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Optical and clinical outcomes of an extended range of vision intraocular lens.

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Abstract:	Purpose: To assess the in-vitro optical quality and halo formation of AcrySof® IQ VivityTM intraocular lens (IOL) and to evaluate the clinical outcomes in patients who had bilateral implantation of this IOL. Methods: The optical quality was evaluated with the PMTF optical bench (LAMBDA-X). Through-focus modulation transfer function area (TF-MTFa) curves between -5.00 and +2.00D were obtained for 3.00 and 4.5 mm of pupil apertures. The halo was assessed in-vitro with a test bench. The clinical study included 30 patients. Uncorrected (UDVA) and best-corrected distance visual acuity (CDVA), and binocular defocus curve were evaluated six months postoperatively. Results: The TF-MTFa curve for 4.5 mm of pupil size show only one peak at distance focus (38.4 units). For 3.00 mm, the TF-MTFa showed a lower peak of MTFa (28.9 units), located at -0.70D, and an extended-depth-of-focus up to -2.20D The halo formed was larger and somehow more intense compared to a standard-monofocal IOL. The clinical outcomes at 6 months revealed satisfactory visual acuity outcomes. All patients achieved a binocular CDVA of 0.1 logMAR or better. The mean visual acuity was better than 0.2 logMAR between +1.00 and -2.00D of defocus. At a vergence of -2.50 D the visual acuity was 0.31±0.09 logMAR. Conclusion: The AcrySof® IQ VivityTM IOL provided a good distance optical and visual quality and provided an extended range of focus of around 2.0 D, allowing to obtain an optimal or functional visual acuity up to 50-40 cm. The halo formed was low intensity.
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Running head: Optical and clinical outcomes of a new EDOF IOL.

ABSTRACT

Purpose: To assess the in-vitro optical quality and halo formation of AcrySof® IQ Vivity™ intraocular lens (IOL) and to evaluate the clinical outcomes in patients who had bilateral implantation of this IOL.

Methods: The optical quality was evaluated with the PMTF optical bench (LAMBDA-X). Through-focus modulation transfer function area (TF-MTFa) curves between -5.00 and +2.00D were obtained for 3.00 and 4.5 mm of pupil apertures. The halo was assessed in-vitro with a test bench. The clinical study included 30 patients. Uncorrected (UDVA) and best-corrected distance visual acuity (CDVA), and binocular defocus curve were evaluated six months postoperatively.

Results: The TF-MTFa curve for 4.5 mm of pupil size show only one peak at distance focus (38.4 units). For 3.00 mm, the TF-MTFa showed a lower peak of MTFa (28.9 units), located at -0.70D, and an extended-depth-of-focus up to -2.20D The halo formed was larger and somehow more intense compared to a standard-monofocal IOL. The clinical outcomes at 6 months revealed satisfactory visual acuity outcomes. All patients achieved a binocular CDVA of 0.1 logMAR or better. The mean visual acuity was better than 0.2 logMAR between +1.00 and -2.00D of defocus. At a vergence of -2.50 D the visual acuity was 0.31±0.09 logMAR.

Conclusion: The AcrySof® IQ Vivity™ IOL provided a good distance optical and visual quality and provided an extended range of focus of around 2.0 D, allowing to obtain an optimal or functional visual acuity up to 50-40 cm. The halo formed was low intensity.

INTRODUCTION

Nowadays, more patients worldwide seek to obtain a wide range of good vision after cataract surgery, which allows them to be spectacles independent or reduce their dependence on it. Standard monofocal intraocular lenses (IOLs), which are the most commonly implanted after cataract surgery, provide an excellent distance visual performance; however, patients need spectacle correction for intermediate and near distances. In the last years, the designs and innovations in presbyopia-correcting IOLs have undergone a revolution over early bifocal IOLs, which provided a good distance and near visual quality, however showed a gap of poor quality at intermediate distance[1,2]. The first improvement to overcome this limitation was the bifocal IOLs designed with lower adds, which showed a better intermediate distance visual acuity than the previous models with higher adds[2-4]. However, this improvement did not fully satisfy the visual demands of a population increasingly interested in activities that require an intensively intermediate vision of good quality. Trifocal IOLs represented significant innovation to solve the shortcomings at the intermediate vision, which results in a higher prevalence of spectacle independence[5-8]. However, the incoming light distribution into multiples foci may induce a decrease in contrast sensitivity and disphotopic phenomena such as halo and glare after surgery[9-12]. These drawbacks may not be well tolerated for some patients, leading to postoperative complaints and unsatisfactory results.

The technology to extend the range of vision, or equivalently, to extend the depth-of-focus (EDOF) in the image space, has recently emerged, aiming at providing good distance and intermediate visual acuity but only functional near visual acuity[13]. Theoretically, the EDOF IOLs have the advantage over other presbyopia-correcting lenses, such as trifocal IOLs, of minimizing the visual disturbances and contrast sensitivity reduction induced by classic diffractive designs. The current scenario, with a great variety of presbyopia-correcting IOLs, makes it mandatory to perform further research focused on IOLs optical characterization and clinical studies to find the best IOL to meet the patients' needs providing the best quality of vision and the higher-level spectacle independence.

Recently an innovation has been developed in the field of EDOF IOLs, a non-diffractive extended-vision IOL (AcrySof® IQ Vivity^{TM}, Alcon, USA) with wavefront-shaping technology. The company's claim for this IOL is to extend the range of vision without visual disturbance. The current study aims to develop a comprehensive analysis of the optical and clinical performance of this new IOL. To this extent, we first assessed in vitro the optical quality and induced halo of the IOL. In a second phase, we analyzed the clinical outcomes in a sample of patients who undergone bilateral cataract surgery with AcrySof® IQ Vivity^{TM} implantation.

METHODS

Intraocular lens

The IOL studied was (AcrySof® IQ Vivity^{TM}, Alcon Labs., Inc., USA). It is a EDOF IOL that used a proprietary technology entitled wavefront-shaping (X-WAVE) by the manufacturer. According to the IOL's description by Khonen[14], the IOL has a monofocal design from the periphery up to the central 2.2 mm diameter region. In this central area the IOL has a "*plateau* 1 µm high". This "*plateau*" creates a 2-surface transition that would induce a "stretching and shifting" of the wavefront. This way, theoretically, the new EDOF IOL creates a continuous extended focus segment rather than several focal points as happens with other diffractive EDOF IOLs[15]. The studied AcrySof® IQ Vivity^{TM} is a 1-piece, hydrophobic aspheric IOL with a blue filter and ultraviolet protection. It has a total length of 13 mm and optical zone of 6 mm. The lens is available from +15.00 to +25.00 D in 0.50 D increments. The optical bench analysis was carried out with lenses of 20.0 D base power.

Optical performance

The optical quality of the IOL was assessed using PMTF optical bench (Lambda-X, software version 1.13.6). This device and the experimental set-up have been described in detail in previous investigations with other IOLs[5, 6, 16]. The optical quality of the IOL was performed using a model eye, including an artificial cornea with +0.135 µm of 4th-order spherical aberration for a 5.0 mm pupil at the IOL plane. The wavelength of the light source was 546 nm.

For this study, the modulation transfer function (MTF) was obtained for a 3.0- and 4.5 mm diameter of aperture at the IOL plane. The focus extension was assessed from the through-focus (TF) MTF curves scanning the image space between +2.0 D and

-5.0 D defocus in 0.1 D steps. For a given focus position within the TF range, two MTF curves in the X and Y directions of the image plane were obtained and averaged. Then, the TF area under the MTF (MTFa) curves was calculated according to previous studies[17-19]. Briefly, the MTFa was obtained at each defocus position by integrating the corresponding averaged MTF curve on the spatial frequency range from 0 to 50 cycles/mm (equivalent to 15 cycles per degree in the object space).

