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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 is decreased because the retinal image is poor, which is related to different issues: increases in patient pupil diameter, ocular

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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  $\pm 6.00$  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, Tokyo, 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  $\pm$  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  $23.57 \pm 3.08$  years and an average spherical equivalent refraction of  $-1.37 \pm 1.64$  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.

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