

Patient-Perceived and Laboratory-Measured Halos Associated with Diffractive Bifocal and Trifocal Intraocular Lenses

Francisco Alba-Bueno, Nuria Garzón, Fidel Vega, Francisco Poyales, and María S Millán

QUERY SHEET

This page lists questions we have about your paper. The numbers displayed at left can be found in the text of the paper for reference. In addition, please review your paper as a whole for correctness.

- Q1:** Au: Repeated author givenname: Francisco in MS.
- Q2:** Au: Please provide 3 to 5 keywords for the article.
- Q3:** Au: The funding information “Spanish Ministerio de Economía y Competitividad y Fondos FEDER” provided has been checked against the Open Funder Registry and we failed to find a match. Please confirm if the Funding section is accurate and also confirm the funder name “Spanish Ministerio de Economía y Competitividad y Fondos FEDER”.
- Q4:** Au: Please provide names of all authors for reference “[3]” (or only the first 10 authors if there are more than 11), as per journal style.
- Q5:** Au: Please provide missing Publisher location/Publisher name/Year of publication for the [9] references list entry.
- Q6:** Au: Please provide names of all authors for reference “[12]” (or only the first 10 authors if there are more than 11), as per journal style.
- Q7:** Au: Please provide names of all authors for reference “[20]” (or only the first 10 authors if there are more than 11), as per journal style.
- Q8:** Au: Please provide names of all authors for reference “[21]” (or only the first 10 authors if there are more than 11), as per journal style.

TABLE OF CONTENTS LISTING

The table of contents for the journal will list your paper exactly as it appears below:

Patient-Perceived and Laboratory-Measured Halos Associated with Diffractive Bifocal and Trifocal Intraocular Lenses
Francisco Alba-Bueno, Nuria Garzón, Fidel Vega, Francisco Poyales, and María S Millán



Patient-Perceived and Laboratory-Measured Halos Associated with Diffractive Bifocal and Trifocal Intraocular Lenses

Francisco Alba-Bueno^{a,b}, Nuria Garzón^c, Fidel Vega^b, Francisco Poyales^c, and María S Millán^b

Q1
5

^aValles Ophthalmology Research (VOR), Institute of Medical and Surgical Ophthalmology (OMIQ), Barcelona, Spain; ^bApplied Optics and Image Processing Group (GOAPI), Universitat Politècnica de Catalunya (UPC BARCELONATECH), Barcelona, Spain; ^cIOA Madrid Innova Ocular, Madrid, Spain

ABSTRACT

Purpose: To examine and assess the halos generated in distance vision by multifocal intraocular lenses (IOLs) using both *in vitro* objective and *in vivo* subjective methods.

Setting: The objective method was carried out in the optics laboratory of the Applied Optics and Image Processing Group (Universitat Politècnica de Catalunya -Barcelona). The psychophysical and subjective methods were carried out in the Instituto de Oftalmología Avanzada Madrid Innova Ocular.

Design: Optical bench results and prospective evaluation of consecutive cases.

Methods: The IOLs examined were TECNIS[®] one-piece bifocals with addition powers of +4.00 D, +3.25 D, and +2.75 D and the trifocals AT-LISA-tri[®] and FineVision[®]. In the objective assessment, we examined halos around the far focus images of a pinhole formed by each IOL in an optical bench. For the *in vivo* study, we recruited 100 patients who had been bilaterally implanted one month earlier with the IOLs under study. Participants were subjected to psychophysical halometry (Halo v1.0) on the eye with better, distance-corrected, visual acuity and were required to subjectively grade halos by responding to the question “How much do halos bother you?”

Results: The objective method revealed that the halo size increased with addition power and that the two trifocals gave rise to a double-halo pattern. Scores in the halometry also indicated a direct relationship between the halo size and addition power. The subjective results indicated fewer complaints about halos associated with the trifocal than bifocal IOLs.

Conclusions: The addition power of the tested IOLs affected both laboratory-measured and patient-perceived halos. Trifocal lenses generated fewer complaints about halos.

Purpose: Multifocal intraocular lenses (MIOLs) give rise to halos observed by patients under conditions of dim lighting. This study compares laboratory characterized halos generated by five MIOLs with patient-perceived halos.

Q2

30 Introduction

Cataract surgery is becoming a refractive surgery procedure in which the patient seeks adequate vision at all distances. This has prompted the constant evolution of multifocal intraocular lenses (IOLs) with the goal of achieving the best vision possible, especially at intermediate and near distances.¹ The lenses currently available on the market include bifocal and trifocal diffractive, refractive or combined refractive/diffractive IOLs with low, intermediate or high addition power each providing distinct vision at different distances.

In addition to the improvement of visual acuity and reduced spectacle dependence achieved in each patient, the primary goal of multifocal IOL implantation is to achieve a good quality of vision. A need has arisen for tools to assess the vision quality of patients undergoing multifocal IOL implantation and the optical quality of the IOLs themselves.^{2–4}

Given that multifocal IOLs have two or more focal points – that is, far, near, and/or intermediate – they may induce

phenomena that affect the quality of vision such as reduced contrast sensitivity and glare and/or halos.^{2,4,5}

The word halo is used to describe a blurred or dim circle of light perceived by patients surrounding the image of a bright spotlight. Numerous factors may contribute to the formation of the halo such as high-order aberrations (especially spherical aberration) and, more importantly in the case of multifocal IOLs, the simultaneous perception of more than one image whereby the focused image is superimposed on another out-of-focus image(s). In fact, one of the main complaints of patients with multifocal IOLs is that they see halos particularly when looking at a bright light source against a dark background such as when driving at night.