Halo assessment

The halo induced by the AcrySof® IQ Vivity™ was assessed in-vitro with a test bench of the Grupo de Óptica Aplicada y Procesado de Imagen (GOAPI, Universitat Politècnica de Catalunya BarcelonaTech, Terrassa, Spain) that has been described in detail elsewhere[18-22] and summarized here for the shake of conciseness. In brief, the setup consists of three parts: the illumination system, the model eye and the image acquisition system.

A green LED source (530 ± 20 nm) illuminated a pinhole object set optically at infinity. The model eye was formed by an artificial cornea and a wet cell with balanced salt solution where the IOL was immersed. The artificial cornea induced the same 4th-order spherical aberration for a 5.0 mm pupil at the IOL plane as the PMTF optical bench. The model eye with the IOL formed an image of the pinhole object at its best focus that was projected through a 10× infinity corrected microscope onto an 8-bit charge-coupled device (CCD) camera (Figure 1).

The image provided by the CCD camera (Figure 1A linear scale of intensity) consisted of the sharp and intense image of the pinhole (referred to from now on as the core) surrounded by a faint halo that becomes more evident when the image is displayed in logarithmic scale (Figure 1B). The energy of the halo and core regions were computed and normalized to the total energy of the image as reported in previous studies[18-22]. To that extent and because the gray level of a pixel of the image is proportional to the energy impinging on that pixel (after prior calibration of the camera), the energy of the light that reaches a particular region of interest of the image (either core or halo) was obtained by integrating the gray level of all pixels belonging to that region.

The halo was evaluated for 3- and 4.5-mm pupil diameters in the best focus plane (0.00 D defocus). Additionally, to assess the effect of a hypothetical postoperative refractive error of 0.50 D on the halo induced, the measurements were also performed for +0.50 and -0.50D of defocus.

Finally, for comparison purposes we performed the same halo assessment of a standard monofocal IOL (Clareon, Alcon Labs., Inc., USA).

Clinical outcomes

The retrospective, observational study examined 60 eyes of 30 cataract patients who underwent bilateral cataract surgery with implantation of the AcrySof® IQ Vivity™ (Alcon Labs., Inc., USA) at Fernández-Vega Ophthalmological Institute, Oviedo, Spain. All patients provided written informed consent, and the nature and possible consequences of the study were explained fully in accordance with the Declaration of Helsinki. Inclusion criteria were patients with cataracts, age between 65 and 85 years, corneal astigmatism ≤ 2.00D, axial length ranging from 22.0 to 25.0 mm, and willingness of attending the postoperative follow-up of 6 months. Exclusion criteria were previous ocular surgery, irregular corneal astigmatism, abnormal iris, or any ocular conditions contraindicating presbyopia-correcting IOL implantation.

Before surgery, all patients had a complete ophthalmologic examination including manifest refraction, corneal topography-tomography (Sirius, CSO Ophtalmic, Italy), slit-lamp biomicroscopy, Goldmann applanation tonometry, and binocular indirect ophthalmoscopy through dilated pupils. Pupil diameter with distance vision was measured at two different levels of illumination using a pupillometer (Colvard; Oasis, San Dimas, CA). Axial length and anterior segment size were measured with a noncontact optical biometer (IOLMaster 700; Carl Zeiss Meditec). The SRK-T and Barrett Universal II formulas were used for IOL power calculation. The targeted refraction was emmetropia.

The same experienced surgeon (J.F.A.) carried out all surgeries. All eyes underwent phacoemulsification with the Centurion Vision System (Alcon Labs., Inc., USA) using topical anesthesia. A 2.2 to 3.2 mm clear corneal incision (CCI) was performed in the steep-axis using the Callisto system (Carl Zeiss Meditec AG, Germany) to reduce preexisting astigmatism. In eyes with astigmatism less than 1.25 D, one CCI (2.2 mm) was performed while in eyes with astigmatism between 1.50-2.00 D, two opposite CCIs (3.2 mm) were carried out. All eyes underwent femtosecond laser-assisted lens surgery using the LenSx platform (Alcon, Labs., Inc., USA) to perform the anterior capsulotomy and fragment of the nucleus, and a 14C Morcher capsular tension ring (CTR) was implanted.

Postoperative follow-up visits were scheduled at 1-day and 1, 3, and 6 months. At six months post-surgery, the clinical protocol to evaluate the visual and refractive outcomes included the following measurements: Monocular and Binocular uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (CDVA) at 100% contrast under photopic conditions (85 cd/m^2). Binocular through-focus logMAR visual acuity (defocus curve; range from -3.00 to +1.00D in 0.50D steps) was measured in patients with a monocular CDVA > 0.1 logMAR.

Data analysis was performed using SPSS for Windows, version 14.0 (SPSS Inc., Chicago, IL). Normality was checked with the Kolmogorov-Smirnov test. Visual and refractive outcomes were analyzed at the 6-month postoperative visit. Means and standard deviations or percentages were used to report postoperative visual and refractive results. The cumulative binocular UDVA and CDVA were calculated at six months post-surgery. For the refractive predictability, the Pearson coefficient was used to analyze the correlation between the attempted refractive sphere refraction and the achieved refractive sphere refraction.

RESULTS

Optical performance

The TF MTFa curves for 3 and 4.5 mm of pupil aperture are shown in Figures 2A and 2B, respectively. For the 4.5 mm pupil, the curve shows a peak of maximum MTFa and thus, a maximum of optical quality at -0.20 D that is slightly shifted but still very close to the nominal defocus position of 0.0 D (corresponding to the best focus for distance vision) for the 20 D IOL. The MTFa value at said focus (position -0.20 D in the through-focus range) was 38.4. From that focus power, the MTFa decays monotonously for both lower (hyperopic) and higher (myopic) powers. For the 3.00 mm pupil, the IOL optical behavior significantly changed. The first finding is that the peak of maximum MTFa is lower (28.9) and it is located at -0.70D. Consequently, there is a myopic shift of 0.50D from the best focal point obtained for 4.5mm pupil diameter. Moreover, the shape of the MTFa curve widens towards the myopic powers with a plateau of MTFa≈20 that reaches defocus values of -2.20 D. From this point to nearer distances (-2.20 D to -5.00 D), the MTFa curve significantly declines.

Halo assessment

The images of the pinhole object obtained with pupils of 3.0 and 4.5mm with the AcrySof® IQ Vivity™ are shown in Figure 3. We recall that the images are displayed in logarithmic scale only for better visualization purposes. **For the sake** of comparison, Figure 3 also includes the images obtained with a standard monofocal IOL (Clareon). Larger halos are formed by the AcrySof® IQ Vivity™ with 3.0- and 4.5 mm- pupils in comparison to the standard monofocal (Clareon, Alcon Labs., Inc., USA). However, it is worth pointing out the different behavior between both IOLs versus pupil size: while in the case of the monofocal design, the larger the pupil, the larger the halo, the AcrySof®

IQ Vivity™ tends instead to produce a smaller halo with the larger 4.5mm pupil. Quantitative confirmation of the above-described trends is given in Figure 4 that shows the energy in the core and halo regions (relative to the total energy of the image) for 3.0- and 4.5-mm pupils for the monofocal Clareon (red bars) and AcrySof® IQ VivityTM (black bars).

