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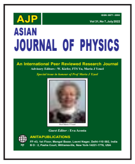

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Halo in extended depth of focus and bifocal intraocular lenses

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Dedicated to Prof Maria J Yzuel (Invited Article)

This work aims to evaluate the size and intensity of the halos generated in distance vision by bifocal and extended depth of focus (EDOF) intraocular lenses (IOLs) as a function of pupil size, lens base power and lens addition. To this end, an EDOF-IOL (Tecnis® Symfony ZXR00) and three bifocal IOLs (Tecnis® +4.00 diopter (D) ZMB00, +3.25D ZLB00 and +2.75D ZKB00) of the same material and asphericity, were tested *in-vitro* in a model eye. The size and intensity of the halos formed in the distance focus were experimentally obtained and measured using image analysis. Geometrical optics was used to theoretically estimate the halo size. We obtained the following results: The experimental halo size in the distance focus agreed with the theoretical estimation and was directly proportional to the pupil size and lens add power, and inversely proportional to eye power (cornea plus IOL power). As for the halo intensity, the larger the halo size, the dimmer it was. The EDOF IOL, with the lowest add power, had the smallest size but brightest halo. Concerning the halo size, the worst conditions (i.e., largest halos) would occur with an IOL of reduced base power (as would be the case of highly myopic patients), large add power, and large pupil. However, the relative intensity of the halo decreases as its size increases. These results contribute to the better understanding of the physical factors (size and/or intensity) that may have an influence on subjective halo perception by patients implanted with such IOLs.

Keywords: Cataract, presbyopia compensation, halos, extended depth of focus, intraocular lens, diffractive multifocal lens

1 Introduction

Multiple studies up to date have shown that the implantation of diffractive bifocal intraocular lenses (IOLs) for cataract or presbyopia correction effectively increases depth of field and enhances near vision while maintaining good visual acuity for distant objects (e.g. [1] and references contained therein). Nevertheless, it is also widely recognized in the clinical community that some of the currently available bifocal IOLs have several drawbacks, such as unsatisfactory visual acuity at intermediate distances [2], reduction of contrast sensitivity compared to monofocal IOLs [3] and induction of photic phenomena like dysphotopsia, glare and halos [4]. With regard to this, new designs such as Tecnis® Symfony ZXR00 IOL claim to provide an extended depth of focus (EDOF) while inducing little photic phenomena.

Glare, halo perception and/or dysphotopsia are recurrently mentioned as one of the main causes for patient dissatisfaction after multifocal IOL implantation [5]. Glare and halo are commonly experienced under dim lighting conditions, for instance, when looking at a spotlight source at night such as car headlights. Even though the discomfort produced by glare and halo tend to mitigate with time, Kamiya *et al* reported in a recent study [6] that halos and glare were the second complaint (after waxy vision) for IOL explantation. This has fueled interest in developing psychophysical halometers [7,8] as well as the use of halo and glare

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simulators [9] to quantify more objectively the level of photic phenomena in patients as another relevant outcome of their visual performance [10].

Complementary to clinical assessment, *in-vitro* optical bench testing of diffractive bifocal [11,12] or EDOF [13-15] IOLs is objective, patient independent, and offers the possibility of controlling factors that are difficult to address in clinical essays such as the pupil size, lens alignment and level of corneal wavefront aberration upon the tested IOL. Pieh *et al* [16] used a computer program to generate and measure the halo diameter in 24 patients with one refractive multifocal IOL and showed a good agreement with the predicted halo size but only as a function of the IOL near addition (+3.5D) and for a single pupil size (3 mm). Alba-Bueno *et al* [17] included in their analysis another important characteristic of the halo: the intensity, which is defined as the halo energy divided by the halo size. For various designs of multifocal IOL (such as refractive, diffractive, apodized, full aperture, and trifocal), the authors showed how the distribution of energy between the foci has an influence on the halo intensity. Yoo *et al* [18] compared the halo generated in an optical test bench in the case of a monofocal, two bifocals (low add and high add power) and a diffractive EDOF. They evaluated the relative halo intensity as a function of defocus to show a negative correlation with the modulation transfer function. None of the aforementioned papers analyzed the influence of the IOL base power on halo features.

In this paper, we carry out a comprehensive study of the halos formed by one EDOF and three bifocal IOLs of increasing near addition, by determining their physical characteristics of size, energy and intensity as a function of the pupil size, lens base power and near add. A monofocal IOL was also included as reference for comparison. Halo measurements and results concern the distance focus of all lenses. They are presented and compared with theoretical estimations obtained using geometrical optics.

2 Materials and methods

2.1 Intraocular lenses

We studied the following Tecnis® (Johnson & Johnson) IOLs: bifocal ZKB00 (+2.75D), ZLB00 (+3.25D) and ZMB00 (+4.0D) IOLs, EDOF Symfony ZXR00 IOL, and monofocal ZCB00 IOL. They all are made of the same material (hydrophobic acrylic, refractive index 1.47) and share the same wavefront aspheric optics design, which implies that for any pupil size, they compensate for the same amount of spherical aberration (SA) of the cornea. The maximum compensation of SA provided by these lenses is –0.27 μm for a 6.0 mm eye pupil. Lenses with refractive base power of 10D, 15D and 20D were considered.