This study was designed to examine associations between the halos perceived by patients (using a subjective and a psychophysical method) and the halos observed in an optical bench setup (*in vitro* objective method) with several multifocal IOLs. The IOLs selected for assessment by these two methods were: three diffractive bifocal lenses with different addition power and two diffractive trifocal IOLs, one of them apodized and the other one non-apodized.

Patients and methods

70 Patients

For the psychophysical and subjective assessment of halos, 100 patients undergoing cataract surgery at the clinic IOA Madrid Innova Ocular (Spain) were recruited. All patients had been symmetrically and bilaterally implanted with either diffractive bifocal or trifocal IOL. Intraoperative or postoperative complications and residual refractions equal or higher than ± 0.75 D in sphere or astigmatism were exclusion criteria. Five study groups of 20 consecutive patients each were established according to the multifocal lens implanted.

The preoperative examination in each participant included biometry using the IOL Master (Carl Zeiss AG, Oberkochen, Germany), Pentacam topography (Oculus, Wetzlar, Germany), Goldmann applanation intraocular pressure measurement, a slit-lamp examination, optical coherence tomography using a Cirrus OCT (Carl Zeiss, Dublin, California, USA) and a fundus exam. The exclusion criteria for the implant of a multifocal lens were corneal astigmatism greater than 0.50 D, and/or glaucoma or any corneal, macula or other disorder contraindicating this type of IOL.

All lenses were implanted through a 2.2 mm corneal incision using the injector supplied by the manufacturer of each IOL. All surgeries were performed by the same surgeon (FP) according to the protocols established at IOA Madrid Innova Ocular. Participants were volunteers and were free to withdraw from the study at any time. The study protocol adhered to the tenets of the Declaration of Helsinki and received institutional review board approval. Written informed consent was obtained from each participant.

Patients attended at least three follow-up visits 24 h, 1 week and 1 month after surgery. The lapse of time between surgery on the right and left eye was shorter than one week. At the 1 month visit following the second surgery, all participants undertook a psychophysical halometry test and a subjective test in which they graded the halos perceived.

Demographic data of the patient groups are provided in Table 1.

Intraocular lenses

The five IOLs implanted in the study were: the TECNIS[®] one-piece bifocals ZMB00 (add power +4.00 D), ZLB00 (add power +3.25 D) and ZKB00 (add power +2.75 D) (Abbott Medical Optics Inc); and the trifocals FineVision[®] (Micro F) (Physiol, Lieje, Belgium) (add power +3.50 D near and +1.75 D intermediate) and AT-LISA-tri[®] (Carl Zeiss Meditec, Jena, Germany) (add power +3.33 D near and +1.66 D intermediate).

The three TECNIS one-piece models share the same platform and only differ in their near addition power. The lens material is hydrophobic acrylic. They are biconvex lenses with an anterior aspheric surface and a posterior one with the diffractive profile that covers the full aperture of the lens. The diffractive rings have step boundaries of the same height intended for approximately 50/50 light distribution between the distance and near foci independently of the pupil size. The wavefront-designed aspheric optics produces a maximum spherical aberration (SA) of $-0.27 \mu\text{m}$ for a 6.0 mm eye pupil. The refraction index is 1.47, length is 13.00 mm and optic zone diameter is 6.00 mm. The lenses consists of open loop haptics (C) and have an interrupted, frosted square ProTEC edge to avoid posterior capsular opacification.

The FineVision[®] lens has a platform with 4 closed haptics. It is composed of a hydrophilic material (25%) of refraction index 1.46 and has a diffractive apodized anterior surface. Its total diameter is 10.75 mm and the optic zone diameter is 6.15 mm. The step height of the diffractive profile gradually decreases toward the periphery (apodization), which results in a continuous change of the light energy distribution among the three primary foci intended to favor distance vision under mesopic conditions. The posterior IOL surface is aspherical, and the lens produces a negative SA of $-0.11 \mu\text{m}$ with a 6.0 mm pupil. Further details of the lens characteristics can be found elsewhere.⁶

The AT-LISA-tri[®] lens has a plate design of total diameter 11.00 mm and optic zone diameter 6.00 mm. Its composition is hydrophilic (25%) with a hydrophobic surface. The optic zone on its anterior surface is trifocal in the central region up to 4.34 mm diameter and bifocal in the periphery. As a consequence, the light distribution among the distance, intermediate, and near foci slightly depends on the pupil size and tends to moderately benefit the distance focus for larger pupils

Table 1. Demographics of the subjects included in this study.