To show the impact of defocus on the halo formed by AcrySof® IQ Vivity™, Figure 5 illustrates the image obtained at the best IOL's focus, and the images with -0.50D, and +0.50D defocus and for both pupils 3.0- and 4.5mm. **Compared to the best focus, a defocus of +0.50 D (hyperopic defocus) induces a larger halo for both pupils, being the difference much more significant for 4.5mm. Whereas for -0.50 D (myopic defocus), the halo size is slightly smaller for both pupil sizes.**

Clinical outcomes

This study comprised 60 eyes of 30 patients (15 men and 15 women). All patients completed the follow-up period of 6 months. Preoperative demographic data of the patients are summarized in Table 1. The mean IOL power was 21.62 ± 1.77 D (range 19D to 25D)

The results at 6-month revealed a **satisfactory** visual acuity after the implantation of AcrySof® IQ Vivity™. The mean **postoperative monocular and binocular UDVA (logMAR) was 0.18 ± 0.17 and 0.10 ± 0.12, respectively.** In turn, the mean **monocular and binocular CDVA (logMAR) six months after surgery was 0.05 ± 0.06 and 0.03 ± 0.04, respectively**. Figure 6 plots the cumulative binocular UDVA and CDVA. All patients achieved a binocular CDVA of 0.1 logMAR or better (≥ 20/25) and 80% had a value of 0.0 logMAR (20/20).

Regarding refractive outcomes, 95% of the eyes (57 eyes) had a refractive sphere within ±0.50 D and 100% within ±1.00 D at six months after surgery **(Figure 7).** Preoperatively, 43.3% of the eyes had a refractive cylinder < 1.00D; whereas six months after surgery, in 78.4% of the eyes, the refractive cylinder was < 1.00D.

Figure 8 plots the postoperative binocular defocus curve for the cases analyzed after the implantation of AcrySof® IQ Vivity™. The curve shows one peak at the expected distance focus (0.0 D of vergence). The mean visual acuity at -0.50 and +0.50D of defocus was 0.02 ± 0.04 logMAR and 0.04 ± 0.03 logMAR, respectively. All patients achieved a visual acuity of 0.2 logMAR or better (≥ 20/32) across the vergence range from +0.50 to -1.50 D (equivalent to 66 cm from the eye), and 60% of the cases 0.1 logMAR or better (≥20/25) in this range of vergences. At a vergence of -2.00 D (50 cm from the eye), the visual acuity was 0.19 ± 0.06 logMAR, 100% and 86.7% of the cases achieved visual acuity of 0.3 logMAR or better (≥ 20/40) and 0.2 logMAR or better, respectively. At a vergence of -2.50 D (40 cm from the eye), the visual acuity was 0.31 ± 0.09 logMAR, 100% and 60% of the cases achieved visual acuity of 0.4 logMAR or better (≥ 20/50) and 0.3 logMAR or better, respectively.

DISCUSSION

The first part of this study reported the in-vitro assessment of the new AcrySof® IQ Vivity™. Our results show that the optical performance of this IOL varied significantly depending on the pupil size (Figure 2). The TF MTFa curve for a 4.5 mm pupil (Figure 2B), showed an optical behavior similar to a monofocal IOL, with a peak of maximum MTFa (and thus, of maximum optical quality) that corresponded to the best focus of the IOL for distance. In fact, the MTFa value at this point (38.4 units) was comparable to that previously reported with a monofocal IOL and an enhanced monofocal IOL[18]. With regard to the TF MTFa curve with 3.0 mm pupil (Figure 2A), it showed three remarkable changes compared to that for 4.5mm. Firstly, the MTFa peak is shifted around -0.50D (myopic shift). To explain this finding, let us consider that with larger pupils, the best focus is reached when the circle of least confusion (i.e., the minimum cross-section of a symmetrical bundle of the rays focusing from the peripheral and paraxial regions of the IOL) is placed in the retina. In contrast, with a smaller pupil, the focusing depends mainly on the paraxial rays. Consequently, the myopic shift found in this IOL when closing the pupil from 4.5 mm to 3.0 mm is due to the zone that “stretches” the wavefront towards higher power which occupies the central-paraxial 2.2 mm[14]. The second notedly difference between optical quality for 3.0- and 4.5- mm was that the maximum MTFa peak for a 3.0 mm was lower than for 4.5 mm (28.9 vs. 38.4 units) and thus, there was a reduction of the optical quality of the IOL. Usually, the smaller the pupil, the higher the optical quality (as long as the pupil diameter does not reach such a small size that diffractive effects become predominant). This paradoxical situation might also be owing to the "*plateau*" area that occupies the central 2.2 mm of the IOL. For a pupil size of 3.00 mm, the useful IOL optical zone would be composed of about 54% "plateau area," while a monofocal-like surface would occupy the remaining area. In contrast, for a pupil size of 4.5 mm, this distribution would change to around 24% for each surface. Consequently, the potential negative impact on the optical quality of this area is expected to be higher for a pupil size of 3.0 mm than for 4.5 mm. Despite this difference, the MTFa value at the peak for 3.0 mm of pupil size was close to 30 units, which was far larger than the reported MTFa threshold from which the visual acuity might decrease (approximately 20 units)[19]. Finally, the TF MTFa curve measured with 3.0 mm pupil shows much clearer focus extension than the curve measured with 4.5mm pupil.

If we jointly analyzed both curves, we could assess the IOL behavior considering the pupil dynamic, which implies larger pupils for distance activities and a progressive pupil constriction at intermediate and near vision due to the accommodation reflex, and that usually is performed under photopic lighting conditions. Attending to this consideration, this IOL would have a behavior comparable to a monofocal IOL for distance vision and an extended range of focus up to around 2.0D, from which the optical quality would significantly decline. This behavior is consistent with the features found in the clinical defocus curve, as will be explained below.

Concerning the halos, overall, we found that larger halos are formed by the AcrySof® IQ Vivity™ compared to the standard monofocal analyzed. **It should be noted that the IOLs analyzed are made with different materials. However, as the comparative measurements were in-vitro, there should be no significant differences due to the material. The potential differences related to the IOL material could arise after a certain time of implantation due to material degradation, glistening.** The finding that the halo size formed by the AcrySof® IQ Vivity™ was more extensive than that of the standard monofocal is not surprising insofar as focus extension is generally accompanied by some degree of halo. However, interestingly, the differences between both IOLs in the halo formed were lower for the 4.5mm pupil size. The AcrySof® IQ Vivity™ tended to produce a smaller halo with the larger 4.5mm pupil. This finding was opposite to those previously found with other design such as enhanced monofocal IOL designed to improve intermediate vision[18] and bifocal and trifocal IOLs[12,23], where the higher the pupil size, the higher the halo. As explained before, the area occupied by the "*plateau*" could have a detrimental effect on the distance optical quality and halo induced by the AcrySof® IQ Vivity™ for small pupils. However, for a pupil of 4.5 mm, the contribution of the 'plateau' region has a relative lower weight thus reducing its negative effect. It is important to note that the halo is particularly bothersome for patients under mesopic and scotopic conditions, i.e., when the pupil size becomes larger. Consequently, in those conditions, this new EDOF IOL focused correctly on the core a high fraction of energy, hence seems to induce halo with low intensity, which could lead to provide, if any, few levels of photic phenomena. Our results showed that the halo formed by this new EDOF IOL is lower intensity than that previously reported with trifocal and bifocal diffractive IOL[12,23] and comparable to that more recently reported with a new monofocal IOL designed to enhance the intermediate vision through a modified aspheric anterior surface[18].