The ZKB00, ZLB00 and ZMB00 IOLs are pupil independent and full aperture diffractive bifocal IOLs. They have anterior aspheric surface and their posterior spherical surface has the diffractive profile. This profile has step boundaries of the same height intended for a balanced light splitting between the distance and near foci independently of the pupil size.

The Symfony ZXR00 EDOF-IOL, is claimed to be designed with a proprietary method [19] based on a combination of refractive and diffractive technologies for providing extended range of vision [13] with combined correction of spherical and longitudinal chromatic aberrations for contrast sensitivity enhancement and reduction of photic phenomena [20]. We reported a detailed analysis of the mechanisms of focus extension and chromatic performance of this lens in a prior work [21]. In particular, it was shown that for a wavelength of 550nm, the design of the Symfony lens agrees with a low addition bifocal IOL (+1.75D) intended for distinct distance and intermediate vision that, unlike conventional diffractive bifocal IOLs, uses the first and second diffraction orders for the far and intermediate foci, respectively [21].

2.2 Experimental setup for halo assessment

Assessment of the halo produced by each lens was made using an optical test bench (Fig 1) with a model eye (artificial cornea plus wet cell) that has been described in detail elsewhere [22-24]. The model eye followed the recommendations of the International Standard Organization [25] and had an artificial cornea that induced an amount of SA at the IOL plane of +0.27 μm (for a 6.0 mm pupil).

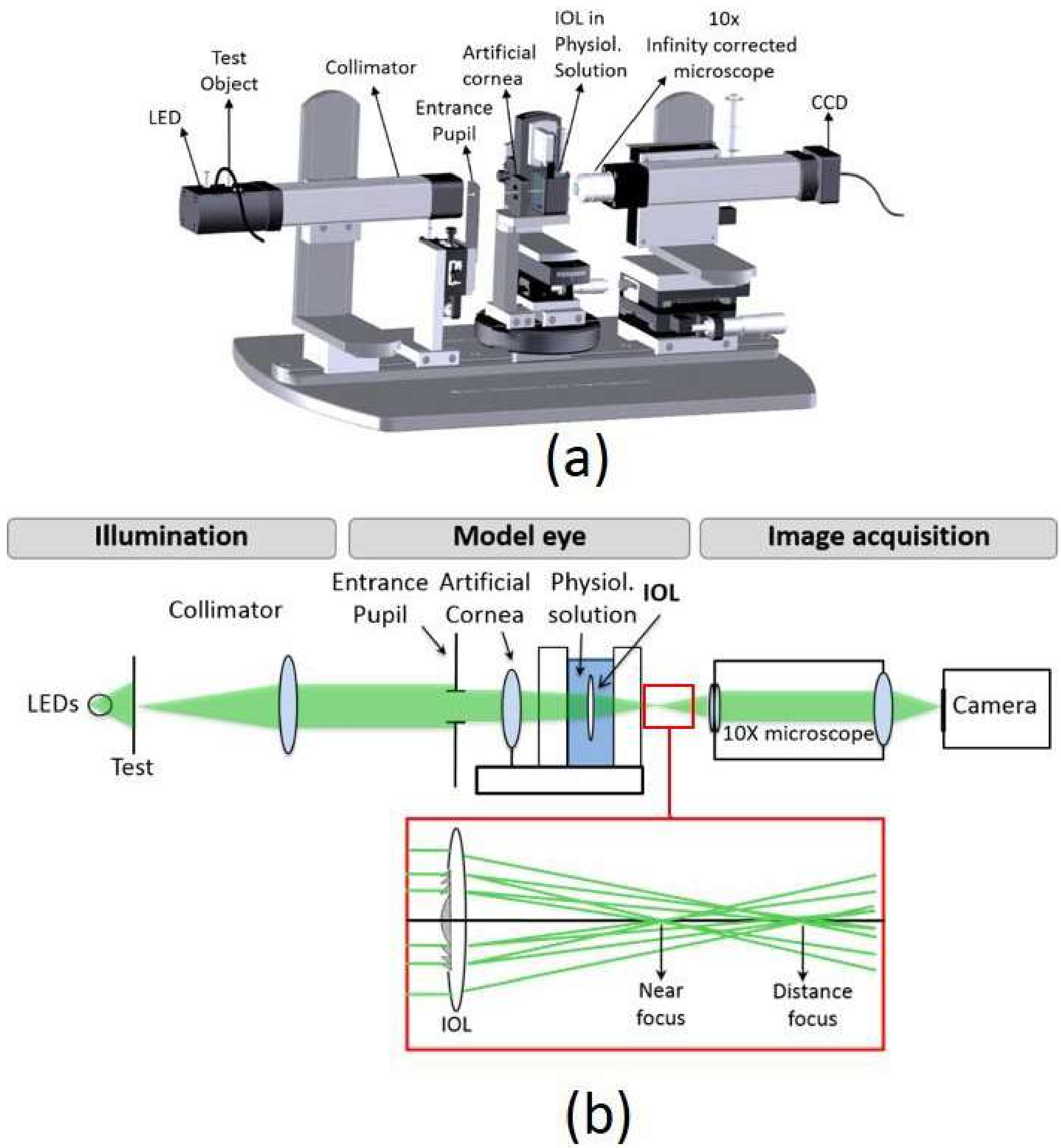

Fig 1. Optical setup used for *in vitro* assessment of the halo formed by EDOF and bifocal IOLs: (a) general view, (b) scheme of the optical setup. Inset: bifocal diffractive IOL. LED stands for light-emitting diode.