Parameter	Tecnis ZMB	Tecnis ZLB	Tecnis ZKB	FineVision	AT-LISA Tri
Mean age (years)	62.60 \pm 6.50	64.58 \pm 2.92	60.15 \pm 6.49	66.46 \pm 5.37	65.47 \pm 4.20
Range of age (years)	[50, 75]	[46, 82]	[48, 83]	[54, 79]	[56, 80]
Pupil diameter under mesopic conditions (mm)	5.28 \pm 0.67	4.94 \pm 0.86	5.55 \pm 0.43	5.20 \pm 0.75	4.91 \pm 0.70
Range of pupil diameter under mesopic conditions (mm)	[3.3, 6.7]	[3.9, 6.2]	[4.3, 6.2]	[4.0, 6.6]	[3.8, 6.3]
Pupil diameter under photopic conditions (mm)	4.70 \pm 0.65	4.65 \pm 0.71	4.63 \pm 0.60	4.09 \pm 0.87	4.40 \pm 0.61
Range of pupil diameter under photopic conditions (mm)	[3.1, 5.9]	[3.0, 5.7]	[3.1, 5.5]	[2.9, 5.3]	[2.9, 5.8]
Mean of Spherical equivalent pre (D)	0.35 \pm 1.72	0.94 \pm 0.73	1.40 \pm 1.31	0.81 \pm 1.30	0.52 \pm 0.96
Range of Spherical equivalent pre (D)	[2.38, -8.25]	[5.87, -8.00]	[5.37, -2.25]	[3.25, -5]	[4.50, -4.00]
BCVA pre (LogMAR)	0.10 \pm 0.04	0.08 \pm 0.03	0.13 \pm 0.17	0.16 \pm 0.15	0.17 \pm 0.12
Range of BCVA pre (LogMAR)	[0.1, 0.7]	[0.3, 0.0]	[0.0, 0.8]	[0.05, 0.8]	[0.1, 0.8]
Mean of Spherical equivalent post (D)	-0.26 \pm 0.37	-0.02 \pm 0.05	-0.08 \pm 0.14	-0.02 \pm 0.09	-0.15 \pm 0.16
Range of Spherical equivalent post (D)	[0.75, -1.28]	[0.50, -1.12]	[0.75, -0.50]	[0.25, -0.50]	[0.75, -0.75]
Mean refractive sphere post (D)	0.04 \pm 0.26	0.03 \pm 0.27	0.16 \pm 0.29	-0.03 \pm 0.19	0.10 \pm 0.20
BCVA post (LogMAR)	0.0 \pm 0.04	0.01 \pm 0.03	0.00 \pm 0.02	0.01 \pm 0.02	0.00 \pm 0.02
Range of BCVA post (LogMAR)	[0.176, -0.125]	[0.079, -0.10]	[0.176, -0.10]	[0.079, -0.09]	[0.15, -0.10]

All values given as mean as standard deviation unless otherwise specified. SD, standard deviation; BCVA, best corrected visual acuity, D diopters

as reported elsewhere.⁷ The aspheric design of the lens introduces SA of $-0.18 \mu\text{m}$ for a 6.0 mm eye pupil.

155 **Optical bench for halo assessment**

Using a theoretical approach, we reported in a prior publication⁸ that the diameter of a halo (D_h) generated by a distant point light source could be calculated using the equation:

$$D_h = d_p \cdot \frac{\Delta P}{P_b} \quad (1)$$

where d_p is the diameter of the illuminated zone of the lens that contributes to the lens' foci other than the distance; P_b is the eye refractive power; and ΔP is the IOL addition power.

This equation is a paraxial approximation to the size of the halo when looking at distance. It does not consider the possibility of a central-apodized diffractive surface (such as ReStor IOLs), which may affect both the halo size and intensity. Neither does Eq. 1 take into account possible high order aberrations nor light scattering by the lens and diffractive rings. However, the possible effects of such factors may be assessed experimentally through *in vitro* halo characterization in optical bench.

For the *in vitro* assessment of the halo produced by each lens in response to a glare source we used an optical bench with an eye model that follows the recommendations of the International Organization for Standardization.⁹ The artificial cornea of our eye model induces a similar amount of spherical aberration in the IOL plane as the average human cornea ($+0.3 \mu\text{m}$ for a 6 mm IOL pupil).^{10,11} The setup of the optical bench used in the laboratory is illustrated in Figure 1.

To determine the halo diameter and its relative intensity, we used as the object a $200 \mu\text{m}$ pinhole illuminated by a narrow-band green LED (peak wavelength 530 nm with full width at half maximum of $\pm 20 \text{ nm}$). This wavelength is quite close to both, the wavelength recommended in the ISO 11979-2:2014 standard ($546 \pm 10 \text{ nm}$) and the one corresponding to the maximum value of the photopic sensitivity of the eye in the visible spectrum (550 nm) for which bifocal and trifocal IOLs are designed

The collimated beam illuminated the model eye with the IOL under test and an iris diaphragm allowed us to have a pupil diameter ranging from 2.0 mm to 5.0 mm (referred to the IOL plane). In this work we selected an IOL pupil of 4.5 mm to examine the effects of the different diffractive designs (that approximately corresponds to a 5.0 mm entrance pupil in the physiological eye). In addition, this pupil size is close to reported values of the pupil of age matched patients under mesopic conditions. All the studied lenses had the same base power (20 D).

The image of the pinhole formed in the plane of the distant focus of the eye model (artificial cornea and IOL immersed in a wet cell) was captured with appropriate resolution by means of a CCD camera fitted to a microscope objective. To improve the visualization of the images with halos we have used a pseudocolor coding of the image intensity represented in logarithmic scale (Figure 2). This useful procedure is commonly applied to monochrome images with high dynamic range such as, in our case, the images of a pinhole surrounded by halo,⁸ but it is worth remarking that the logarithmic scaling and pseudocolor coding tool has been applied in Figure 2-4 of the paper

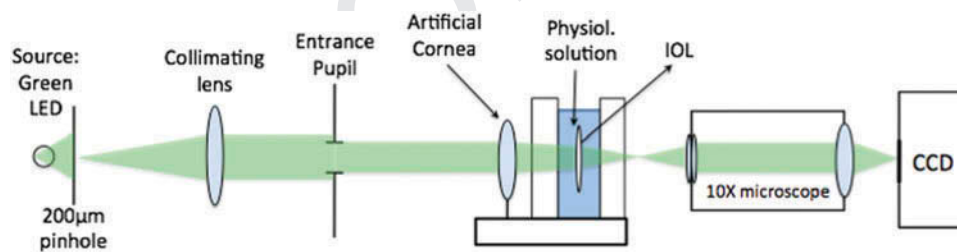


Figure 1. Diagram of the optical bench used for *in vitro* assessment of IOLs.