It should be mentioned that slight positive or negative over refractions are not unusual after cataract surgery. Beyond the clinical implications in terms of visual acuity, which will be discussed below, it is essential to evaluate whether a slight residual refractive error may increase the halo induced by the IOL. Our results found that a defocus of +0.50D (hyperopic defocus) caused a larger halo than at the best focus, **especially for 4.5 mm of pupil size,** whereas -0.50D (myopic defocus) did not substantially modify the halo size. This finding suggests that a slight postoperative hyperopic residual refractive error (although, as discussed below, it could have no significant implications in terms of visual acuity) might increase the photic phenomena.

The in-vitro optical performance analysis of the new AcrySof® IQ Vivity™ allows us to conclude that overall, this new EDOF IOL provides good distance optical quality and optimal at intermediate foci (up to 2.00D; equivalent to 50 cm from the eye). However, as expected, insufficient optical quality to achieve an optimal visual quality at distances closer than 40 cm. Furthermore, the halo induced has significantly lower intensity than the ones produced by trifocal and bifocal diffractive IOLs[12,23] and comparable to new enhanced monofocal IOL[18]. Based on this in-vitro analysis, we retrospectively evaluated the clinical outcomes of bilateral AcrySof® IQ Vivity™ implantation in a selected sample of patients with cataracts for whom a standard monofocal IOL would have been our indication, but they were also interested in minimizing dependence on spectacles after surgery.

Our results, at 6 months postoperatively, showed satisfactory refractive outcomes. 95% of the eyes had a refractive sphere within ±0.50 D and 100% within ±1.00D. The refractive cylinder was also significantly reduced through clear corneal incisions. 78.4% had a refractive cylinder < 1.00D, whereas preoperatively was 43.3%. Despite these satisfactory refractive outcomes, it is worthy of notice that 13 eyes (21.6%) had a postoperative refractive cylinder between 1 and 1.50D, which could limit the UDVA restoration[24]. Although, on the other hand, a small amount of refractive cylinder can enhance the uncorrected intermediate VA[25, 26].

Concerning distance visual acuity outcomes, six months after surgery, the mean binocular UDVA and CDVA of 0.10 ± 0.12 (logMAR) and 0.05 ± 0.06 (logMAR), respectively. All patients achieved a binocular CDVA of 0.1 logMAR (20/25) or better. These results are similar to those recently reported by Arrigo et al.[27], who evaluated the real-life experience related to the implant of AcrySof® IQ Vivity™.

With the analysis of the defocus curve (Figure 8), the first finding is that there is an excellent tolerance to a slight postoperative refractive error. The mean visual acuities at -0.50 and +0.50D of defocus was very close to that at the best distance focus (0.02 ± 0.04 logMAR and 0.04 ± 0.03 logMAR, respectively). However, as previously detailed, postoperative hyperopia could lead to an increase of photic phenomena. Moreover, the shape of the curve shows the extension of depth of focus. The mean visual acuity was better than 0.2 logMAR (20/32) between +1.00 and -2.00D of defocus. At a vergence of -2.50 D (40 cm from the eye), the visual acuity was 0.31 ± 0.09 logMAR (20/40). These results showed that this new EDOF IOL provides a good distance visual acuity, optimal or functional up to a distance between 50-40 cm from the eye.

AcrySof® IQ Vivity™ IOL belongs to the EDOF IOLs family, which have as general objective to cover the gap between multifocal IOL and monofocal IOL, providing a distance visual acuity similar to the monofocal IOL and improving visual acuity at intermediate distances, causing fewer photic phenomena than trifocal and bifocal IOL. Several studies have reported visual outcomes with different EDOF IOLs[13]. However, different optical designs and technologies are used in the current available EDOF IOLs (small-aperture design, bioanalogic IOL, diffractive or non-diffractive optics)[13]. Each design has its advantages and drawbacks, making it difficult the comparison between them. However, a comprehensive study of each IOL is of particular importance so that the surgeon can face the challenge of giving the best indication for each IOL aiming to meet the patient's expectation. Based on the in-vitro optical performance results, we observed that this new EDOF IOL provided a good distance optical quality, which translated into a good distance visual acuity in the clinical study. In turn, from an optical standpoint, the IOL showed an extended range of focus up to around 2.0D, with 3.0 mm pupil, which allowed obtaining in the clinical defocus curve an optimal or functional visual acuity up to a distance between 50-40 cm from the eye from which the visual acuity considerably worsened. Concerning the halo, the AcrySof® IQ Vivity™ IOL seems to induce halo with low intensity for a pupil of 4.5 mm (mesopic pupil), which could lead to cause, if any, few levels of photic phenomena. A limitation of the current study was not to evaluate the subjective symptomatology related to photic phenomena using a patient-reported outcomes validated questionnaire for that purpose. Despite this limitation, in our routine practice after cataract surgery, all patients are asked if they perceived disturbing halos and glare and how bothersome these visual disturbances were. No patients reported disturbing halos or glare. This finding agrees with a recent study that reported the real-life experience three months after AcrySof® IQ Vivity™ implantation[27]. The authors concluded patients tolerated the IOL very well, and the haloes and glare (although they occurred in about 30% of the patients) were highly tolerated. Similar to ours, the inclusion criteria were patients with clinically relevant cataracts.

In summary, our findings showed that this new EDOF IOL provided a good distance optical and visual quality and yielded an extended range of focus up to around 2.0D, which allowed obtaining an optimal or functional visual acuity up to a distance between 50-40 cm. Furthermore, the halo formed has significantly lower intensity that the ones produced by trifocal and bifocal diffractive IOLs. All these findings suggest that this new EDOF IOL could be a good indication for cataract patients for whom, up to now, a standard monofocal IOL would have been the indication.

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FIGURE LEGEND

Figure 1. (A) Image of the pinhole object in linear scale of intensity obtained at the best focus position of the Vivity IOL. The energy in the core region and halo was obtained inside and outside the yellow circle respectively. (B): same image but in logarithmic scale, exclusively for halo visualization. Pupil size 3.0 mm.

Figure 2. Through focus MTFa curves obtained with the AcrySof® IQ Vivity™ IOL with (A) 3.0 mm and (B) 4.5mm pupil.

Figure 3. Images of the pinhole formed at their best focus by the monofocal standard IOL Clareon (top) and AcrySof® IQ Vivity™ (bottom) with 3.0- and 4.5-mm pupils. The images are in logarithmic scale of intensity.

Figure 4. Core (A) and halo energy (B) obtained with 3.0- and 4.5-mm pupil sizes with the standard monofocal Clareon (red bars) and AcrySof® IQ Vivity™ (black bars).

Figure 5. Images of the pinhole formed at their best focus, and with defocus of -0.50D, and +0.50D by the AcrySof® IQ Vivity™ with 3.0- (top) and 4.5-mm pupils (bottom). The images are in logarithmic scale of intensity.

Figure 6: Cumulative binocular uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) at 6 months post-surgery.

Figure 7: Postoperative manifest refractive sphere accuracy.

Figure 8: Mean, binocular visual acuity (logMAR) with best correction for distance, as a function of the chart vergence. Y-axis on the right shows the Snellen feet equivalent of visual acuity, and X-axis vergence (bottom diopters and top equivalence in cm). Error bars represent the SD.

Table 1. Preoperative patients' data.