The light source was a green light emitting diode with emission centred at 530±32 nm, which illuminated a 200 μm pinhole object located at the front focal plane of a collimator (200 mm focal length). An iris diaphragm was used to control the lens aperture and hence, the level of corneal SA of the wavefront that impinged upon the tested IOL. All the pupil diameters mentioned in this work are referred to the IOL plane [22, 23].

2.3 Experimental determination of the halo size and intensity with image analysis

The model eye with either a bifocal or an EDOF IOL formed two simultaneous images of the pinhole object. In the case of a bifocal IOL, such two images were the distance and the near images, whereas in the case of an EDOF IOL, they were the distance and the intermediate images. The distance image, with the superimposed out-of-focus image formed by either the near or intermediate power of the IOL, was magnified and focused onto an 8-bit CCD camera by means of a 10× infinite corrected microscope mounted on a high-precision translation holder.

Figure 2 illustrates how the halo size and intensity were experimentally measured for each IOL. The pinhole is a small but extended object which subtends an angle with respect to the model eye that is equivalent to observing a car headlight of 10 cm in diameter at 100 m [13]. The image in Fig 2 (a), captured at the distance focus of the model eye with the bifocal ZKB00 IOL, consists of the sharp image of the pinhole surrounded by a faint round halo. This halo becomes quite evident when the image is displayed in logarithmic scale of intensity (Fig 2 (c)).

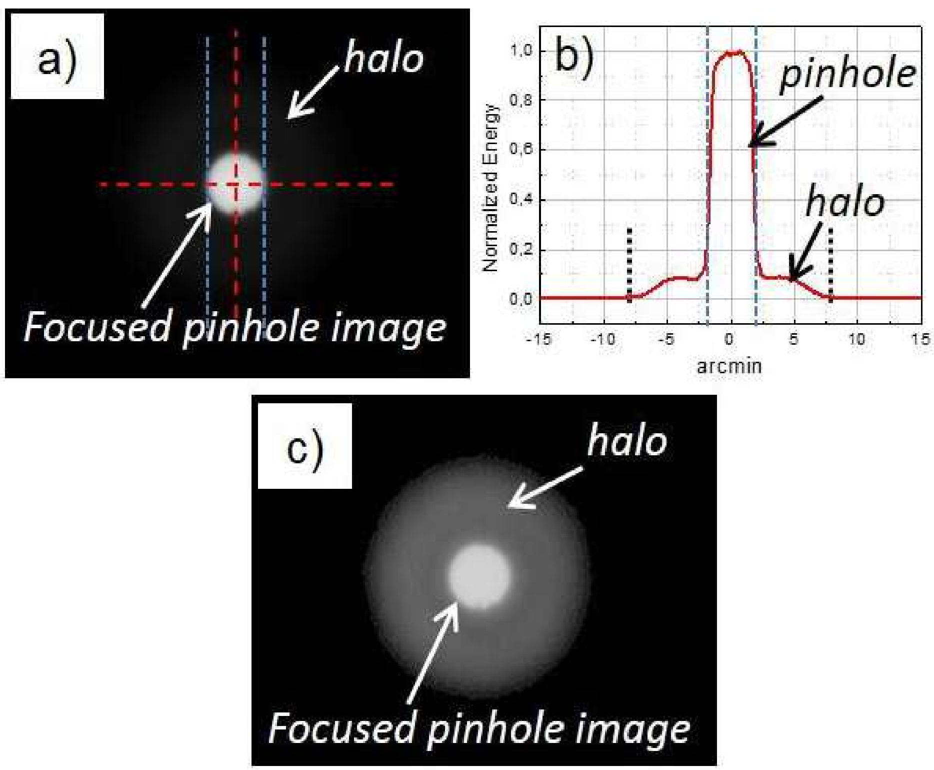

Fig 2. (a) Image of the pinhole object at the distance focus of the bifocal ZKB00 IOL, in linear scale of intensity. Blue lines set the size of the in-focus image of the pinhole. (b) Normalized energy profile obtained by averaging the profiles along horizontal and vertical red lines in (a). The dotted black lines set the halo diameter. (c) Same as (a) but in logarithmic scale of intensity for a better halo visualization.