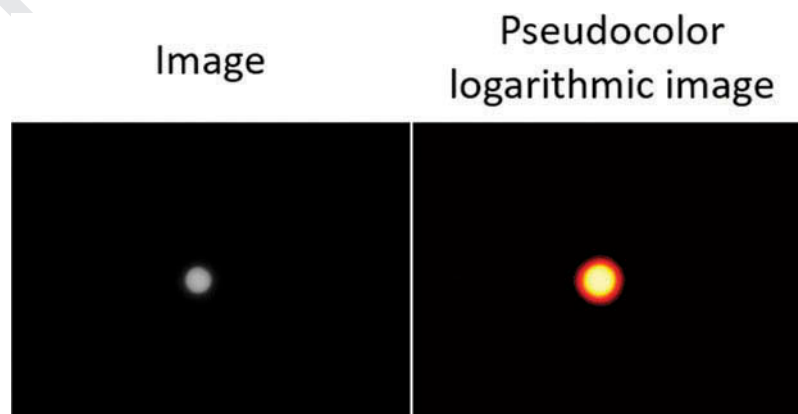


Figure 2. (Left) Original image of the pinhole object produced by an aspheric monofocal IOL in the eye model (pupil 4.5 mm). This lens partially compensates for the spherical aberration of the artificial cornea. (Right) Pseudocolor coding of the same image after applying a logarithmic transformation to its intensity. The halo (red region surrounding the pinhole) is due to the remaining spherical aberration of the eye model.

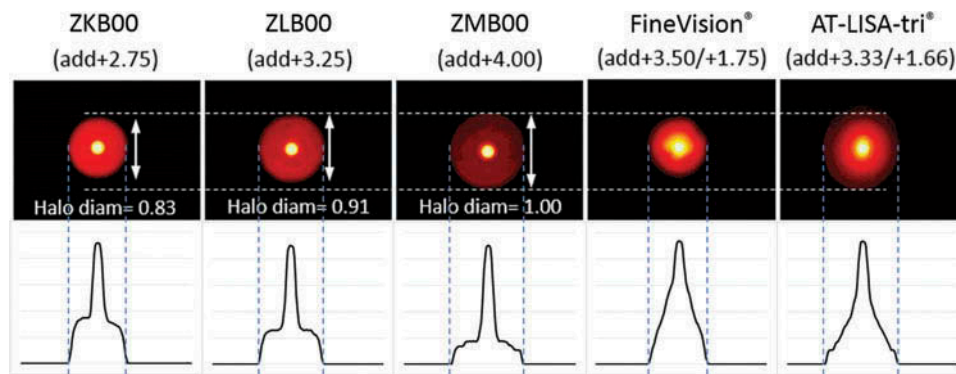


Figure 3. Pseudocolor logarithmic scale images of the distance focus of the studied IOLs (base power 20 D, pupil size in the IOL plane 4.5 mm). Horizontal lines are set at the boundaries of the halo of the ZMB00 IOL. Normalized halo diameter is shown under the images of the Tecnis IOLs. A cross-sectional intensity profile in logarithmic scale (averaged between X and Y profiles) under each image is included for a better visualization of the halo features.

