 ± 1.00 (5.03, 5.97)	0.02	5.20 ± 1.15 (4.66, 5.74)	5.45 ± 1.15 (4.91, 5.99)	0.13	5.60 ± 1.19 (5.04, 6.16)	5.50 ± 1.40 (4.85, 6.15)	0.71	6.00 ± 1.21 (5.43, 6.57)	5.95 ± 1.23 (5.37, 6.53)	0.79
P-value**	0.03	0.04	–	<0.01	<0.01	–	<0.01	<0.01	–	<0.01	<0.01	–
BPT +2.50	4.20 ± 1.06 (3.71, 4.69)	4.95 ± 1.15 (4.41, 5.47)	<0.01	4.15 ± 1.18 (3.60, 4.70)	4.05 ± 1.39 (3.39, 4.70)	0.78	4.35 ± 1.46 (3.67, 5.03)	4.55 ± 1.64 (3.78, 5.32)	0.55	4.65 ± 1.69 (3.86, 5.44)	4.55 ± 1.85 (3.68, 5.42)	0.68
P-value**	<0.01	<0.01	–	<0.01	<0.01	–	<0.01	<0.01	–	<0.01	<0.01	–
P-value***	<0.01	<0.01	–	<0.01	<0.01	–	<0.01	<0.01	–	<0.01	<0.01	–

P-value* = Difference with yellow filter compared with without yellow filter (Wilcoxon test); P-value** = Difference with binocular vision via spectacles (Wilcoxon test); P-value*** = Difference achieved with all CLs (Friedman test); Spc: Spectacles; MV: Monovision; Asph Low: Aspheric with low addition; Asph high: Aspheric with high addition; BPT +1.50: Balanced progressive technology with addition of +1.50 D; BPT +2.50: Balanced progressive technology with addition of +2.50 D; YF: Yellow filter; and c/d: cycles per degree.

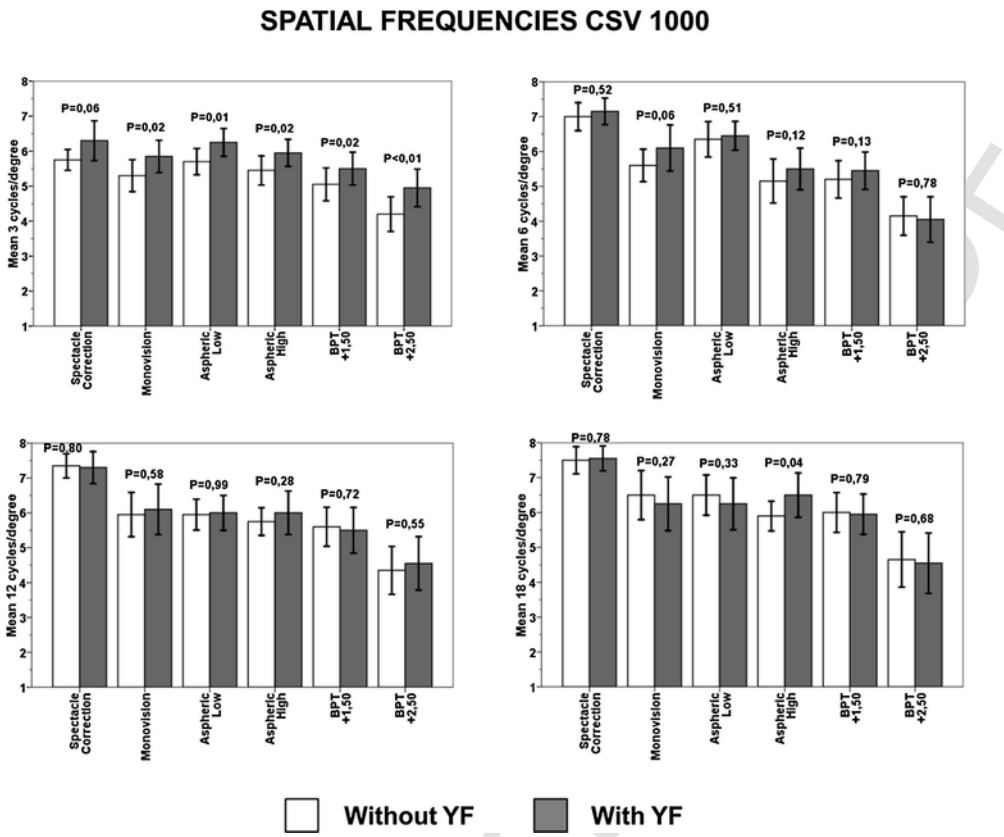

Fig. 1. Representation of contrast sensitivity values for each CL fitting and spectacle correction, with 95% confidence intervals and P-values.Top left, frequency of 3 cycles/degree. Top right, frequency of 6 cycles/degree. Bottom left, frequency of 12 cycles/degree. Bottom right, frequency of 18 cycles/degree.