The logarithmic scale of intensity is used in Fig 2(c) and the next figures of this work henceforth, for the sake of visualization exclusively [11]. In the calculations, however, solely the original intensity values of the images, in the linear scale provided by the CCD camera were used. The halo size was determined from the image profiles taken along two crossed axes (vertical and horizontal red axes marked in Fig 2 (a). The average profile shown in Fig 2 (b), exhibits a central part with the highest energy corresponding to the in-focus pinhole image plus a pedestal of lesser energy whose extension is the halo diameter (δ_{halo}). In addition, since the grey level of a pixel of the image is proportional to the energy impinging on that pixel, it is possible to compute both, the energy of the total image (E_{total}) and the energy within the region of the halo (E_{halo}), by integrating the grey level of all the pixels belonging to the region of interest as reported elsewhere [22,23,26].

The halo energy, normalized to the total energy of the image, NE_{halo}, is given by the ratio

$$NE_{halo} = \frac{E_{halo}}{E_{total}} \tag{1}$$

The halo intensity takes into account the area on which the halo energy is spread and is determined from the ratio

$$I_{halo} = \frac{NE_{halo}}{A_{halo}} \tag{2}$$

being A_{halo} the halo area calculated using the halo diameter δ_{halo} and assuming a circular shape.

2.4 Theoretical determination of the halo size

In two closely related works [16,17], the authors used first-order geometrical optics to deduce the theoretical diameter of a halo $(\delta_{halo})_{theor}$ formed by an eye with a bifocal IOL when looking at a distant point light source

$$(\delta_{halo})_{theor} = d_{IOL}\frac{\Delta P}{P_{eye}}, \tag{3}$$

where d_{IOL} is the illuminated lens diameter or pupil size at the IOL plane, P_{eye} is the eye refractive power for distance vision, and ΔP is the IOL addition power. Equation (3) assumes a constant diffractive design of the IOL within the illuminated area of diameter d_{IOL}.

To calculate P_{eye} in our case, we took into account: the power of our model cornea (23D), the refractive base power of the studied IOLs (10D, 15D and 20D), the relative distance between the elements in our eye model and their refractive indexes as reported elsewhere [23].

3 Results

Figure 3 shows the images of the pinhole object obtained with the EDOF and bifocal IOLs. The images obtained with the monofocal ZCB00 IOL are also included at the top of Fig 3. In comparison with the monofocal lens, the EDOF and bifocal IOLs formed a noticeable halo that increased linearly in size when the pupil also increased. Further insight of the dependence of halo size on the pupil diameter can be seen as given in Fig 4. Moreover, and for each pupil, the larger the near add power of the IOL, the larger the halo. As such, the largest halos were obtained with the bifocal ZMB00 of +4.0D add power.

The halo size, halo energy and halo intensity are shown in Fig 5 as a function of the add power of the IOLs. In agreement with the theoretical predictions calculated using Eq (3), there is a linear increase of the halo size as a function of the add power of the IOL (Fig 5a). On the other hand, the normalized energy of the halo (Fig 5b) remains quite similar for the various IOLs and shows little variation with the IOL add power. In all cases their values are around 50% to 55% of the total energy of the image.

Interestingly, the increase of the halo size as a function of the IOL add power (Fig 5a), combined with the fact that the energy content of the halos shows little variation with this parameter (Fig 5b), leads to a significant decrease of the halos intensity when the IOL add power increases (Fig 5c), a result that can be also acknowledged in Fig 3. With regard to this, the EDOF IOL with the lowest add power, has the smallest but brightest halo.

Finally, the dependence of size, energy and intensity of the halos with the IOL base power was explored (Figs 6,7). Figure 6 shows the images obtained with lenses of 10D, 15D and 20D in the eye model in the case of the Symfony ZXR00 EDOF and the bifocal ZLB00. For these lens base powers, the refractive power of the whole model eye (cornea plus IOL) P_{eye} on the optical bench was 27.8D, 30.2D and 32.5D, respectively.