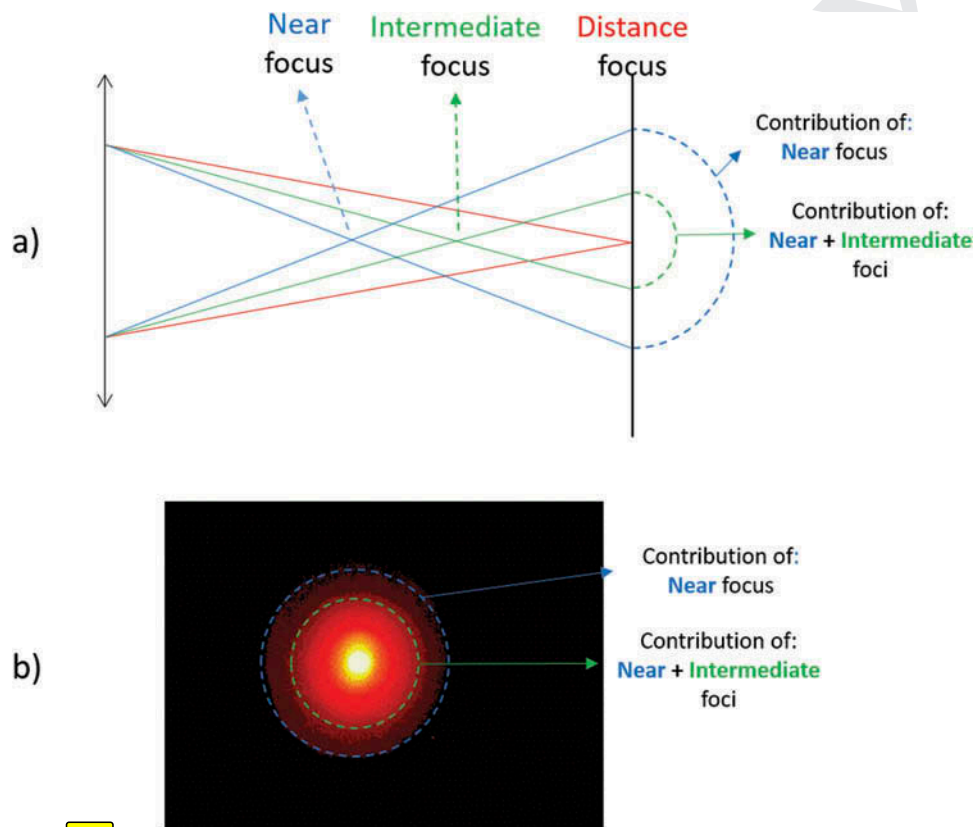


Figure 4. a) Diagram showing how the double contribution of the near and intermediate powers to the halo in the distance focus of a trifocal IOL. b) Image of the halo produced in the distance focus of the trifocal AT-LISA-tri® intraocular lens.

exclusively for the sake of visualization. The numerical results, however, have been obtained from the images as acquired by the camera, that is, prior to any manipulation.

Finally, it should be noted that although halos might be also present in near vision^{12,13} this study only examines those produced when viewing a distant object. This type of halo is the most common patient complaint.

Psychophysical test

To measure the size of the halo produced in the patients in response to a glare source we used the open-access software package Halo v1.0 (Laboratory of Vision Sciences and

Applications, University of Granada, Spain) which is described in detail elsewhere.^{14–16} This test is performed on a computer screen, and detects and quantifies (using a numerical index) the halo extension perceived by a subject under conditions of low lighting. During the test, the subject identifies peripheral light stimuli that emerge randomly around a central spotlight of high luminance on a dark background. The variable recorded is the discrimination index which provides information on the halo perceived by the subject. This index is related to the radius of the area where the peripheral stimuli cannot be detected by the subject and range from 0 to 1 in decimal scale. The higher the discrimination index, the lesser the halo effect.¹⁵

220

225

230

The test was placed at 4 meters from the patient and applied monocularly. It was presented under scotopic conditions to the eye with best best-corrected distance visual acuity.

235 Halo grading

Each participant was requested to answer the question “How much do halos bother you?” using a scale from 1 up to 5. In this scale, a score of 1 indicated that halos observed were very annoying and a score of 5 indicated that halos produced no discomfort whatsoever.

Statistical analysis

All statistical tests were performed using the SPSS software package for Windows (version 22.0, SPSS Inc., Chicago, IL, USA). The normal distribution of data was confirmed using the Kolmogorov–Smirnov test. Variables were compared among the different IOLs by one-way analysis of variance (ANOVA). Significance was set at $p < 0.05$. The results are provided as the mean \pm standard deviation (SD).

Results

250 Halo assessment in the optical bench

The images captured in the distance focus for each IOL are shown in Figure 3. It may be observed in the images of the three TECNIS® lenses (bifocals) that, as predicted by the paraxial approximation (Equation 1), halo size increases proportionally with addition power (ΔP). For a better

visualization of this effect, we have added two horizontal dashed lines at the boundaries of the halo of the IOL with the highest addition power (ZMB00) that allow us to compare its size with the two TECNIS® IOLs with lower addition (ZLB00 and ZKB00). Normalized numeric values of these size measurements are included in Figure 3. Cross-sectional intensity profiles under each image are included as well. It is worth emphasizing that as the halo diameter increases, its intensity decreases because the energy is distributed across a larger area.

The size of the halos produced by the trifocal IOLs AT-LISA-tri® and FineVision® lenses are slightly larger and smaller, respectively, than the halo size of the bifocal IOL of comparable near add power (ZLB00). Moreover, unlike the bifocals, these trifocal IOLs show a more complex distribution of the energy in the halo with two concentric rings around the image of the pinhole: an outer, low intensity ring that corresponds to the out of focus image of the near focus; and a smaller, high intensity inner one where the defocus images of both the near and intermediate powers overlap, that corresponds to the region of the image where overlap the defocused images of the intermediate and near foci (Figure 4). The transition between the inner to the peripheral region of the halo is found to be relatively smooth or sharp depending on the design of the IOL.

Psychophysical test

The halo measurements obtained using the Halo v1.0 program for each IOL are provided in Figure 5(a). The outcome of this test is a discrimination index ranging between 0