	Mean ± SD	Range [Min, Max]
Age (years)	76.69 ± 5.95	[65, 85]
Refraction sphere (D)	+0.29 ± 2.68	[-6.50, +5.0]
Refraction cylinder (D)	-0.96 ± 0.57	[-2.0, 0]
Spherical Equivalent (D)	-0.19 ± 2.67	[-7.00, +4.50]
CDVA (logMAR)		
Monocular	0.21 ± 0.27	[1.00, 0.10]
Binocular	0.07 ± 0.07	[0.2, 0.00]
UDVA		
Monocular	0.77 ± 0.48	[2.00, 0.10]
Binocular	0.51 ± 0.36	[1.40, 0.10]
Minimum Keratometry (D)	43.69 ± 1.40	[41.00, 46.25]
Maximum Keratometry (D)	44.25 ± 1.42	[41.75, 47.25]
ACD (mm)	2.89 ± 0.48	[1.91, 4.16]
Pupil diameter (mm)		
Photopic (85 cd/m^2)	2.85 ± 0.58	[2.01, 3.97]
Mesopic (3 cd/m^2)	4.62 ± 0.77	[2.82, 5.98]
Axial Length (mm)	23.47 ± 0.72	[22.06, 24.97]

D: diopters; CDVA: Corrected Distance Visual Acuity; UDVA: Uncorrected Distance Visual Acuity; ACD: anterior chamber depth; SD: standard deviation.

Figure 1

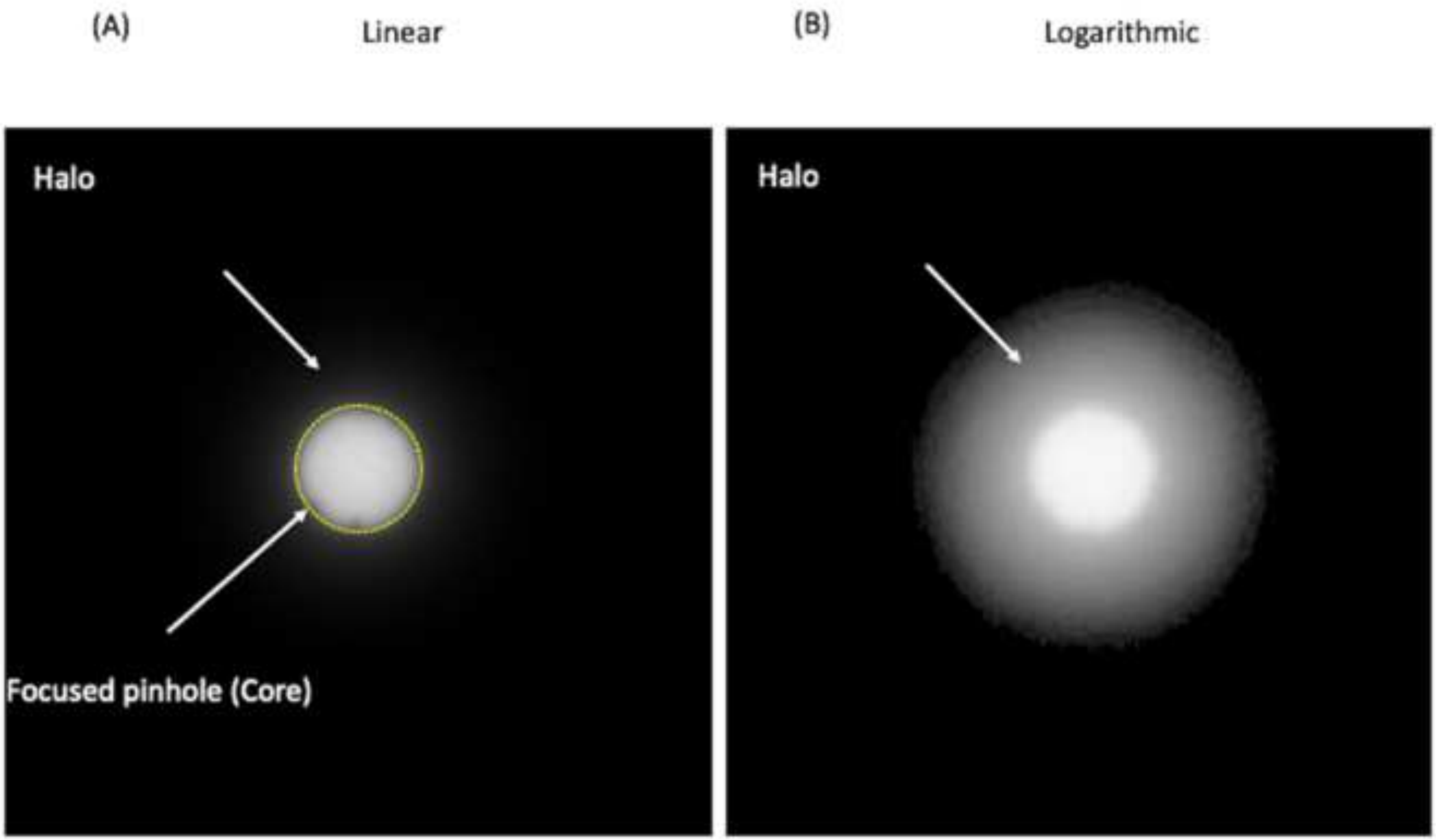

Figure 2

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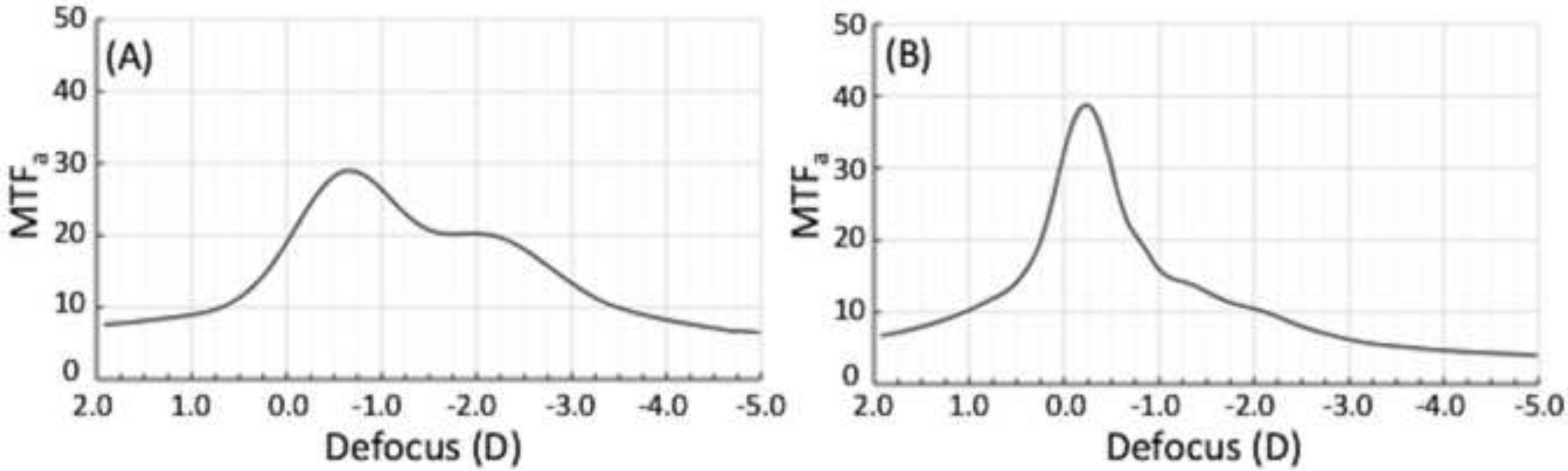