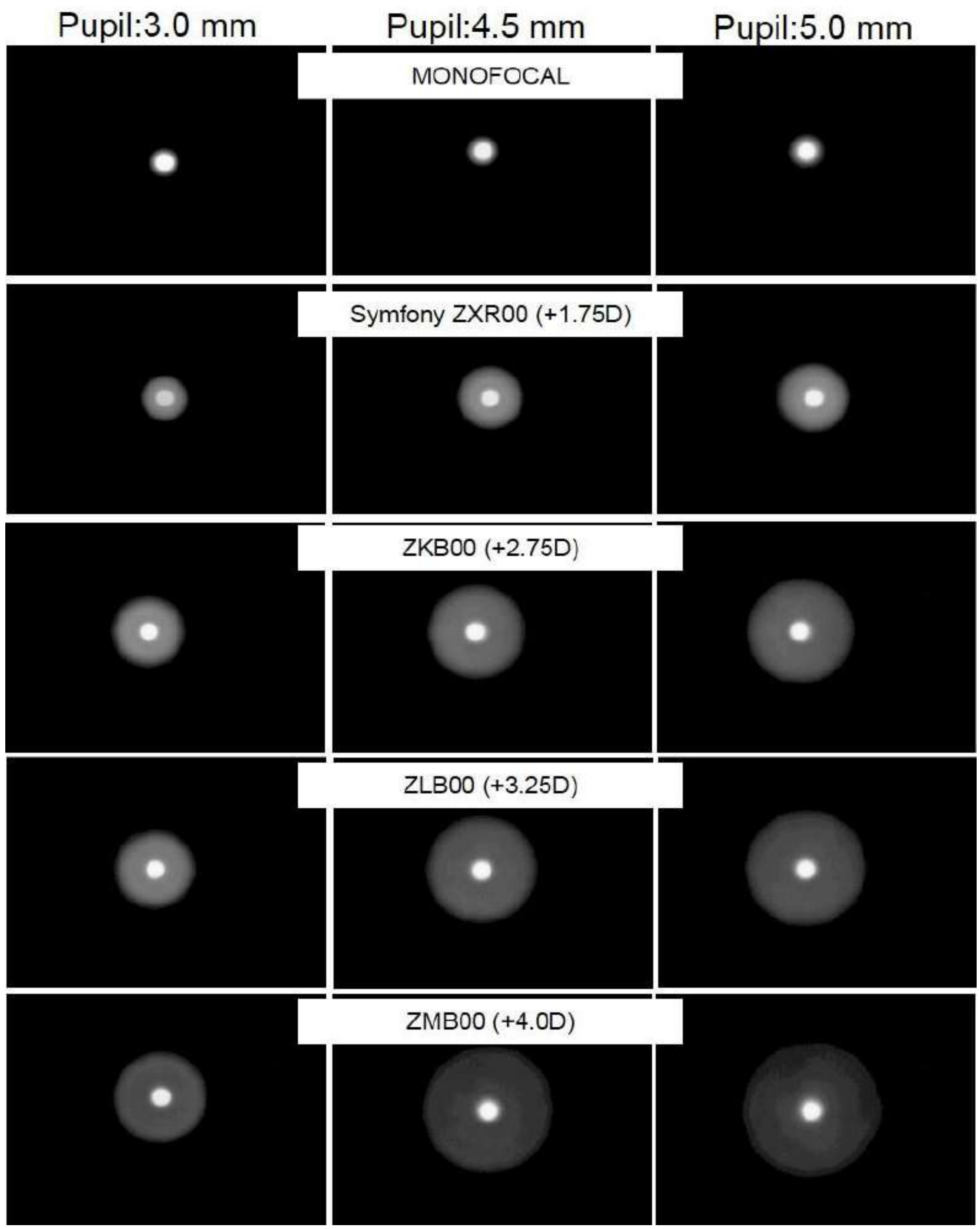

Fig 3. Images of the pinhole object, in logarithmic scale of intensity, obtained with pupils of 3.0, 4.5 and 5.0 mm. All the IOLs had a base optical power of 20D.

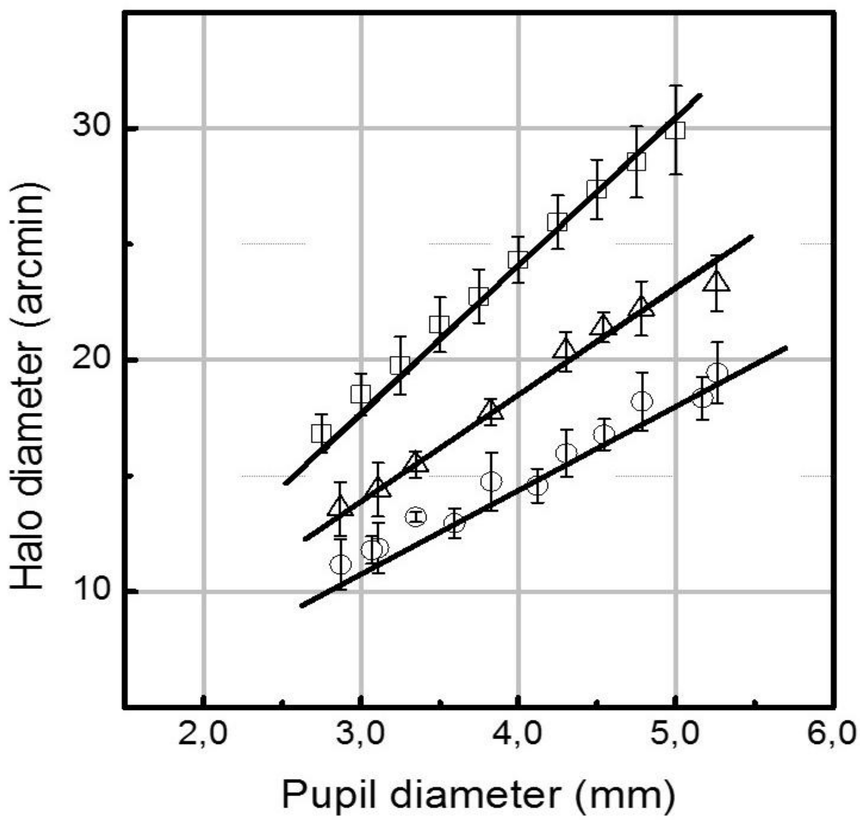

Fig 4. Experimental (open symbols) and theoretical (solid lines) halo size dependence on pupil diameter obtained with the Symfony ZXR00 (+1.75D) EDOF IOL (○,▬) and bifocal IOLs ZKB00 (+2.75D) (Δ,▬) and ZMB00 (+4.0D) (□, ▬). All the IOLs had a base optical power of 20D. Experimental results are depicted by their mean values ± standard deviation. Theoretical halo size was determined with Eq (3).