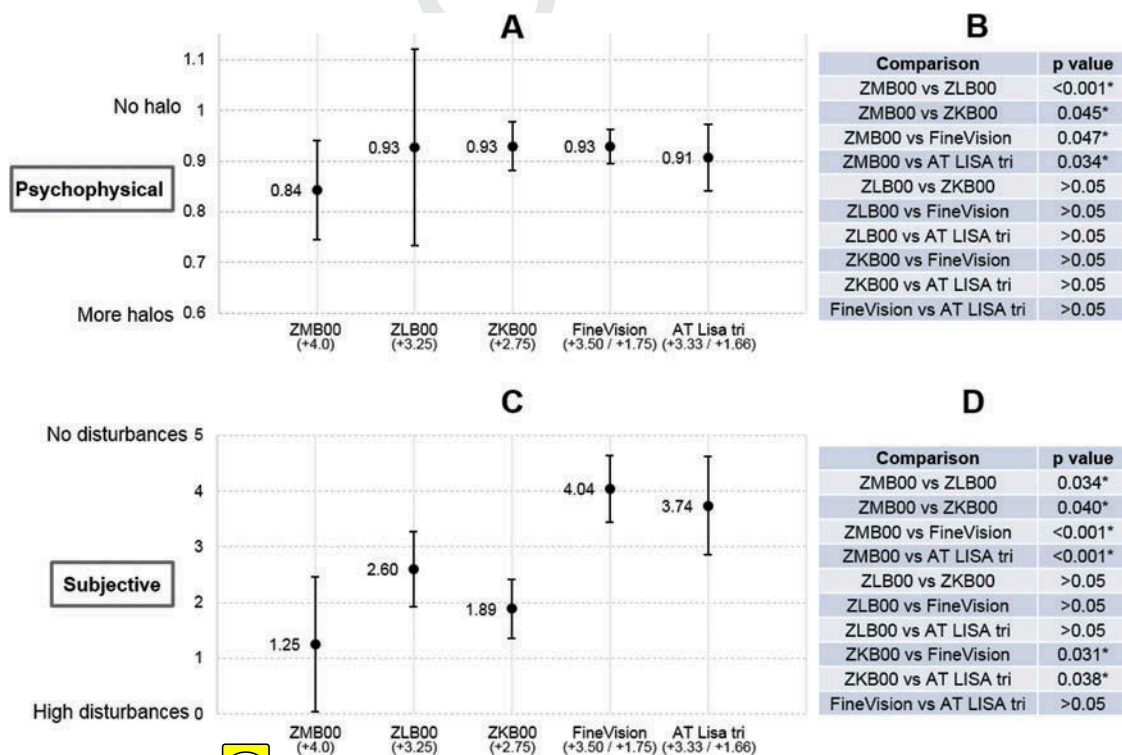


Figure 5. A) Discrimination index (mean \pm SD) obtained with the software Halo v1.0 in each group of patients to assess their perception of halos. B) Subjective grading of halos. C) p-values obtained for comparison among the different IOL models assessed using the psychophysical method. D) p-values obtained for comparison among the different IOL models assessed using the subjective method.

(strongest halo) and 1 (absence of halo). The lowest discrimination index ($0.84 \pm \text{SD}$) corresponded to the patients with the IOL with the highest addition (ZMB00 + 4.00) while with the rest of the IOLs the discrimination indices ranged between $0.91 \pm \text{SD}$ and $0.93 \pm \text{SD}$. Since the lower the discrimination index, the strongest the halo effect, one can conclude that the largest perceived halo corresponded to the ZMB00 IOL. Moreover, the only statistical significant difference detected was for ZMB00 versus the other four lenses ($p < 0.05$) (Figure 5(b)).

Halo grading

The subjective halo grading scores for the five IOLs, which indicate how much the patients were bothered by halos, are given in Figure 5(c). The lowest score, indicating that the perceived halo was quite annoying to the patient, was for the bifocal IOL with the highest addition (ZMB00 + 4.00 D) while the patients with the trifocal IOLs were the less bothered by halo. Again the ZMB00 (+4.00 D) lens did differ significantly with respect to the other IOLs as did the ZKB00 (+2.75 D) versus FineVision® or AT-LISA-tri® (both $p < 0.05$) (Figure 5(d))

Discussion

This study addresses the topic of halos associated with IOLs using three well-differentiated methods: an *in vitro* method in which the halos generated by five different multifocal IOLs were characterized in an optical bench; a psychophysical method that assesses sensory and cognitive responses to a stimulus (halo induced by a glare source) in subjects implanted with the IOLs; and a subjective method in which subjects implanted with the IOLs self-assess the halos they observe.

Using the optical bench, we characterized the halo that forms when a focused image superimposes one or more out of focus images produced by the different powers existing in the illuminated optical zone of the multifocal IOL. In the case of trifocal lenses, the halo seems to be mainly produced by the joint contribution of the out of focus images corresponding to the intermediate and near add powers. Such differences in the halo features between the two trifocal IOLs can be attributed to differences in near and intermediate add power between them. Further contributions to these differences in the halo characteristics would come from differences in the type of lens material (hydrophilic acrylic with hydrophobic surface in the case of the AT-LISA-tri® and hydrophilic acrylic in the case of the FineVision), different compensation of the corneal spherical aberration (-0.20 and $-0.11 \mu\text{m}$ respectively) and differences in how each trifocal design splits light into the three foci as a function of the pupil size.

The Halo v1.0 psychophysical test, besides assessing the discrimination capacity of an individual as an important aspect of vision, also characterizes their visual performance under low light conditions such as night vision. This method offers objective information on night vision disturbances such as glare or halos around lights – as reported by patients – and on their capacity to discriminate small light stimuli next to a

glare source. This method was used instead of other devices such as Starlight System (Novosalud, Spain) or the MonCv3 (Metrovision, France) because of its simplicity and reduced cost (computer assisted, freeware).

The last method employed here assesses the patient's perception of halos in terms of the level of discomfort they produce. This information is purely subjective since halos of similar size and intensity could affect differently each other's vision. Other authors stated that the subjective perception of halos diminish over the time in the post-operative. Changes in the perception of halos during time was, however, out of the scope of this work.

The findings of this study indicate that halos induced by multifocal intraocular lenses can vary in size and intensity according to the lens add powers or to the design of its optical zone.