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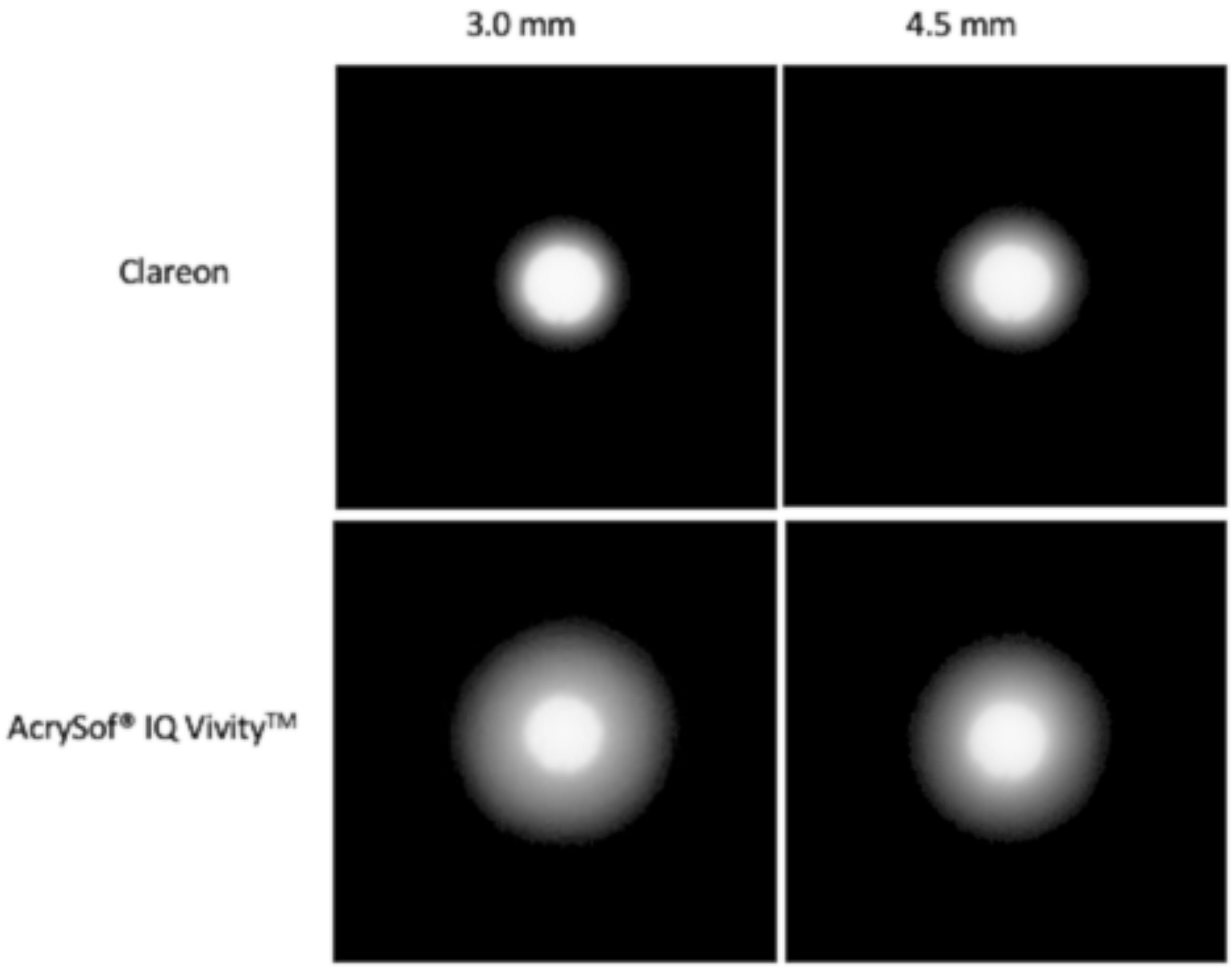

Figure 4

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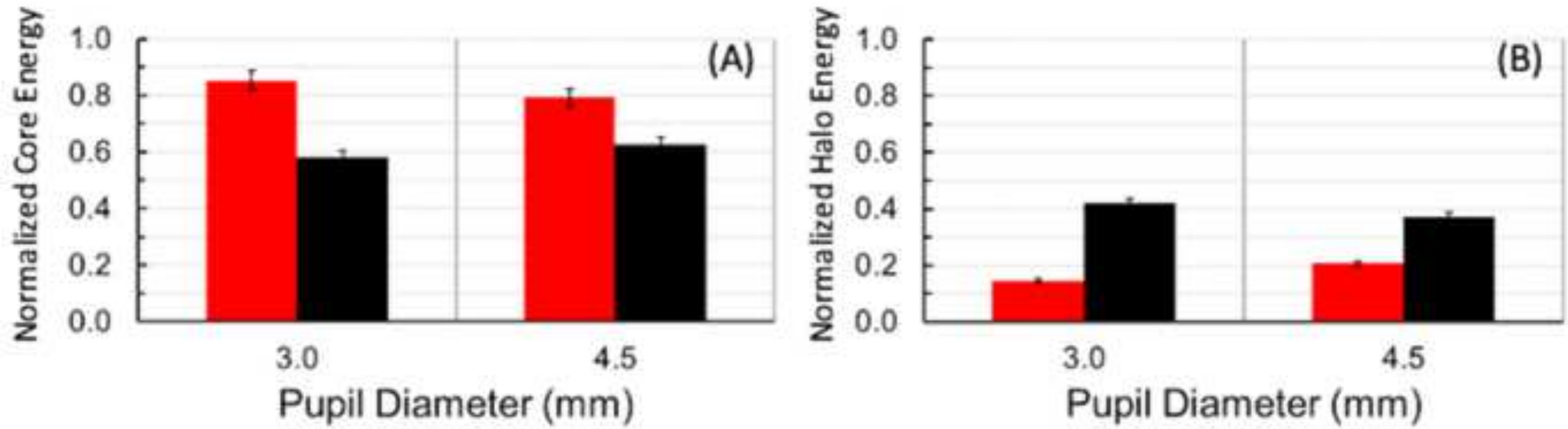