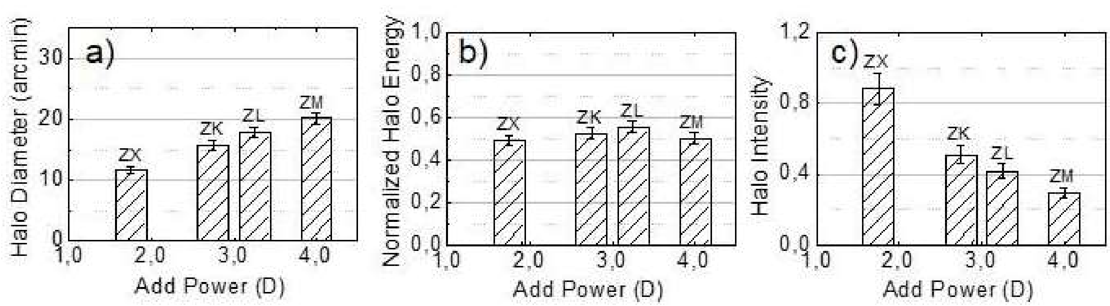

Fig 5. Halo diameter (a), normalized halo energy (b), and halo intensity (c) obtained with a 3.0 mm pupil. ZX stands for Symfony ZXR00 (+1.75D) EDOF IOL, while ZK, ZL and ZM stand for the bifocal IOLs: ZKB00 (+2.75D), ZLB00 (+3.25D), and ZMB00 (+4.0D), respectively. All the IOLs had a base optical power of 20D. Results (mean values ± standard deviation) are depicted.

Figure 6 shows that for both IOLs, the largest halo was obtained when the lenses had the lowest base power (10D) as would be the case of implants selected for high myopic eyes. Moreover, when the two IOLs are compared it can be seen that, for the same lens base power, the smaller halo with higher intensity occurs with the IOL of lower add power, i.e. the Symfony ZXR00 EDOF IOL.

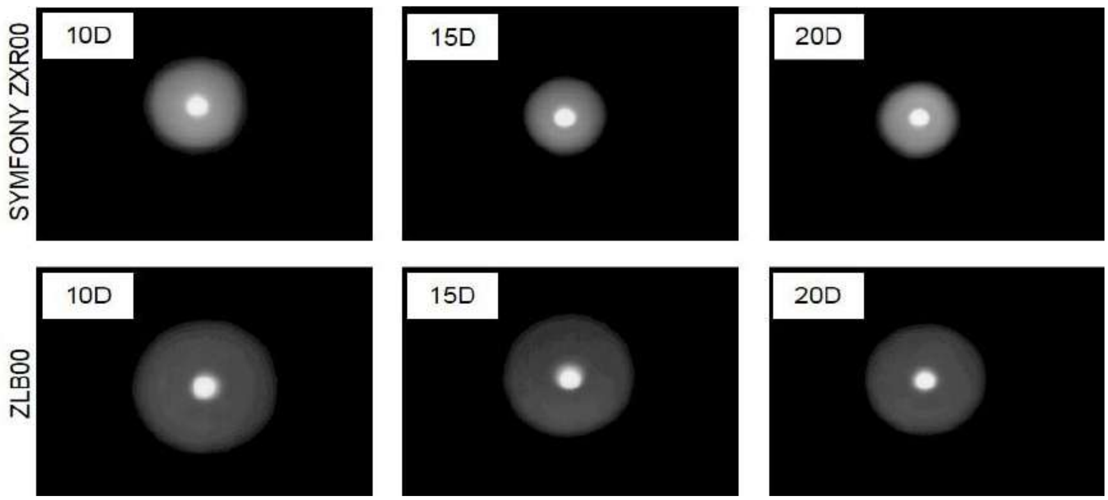

Fig 6. Images of the pinhole object, in logarithmic scale of intensity, obtained with two IOLs of 10D, 15D and 20D base power. Top: Symfony ZXR00 (+1.75D) EDOF IOL. Bottom: ZLB00 bifocal IOL (+3.25). Images acquired with a 4.5mm pupil.