The bifocal diffractive IOLs tested here were the TECNIS one-piece models ZMB00 (+4.00 D), ZLB00 (+3.25 D), and ZKB00 (+2.75 D), which solely differ in the radii and the number of diffractive rings to provide different additions. In our study, these lenses gave rise to a greater halo size as the add power of the IOLs increased in agreement with the relationship predicted by the paraxial approximation of Eq. 1. Moreover, since all of them equally split the energy between their near and distance foci, the larger the halo the lower its intensity as we experimentally proved (Figure 3) and had been previously reported.⁸ Our halometry and subjective test results for these lenses were highly consistent. Significant differences using both methods were detected between the highest addition power lens (ZMB00 + 4.00 D) and those of intermediate and low addition (ZLB00 + 3.25 D and ZKB00 D + 2.75 D respectively), with no differences detected between the last two. In addition to halo size differences, the *in vitro* objective method evidenced differences in terms of intensity of the halo. Although it is reasonable to assume that the intensity of the halo, and thus its apparent brightness, should have an influence on the perceived halo size by a patient, it is important to realize that the *in vitro* assessment of the halo intensity, is carried out keeping the light source intensity below the saturation threshold of the CCD camera (Figure 3). On the contrary, with the psychophysical test the measurement of the halo size is performed from the patient's response to a glare source, i.e., a central high luminance source and thus, it is a *supra-threshold* method that rules-out differences in halo intensities.

As for the two trifocal IOLs, results of the psychophysical and subjective tests indicated no significant differences between them.

The psychophysical halometry data revealed that the IOL inducing worse discrimination capacity (i.e., with the largest halo) was the bifocal lens with greatest addition power (ZMB00 + 4.0 D). The remaining lenses, with addition powers between +2.75 D (ZKB00) and +3.50 D (FineVision®), failed to vary significantly. These results were consistent with the subjective halo grading performed by the patients (Figure 5) since the ZMB00 lens also behaved worse than the other lenses.

When we compared the two trifocal IOLs with the bifocal lens of nearest addition (ZLB00), the psychophysical halometry and the optical bench results were in good agreement. The psychophysical method did not show statistically significant

differences and, as we can see in Figure 3, images of their halos in the optical bench are quite similar as well. Moreover, although the trifocal IOLs were subjectively graded better than the bifocal of nearest addition power (ZLB00, Figure 5(c)), this differences were not statistically significant (Figure 5(d)). An unexpected result regarding the subjective halo grading was obtained: ZKB00 (low add) and ZMB00 (high add) bifocal lenses were graded to be significantly worse than the trifocal IOLs, while the ZLB00 (intermediate add) was graded to be similar. It cannot be discarded that this effect can be due to the sample size or the relatively high dispersion of the data.

In general terms, it is widely accepted that multifocal IOLs offer better uncorrected intermediate and near vision than any monofocal IOL. However, given their associated photic disturbances, multifocal lenses produce more patient complaints than monofocal lenses despite achieving visual acuities of logMAR 0 or better.^{18,19} This determines that the choice of IOL has to be carefully made especially when the patient's expectations following surgery involve low level of photic effects.²⁰

Among the limitations to this study, we should mention that the psychophysical method used here to assess halos although validated could be improved. A more precise method should include an eye tracker, use threshold rather than supra-threshold approaches and new metrics to understand how our visual system interprets information on such dysphotopsia phenomena according to the image created on the retina. These improvements can diminish the standard deviations and may contribute to a better reproducibility of the results. Note that in other studies, the values of the measured halos with multifocal IOLs are considerably different.²¹

A further limitation to our study concerns the number of individuals (only 20 per IOL) participating in the subjective study and the lack of a control group (monofocal). Anyhow, the software used in the psychophysical method should have to be reconfigured to include monofocal patients implanted with monofocal IOLs because their sensitivity to detect the peripheral stimuli is much higher. Even in the case of having a monofocal control group, this fact would not have allowed us to establish a meaningful comparison between their results and those obtained with the multifocal group. Further investigation on this topic should consider physiological effects such as Stiles Crawford, or the possibility of a neuro-adaptation that may mitigate the relevance of objective versus subjective halometry. Finally, while the measurements of the halo characteristics made in the optical test bench were carried out with monochromatic green light, halo assessment in the patients was performed with white light.

In conclusion, our examination of five diffractive multifocal IOLs in a model eye has shown that the addition power of the lens has a significant influence on the intensity and size of the halo: the higher the addition, the larger the halo size and the lower its intensity. When the halo assessment is carried out with a subjective method, individuals with trifocal IOLs were less bothered by halos than those with bifocals.

Acknowledgments

Some of the data reported here were presented as a poster at the XXXIII ESCRS Meeting held in Barcelona in September 2015 (awarded first prize).

Declaration of interest

The authors report no conflict of interest. The authors alone are responsible for the content and writing of the paper.



At the point of the submission of this paper, Francisco Alba-Bueno was an employee of the department of Medical & Regulatory Affairs of Alcon-Novartis. During the research and writing period of this paper he used to work for Valles Ophthalmology Research (VOR) – Institute of Medical and Surgical Ophthalmology (OMIQ).

Funding

This work was supported by project DPI2013-43220-R from the Spanish Ministerio de Economía y Competitividad y Fondos FEDER.