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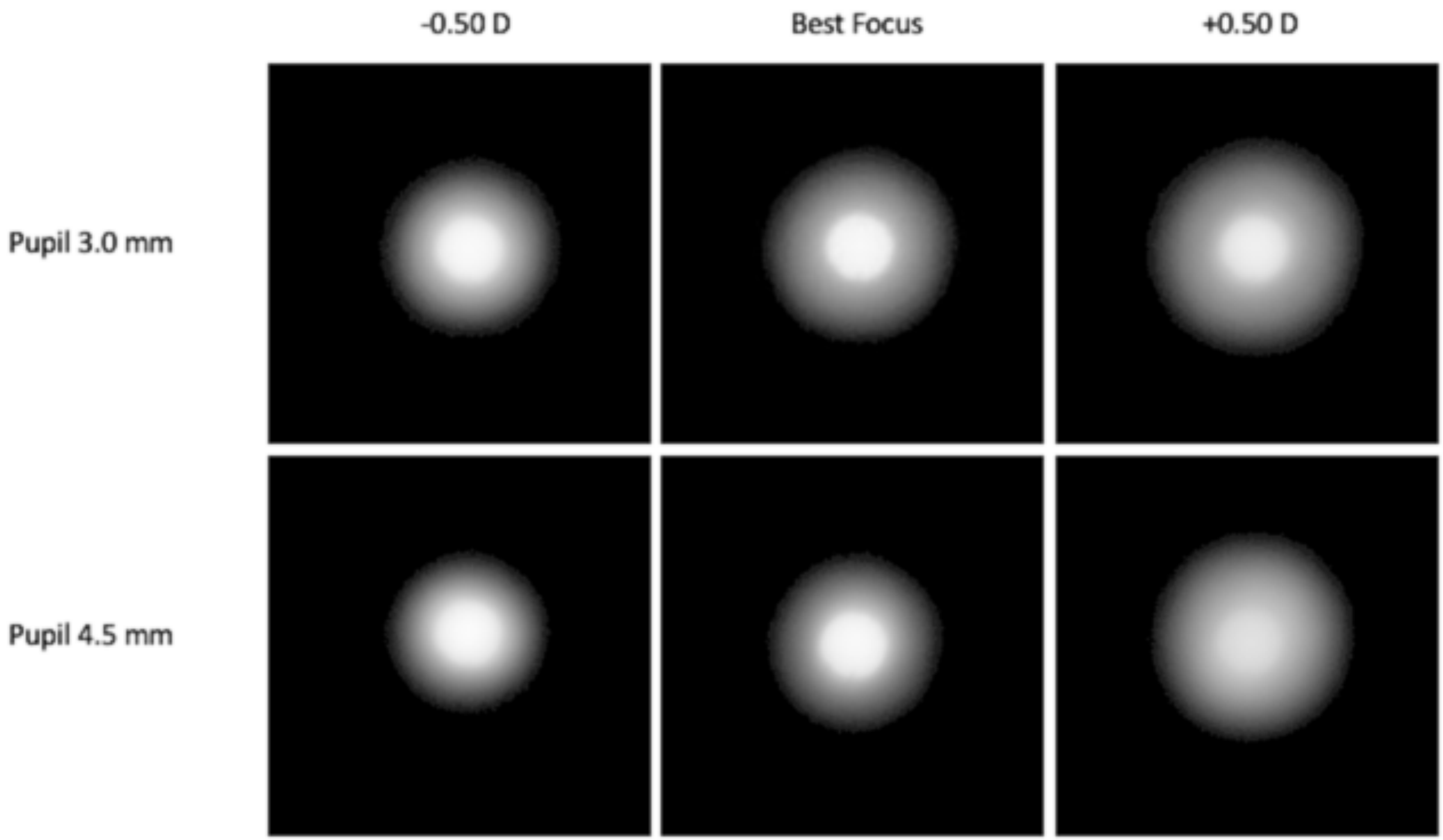

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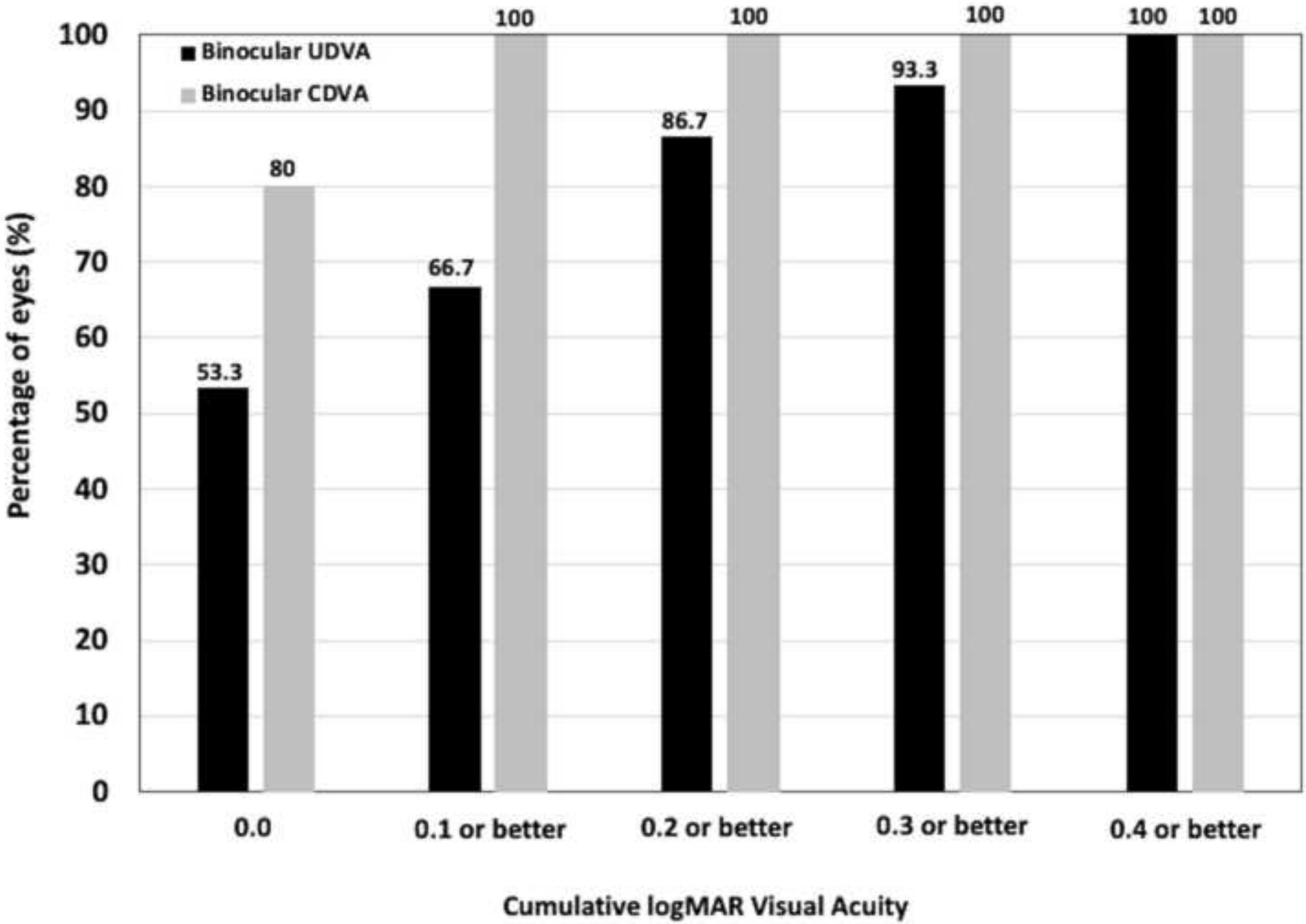


Binocular UDVA
Binocular CDVA
Percentage of eyes (%)
100
90
80
70
60
50
40
30
20
10
0
53.3
80
66.7
100
86.7
100
93.3
100
100
100
0.0
0.1 or better
0.2 or better
0.3 or better
0.4 or better
Cumulative logMAR Visual Acuity