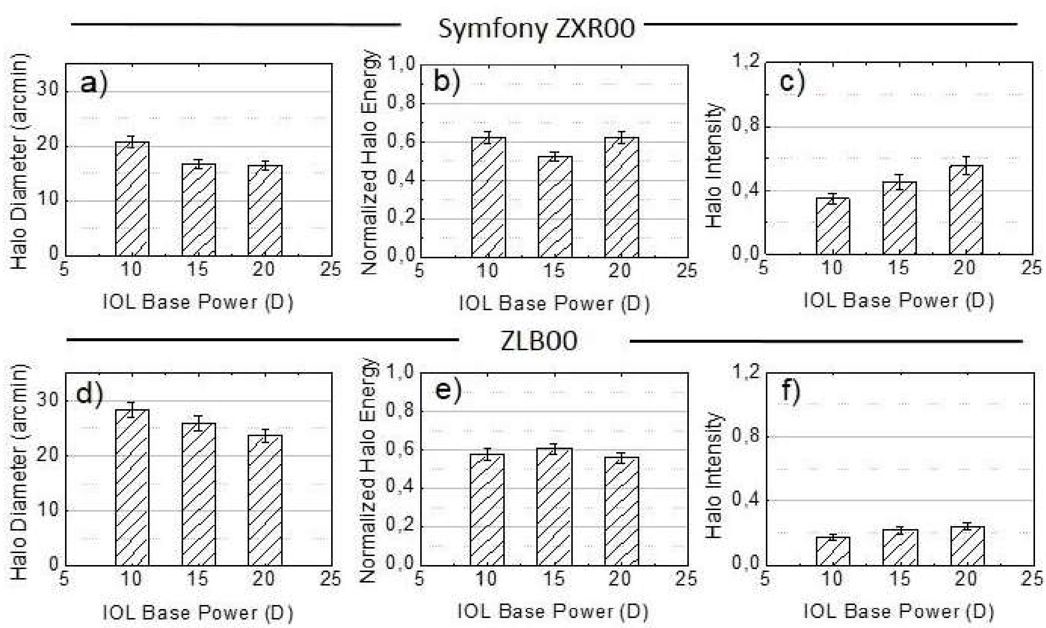

Fig 7. Halo size (a, d), normalized halo energy (b, e), and halo intensity (c, f) as a function of the IOL base power obtained with the Symfony ZXR00 EDOF IOL (+1.75D) (a, b, c), and the bifocal ZLB00 IOL (+3.25 D) (d, e, f). Results (mean values ± standard deviation) were obtained with a 4.5mm pupil.

The qualitative observations made above are quantitatively supported by the results shown in Fig 7, where the measured size, energy and intensity of the halos are represented versus the base power of the IOLs. According to these results, the halos formed by both IOLs were quite similar in energy for all the three lens base powers tested (Figs 7(b),(e)); their sizes were different though (Figs 7(a), (d)). As a consequence, the halo intensities of the two IOLs, the Symfony ZXR00 (Fig 7c) and the ZLB00 (Fig 7f) are significantly different (see also Fig 6).

4 Discussion and Conclusion

Several clinical studies have reported that patients implanted with full aperture and apodized diffractive bifocal IOLs experienced more severe glare and halo symptoms than patients with monofocal IOLs [27-29]. Our results are consistent with these clinical observations since we have shown in Fig 3 that, in comparison with the monofocal IOL, whose halo is very small and hardly noticed, the EDOF and bifocal IOLs produce a noticeable halo at their distance focus. A tiny halo in the case of the monofocal IOL was also reported in the study of Yoo *et al* [18] and acknowledges for a negligible amount of remnant SA due to the good compensation of the corneal SA produced by the aspheric design of the lens [20,22]. Since the studied bifocal and EDOF IOLs share the same material and aspheric design as the monofocal IOL, it is reasonable to assume that the contribution of the residual SA to the halo in these IOLs must be also negligible.

Let us then analyse the rest of factors, such as the energy of the out-of-focus image produced by the near/intermediate focus, light diverted to spurious higher diffraction orders [30] and scattering produced by diffractive steps [31], which contribute to the halo. In the case of the bifocal ZKB00, ZLB00 and ZMB00 IOLs, they all have the same diffractive design with constant step height across the pupil. Their pupil-independent design directs 44% of the incoming energy (for the 530nm wavelength used in our experimental work) to the near focus and 18% to spurious diffraction orders [21,30]. Moreover, since the diffractive steps are located at distances from the optical axis given by Eq (4) [32]

$$r(m) = \sqrt{\frac{2m\lambda}{\Delta P}} \tag{4}$$

where m is the integer which corresponds to the m-th zone or diffractive ring, λ is the design wavelength (550 nm) and ΔP is the add power (in diopters), we computed the number m of diffractive rings illuminated for a given pupil size. As such, for a 4.5 mm pupil, the number of illuminated rings that contribute to the scattering process are 18 out of 22 for the ZMB00 IOL, 15 out of 18 for the ZLB00 IOL, and 12 out of 15 for the ZKB00 IOL. Since the light scattered just by one diffractive step must be very little, and the number of illuminated steps is low, we neglect the contribution of light scattering to the halo energy and make the following two predictions:

- There must be only small differences between the energy content of the halos produced by these IOLs and,
- The value of the halo energy must be mainly determined by the contribution of the out-of-focus near image (≈44%) plus the contribution of the spurious diffraction orders (≈18%), and thus should be around 62% for all the bifocal IOLs independently of the pupil size, near add or the lens base power.

Our results are in good agreement with these estimations.