References

- Agresta B, Knorz MC, Kohnen T, Donatti C, Jackson D. Distance and near visual acuity improvement after implantation of multifocal intraocular lenses in cataract patients with presbyopia: A systematic review. *J Refract Surg.* 2012 Jun;28(6):426–35. doi:10.3928/1081597X-20120518-06.
- de Vries NE, Nuijts RM. Multifocal intraocular lenses in cataract surgery: Literature review of benefits and side effects. *J Cataract Refract Surg.* 2013 Feb;39(2):268–78. doi:10.1016/j.jcrs.2012.12.002.
- Holladay JT, Van Dijk H, Lang A, Portney V, Willis TR, Sun R, et al. Optical performance of multifocal intraocular lenses. *J Cataract Refract Surg.* 1990 Jul;16(4):413–22. doi:10.1016/S0886-3350(13)80793-6.
- Calladine D, Evans JR, Shah S, Leyland M. Multifocal versus monofocal intraocular lenses after cataract extraction. *Cochrane Database Syst Rev.* 2012;9:CD003169.
- Vingolo EM, Grenga P, Iacobelli L, Grenga R. Visual acuity and contrast sensitivity: AcrySof ReSTOR apodized diffractive versus AcrySof SA60AT monofocal intraocular lenses. *J Cataract Refract Surg.* 2007 Jul;33(7):1244–47. doi:10.1016/j.jcrs.2007.03.052.
- Gatnel D, Pagnouille C, Houbrechts Y, Gobin L. Design and qualification of a diffractive trifocal optical profile for intraocular lenses. *J Cataract Refract Surg.* 2011 Nov;37(11):2060–67. doi:10.1016/j.jcrs.2011.05.047.
- Vega F, Alba-Bueno F, Millán MS. Energy efficiency of a new trifocal intraocular lens. *Europ Opt Soc Rap Public.* 2014;9:14002. doi:10.2971/jeos.2014.14002.
- Alba-Bueno F, Vega F, Millán MS. Halos and multifocal intraocular lenses: Origin and interpretation. *Arch Soc Esp Ophthalmol (English Edition).* 2014;89(10):397–404.
- ISO. Ophthalmic implants - Intraocular lenses. Part 2: optical properties and test methods. In: ISO11979-2:2014.
- Guirao A, Redondo M, Artal P. Optical aberrations of the human cornea as a function of age. *J Opt Soc Am A Opt Image Sci Vis.* 2000 Oct;17(10):1697–702. doi:10.1364/JOSAA.17.001697.
- Wang L, Dai E, Koch DD, Nathoo A. Optical aberrations of the human anterior cornea. *J Cataract Refract Surg.* 2003 Aug;29(8):1514–21. doi:10.1016/S0886-3350(03)00467-X.
- Pieh S, Lackner B, Hanselmayer G, Zöhrer R, Sticker M, Weghaupt H, et al. Halo size under distance and near conditions in refractive multifocal intraocular lenses. *Br J Ophthalmol.* 2001 Jul;85(7):816–21. doi:10.1136/bjo.85.7.816.
- Vega F, Alba-Bueno F, Millán MS, Varon C, Gil MA, Buil JA. Halo and through-focus performance of four diffractive multifocal intraocular lenses. *Invest Ophthalmol Vis Sci.* 2015 Jun;56(6):3967–75. doi:10.1167/iov.15-16600.
- Castro JJ, Ortiz C, Pozo AM, Anera RG, Soler M. A visual test based on a freeware software for quantifying and displaying night-vision disturbances: study in subjects after alcohol consumption. *Theor Biol Med Model.* 2014 May 7;11(Suppl 1):S1. doi:10.1186/1742-4682-11-S1-S1.
- Castro JJ, Jimenez JR, Ortiz C, Alarcon A, Anera RG. New testing software for quantifying discrimination capacity in subjects with

- 520 ocular pathologies. *J Biomed Opt.* 2011 Jan-Feb;16(1):015001. doi:10.1117/1.3526702.
16. Anera RG, Castro JJ, Jimenez JR, Villa C, Alarcon A. Optical quality and visual discrimination capacity after myopic LASIK with a standard and aspheric ablation profile. *J Refract Surg.* 2011 Aug;27(8):597–601. doi:10.3928/1081597X-20110303-01.
- 525 17. Kamiya K, Hayashi K, Shimizu K, Negishi K, Sato M, Bissen-Miyajima H. Multifocal intraocular lens explantation: A case series of 50 eyes. *Am J Ophthalmol.* 2014 Aug;158(2):215–220 e211. doi:10.1016/j.ajo.2014.04.010.
- 530 18. Mojzis P, Pena-Garcia P, Liehneova I, Ziak P, Alio JL. Outcomes of a new diffractive trifocal intraocular lens. *J Cataract Refract Surg.* 2014 Jan;40(1):60–69. doi:10.1016/j.jcrs.2013.06.025.
19. Gundersen KG, Potvin R. Comparative visual performance with monofocal and multifocal intraocular lenses. *Clin Ophthalmol.* 2013;7:1979–85. 535
20. Kretz FT, Breyer D, Diakonis VF, Klabe K, Henke F, Auffarth GU et al. Clinical outcomes after binocular implantation of a new trifocal diffractive intraocular lens. *J Ophthalmol* 2015;201596289110.1155/2015/962891 540 
21. Carballo-Alvarez J, Vazquez-Molini JM, Sanz-Fernandez JC, Garcia-Bella J, Polo V, Garcia-Feijoo J, et al. Visual outcomes after bilateral trifocal diffractive intraocular lens implantation. *BMC Ophthalmol.* 2015 Mar 14;15:26. doi:10.1186/s12886-015-0012-4. 545 

PROOF ONLY