Figure 7

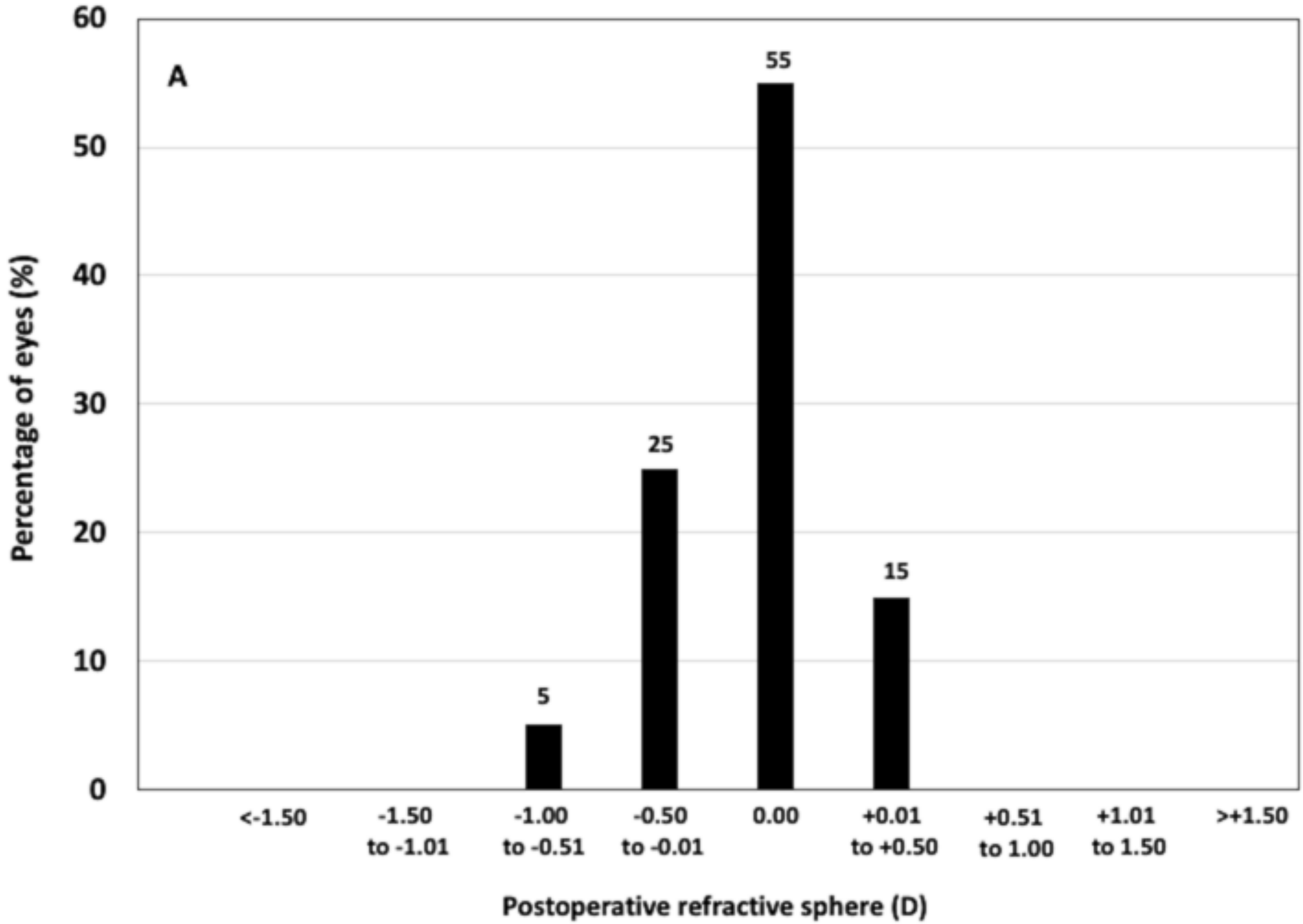
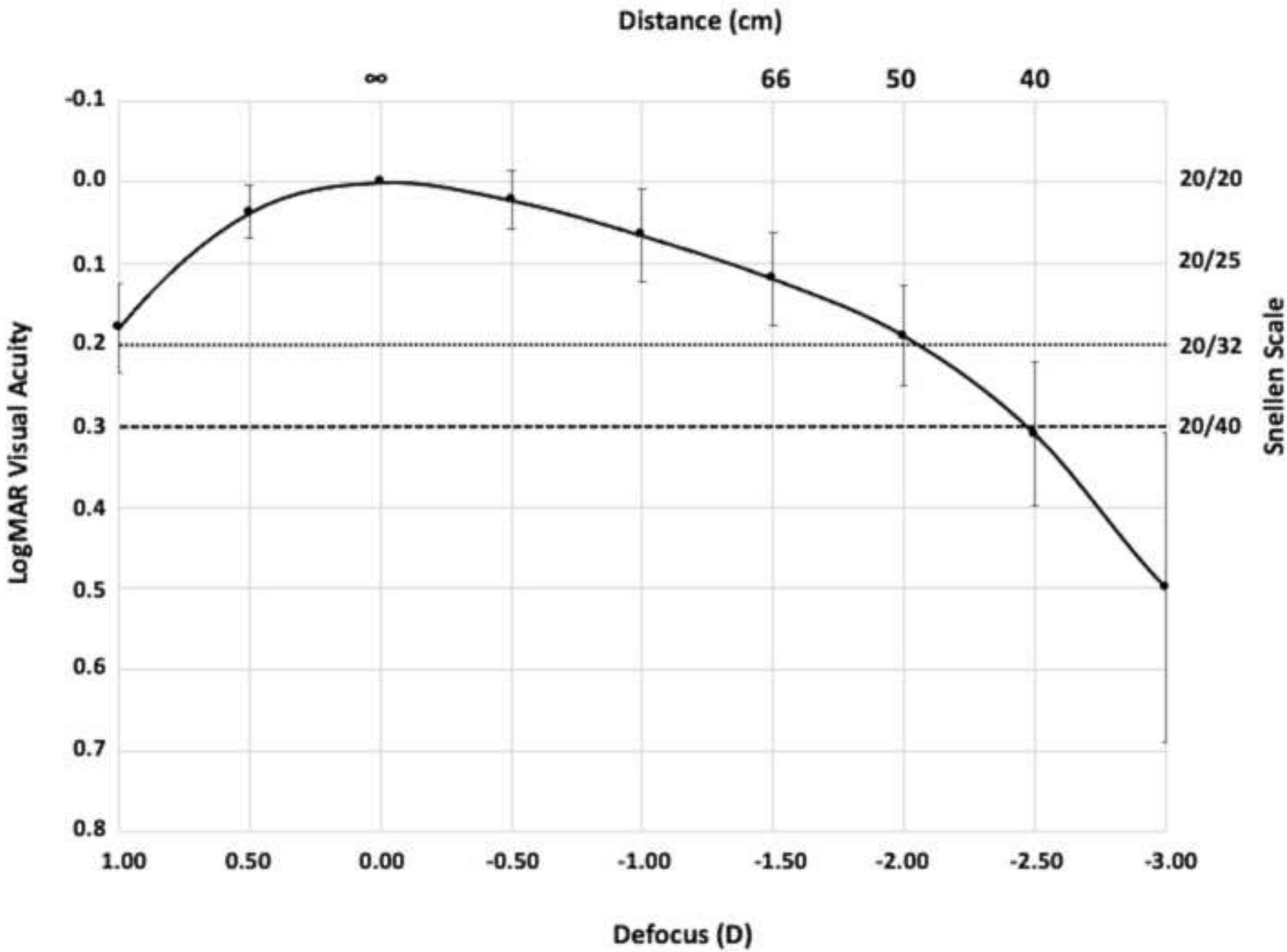

A
Percentage of eyes (%)
0
10
20
30
40
50
60
5
25
55
15
<-1.50
-1.50 to -1.01
-1.00 to -0.51
-0.50 to -0.01
0.00
+0.01 to +0.50
+0.51 to 1.00
+1.01 to 1.50
>+1.50
Postoperative refractive sphere (D)

Figure 8


Distance (cm)
∞
66
50
40
-0.1
0.0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
LogMAR Visual Acuity
20/20
20/25
20/32
20/40
Snellen Scale
1.00
0.50
0.00
-0.50
-1.00
-1.50
-2.00
-2.50
-3.00
Defocus (D)

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