In the case of the Symfony EDOF IOL, it has been shown that its diffractive profile consists of nine rings or echelletes distributed in two regions: central and peripheral [19,21]. The central zone has a diameter of 2.75 mm and is formed by three echelletes of 3π-phase shift steps that ideally deviate an amount of energy of ≈41% to the 2nd diffraction order, which is used in combination with the refractive base power of the lens to form the intermediate focus of the EDOF IOL. These features explain why in terms of the halo energy, the Symfony EDOF IOL behaves quite similar to its counterpart bifocal IOLs up to pupils of 3.0 mm (Fig 5 (b)). The peripheral zone of the Symfony EDOF IOL includes echelettes of 2.73π-phase shift steps intended for sending less energy (≈21%) to the intermediate focus. This fact should ideally contribute to reduce the relative energy of the halo as the pupil increases. However, we have not found significant differences in the halo energy between the Symfony EDOF IOL and the rest of bifocal IOLs for larger pupils. To explain this result, one has to take into account that, for the experimental wavelength (530nm) we used, the diffraction energy efficiencies of central (up to 2.75 mm) and peripheral (up to 4.5 mm) zones of the EDOF IOL contributing to the intermediate focus are 50% and 28%, respectively [21], with approximately 18% of the energy contributing to spurious diffraction orders in each zone. Moreover, by incorporating the areas of the central (37%) and peripheral (63%) zones as weight factors [21,23], one can estimate that the fraction of the energy directed to the intermediate focus, which is the main contribution of the energy of the halo at distance, should be around 54%, which is in good agreement with the experimental results of the halo energy found in the EDOF IOL (Figs 5(b),7(b)).

With regard to the halo extent, we have found in all the studied IOLs (bifocals and EDOF) that, in agreement with theoretical predictions (Eq 3), the halo size increases linearly with both, the IOL add power (Fig 5(a)) and the pupil diameter (Fig 4).The halo size is inversely proportional to eye power and therefore, slowly decreasing with the IOL base power as it can be derived from Figs 7(a),(d). Thus, in terms of the halo size, the *a priori* worst conditions would occur for a high myopic patient -who required a lens of reduced base power-, implanted with an IOL of high add power (as would be the case of the bifocal ZMB00 +4.00D), and looking at a distant spotlight under mesopic illumination (i.e., with large pupil diameter). As such, Kretz *et al* [33] reported worse outcomes in terms of halos and glare with the high add bifocal Tecnis ZMB00 +4.00D than with the low add ZKB00 +2.75D [34]. In other paper, Kim *et al* [35] documented a significant presence of glare and halos in all the groups of patients implanted with any of the studied bifocal IOLs (ZKB00, ZLB00 and ZMB00), with a lower incidence in the groups implanted with the lower near adds bifocal IOLs (ZKB00 +2.75D and ZLB00 +3.25D) than in patients with the higher near add (ZMB00 +4.0D), although these differences were not statically significant. The authors hypothesized that this lack of relevant differences among bifocal IOLs could be due to the fact that, although the halo size was smaller for a lower near add power, its intensity could be higher [35]. Our experimental measurement of the halo intensity as a function of the IOL near add (Fig 5(c)) supports this interpretation.

Our results show that the Symfony EDOF IOL produces halos of the smallest size but with highest intensity, which may explain why Escandon-Garcia *et al* [36] did not find better performance in terms of objective dysphotopsia, in patients with the Symfony EDOF IOL compared to patients with trifocal IOLs. Other studies however, have reported that the Symfony lens induces less photic phenomena than counterpart IOLs [37]. Thus, further work is still necessary to fully understand which halo configuration (small size and high intensity versus large size with low intensity) is perceived by patients as the most disturbing [10].

Finally, several limitations of the present study should be pointed out. First, what has been assessed in the optical test bench is the formation and physical characteristics (size, energy and intensity) of the halos and cannot be directly extrapolated to the outcomes obtained in patients either through the use of questionnaires [33,34] or from measurements with halo and glare simulators [8,9]. In addition, the subjective prominence of glare and halo effects in patients also depends on the intensity of the glare source relative to the detection threshold. The formation of a halo as shown in our study is a necessary but not sufficient condition for the subjective perception of the halo by a pseudophakic patient which is influenced by many other factors, such as neuroadaptation. As such, the degree of discomfort caused by photic phenomena as perceived by patients has been shown to decrease over time [6,38]. Second, in the model eye the IOL is aligned with the cornea and then no tilt exists between the two elements. In the normal eye, however, this tilt is of the order of 5º temporally and 1.5º superiorly and introduces additional aberrations that may contribute to the halo. In addition, measurements were carried out with the IOL centred on the model eye axis, whereas clinical studies have shown that with continuous curvilinear capsulorhexis the implantation of the IOL in the capsular bag may lead to decentration within the 0.1 to 0.3 mm range [39], and this decentration affects the optical performance of the IOLs [40]. Finally, our study was carried out with monochromatic green light.

Although other authors have also characterized the Symfony EDOF IOL *in-vitro* with monochromatic light [14,15,21], it has been reported that white light should be better for characterizing this lens so as to fully exploit its potential chromatic correction capacity [13,41].

To sum up, we have found that for a particular pupil size, the Symfony EDOF IOL produces halo of smaller size but of higher intensity than its counterpart bifocal IOLs. The largest halo occurs by the combination of two factors: an IOL of low refractive base power (as would be the case of implants selected for highly myopic eyes) and high near addition (such as the ZMB00 +4.0D).

Conflict of interest

The authors have no financial or proprietary interest in any material or method mentioned.

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