pact of addition on vision, measurements were conducted 20 min after CL insertion. Moreover, subjects used their spectacle correction, wearing multifocal and monovision CLs to isolate the addition effect and ensure proper correction of the spherical and cylinder refraction. This method allows patients to experience the first sensation of multifocal correction, along with measurement of binocular VA, stereopsis and CS. These results could complement patients' comparisons between different CL designs or their comparisons with prescribed multifocal CLs, facilitating measurement of the impact of presbyopia correction on quality of vision. This information could be of great value in choosing the most adequate CL design. The simple test could also reduce the wearing time in cases with short-term unacceptable sensation. Patients could be re-fitted with different CL designs, helping to minimize dropout.

Binocular VA may be less affected by multifocal adaptation because its quality remains high, without statistically significant differences [3,9]. The results showed that binocular VA does not decrease with monovision correction compared with VA with spectacles. Gupta et al. [5] reported significantly better VA (distance and near) with monovision than that achieved with multifocal CLs in this study [9]. Binocular VA seems to be the same with monovision CLs, multifocal CLs or spectacle correction [3,15,23]. However, Llorente-Guillemot et al. [25] reported differences in binocular VA between spectacles and multifocal CLs (near and distance under mesopic and photopic conditions).

Stereopsis [3,15] is reduced with multifocal CLs and even more with monovision CLs [5,23], as study results showed. Sivardeen et al. [9] found statistically significantly improved stereopsis with BPT than with aspheric CL designs and monovision, in contrast to the results presented in Table 1.

Certain studies have reported that CS decreases with age [20], especially with early cataracts [19]. However, many reports have confirmed that multifocal CL wear decreases CS, especially at the beginning of wear [5,9,17,25]. The outcomes suggest that aspheric designs could offer better CS than BPT designs. These differences could be related to patient characteristics (age, refraction, and degree of presbyopia, among others), making comparison between studies difficult [3,5,23,24].

Using a YF could increase VA and CS at low and middle-range spatial frequencies (1.5 to 6 cycles/degree) [26,27], as was found in this study. However, none statistically significant VA improvement was found [28], probably due to the small sample size. More research is necessary before recommending the use of a YF to improve visual function with the use of multifocal CLs.

There is no consensus among studies on multifocal CLs, and it is necessary to propose studies reducing the number of variables. Sivardeen et al. [11] analysed previous studies and examined the differences in design and measurements. Their outcomes showed statistically significant differences in defocus curve profiles between the CLs used. However, this study did not find correlations between pupil size, aberrations and CL decentration, which do not seem to be affected by CL design but may be related to patient selection in terms of success in presbyopia compensation with CLs. For these reasons, it may be difficult to conclude that certain designs are better or to find a relationship between the CL design and patient characteristics (age, refractive error or pupillary diameter). It is possible that studies with fewer variables [8,13] could find stronger correlations in cases in which fitting fails. For this reason, this new method is proposed to eliminate the refractive error effect using spectacles and all CLs with neutral power at distance during the first trial of presbyopia management with CLs. This simple test could be of great utility to patients and eye care practitioners because patients could have a real experience of the impact of multifocality on over their vision, which could in turn help in the choice and acceptance of different CL designs.

This study has certain limitations. It was a pilot study with a small sample size and with young participants, and because the study design tries to isolate the presbyopia correction effect with CLs to compare different CL designs, the results cannot be extrapolated to visual function in presbyopic patients. Choosing a young sample of non-presbyopic patients could be criticized, but with this sample of patients any effect of ocular ageing on the results is avoided, so the detected differences in visual function are likely related to presbyopia correction with CLs. Additionally, accommodation affects inadequacies in near binocular VA values. However, this study provided a new method to analyse the short-term effect of presbyopia correction on patients' perception, which could help to improve the fitting success of multifocal CLs in the future. Further research, including study of presbyopic populations, is required to assess the impact of this method in such groups. Moreover, it is necessary to conduct more studies to improve presbyopia correction designs, reducing their impact on visual function. The method described here provides a simple and rational way to assess this impact, which could help in monitoring visual function during the adaptation period.

In conclusion, this pilot study developed a new method to analyse the effect of multifocal CLs on binocular VA, stereopsis and CS using the habitual spectacle correction of the subject. This method allowed comparison of the effects of CL designs on visual function, isolating the effect of multifocality. This method could be useful in pre-fitting multifocal CLs, but more research involving presbyopic patients and long-term follow-up will be necessary to prove its clinical applicability.

Disclosure

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