

Beam-shaping Extended Range of Vision Intraocular Lens: Optical Assessment With Corneas of Increasing Spherical Aberration

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ABSTRACT

PURPOSE: To assess the optical quality and halo formation of a beam-shaping extended depth-of-focus (EDOF) intraocular lens (IOL) (AcrySof IQ Vivity; Alcon Laboratories, Inc) with corneas of long-range spherical aberration (SA) such as those resulting from myopic laser ablations.

METHODS: The optical quality of the EDOF IOL and a reference monofocal IOL was evaluated with three corneas (A, B, and C, with SA =+0.135, +0.290, +0.540 μm , respectively, for a 5.15-mm pupil at the IOL plane). The through-focus modulation transfer function area (MTFa) curves were obtained between -5.00 and +2.00 diopters (D) defocus range. The halo was also assessed with the three corneas.

RESULTS: Through-focus MTFa curves for a 4.5-mm IOL pupil showed a slight decrease in the maximum MTFa value


provided by the EDOF IOL compared to the monofocal IOL in the three corneal situations (A: 45.9 vs 38.6 units; B: 41.1 vs 33.1 units, and C: 26.9 vs 23.8 units). For the 3-mm pupil, the EDOF IOL also had lower maximum MTFa than the monofocal IOL; however, the depth-of-focus increased to -2.20 D. With corneas A and B, the halo induced was of low energy with both IOLs. With cornea C, the EDOF IOL created a much larger and intense halo.

CONCLUSIONS: The EDOF IOL provided a good distance optical performance and an extended range of focus of approximately 2.00 D, with a halo of low intensity when evaluated with a corneal SA similar to the one induced by a low to moderate myopic ablation. With a high myopic ablation, the halo induced would be of considerable size and energy.

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Laser corneal refractive surgery has demonstrated excellent safety and efficacy for myopia correction,^{1,2} leading its performance in millions of patients to achieve spectacle or contact lens independence. However, this independence expires with presbyopia and cataract development. Lens surgery with a presbyopia-correcting diffraction-based intraocular lens (IOL) implantation has shown promising results in these patients³⁻¹⁴ because the procedure provides pseudo-accommodation to the eye. Nevertheless, both procedures (corneal refractive surgery and IOL implantation) may induce visual drawbacks concerning an increase in corneal higher order aberration,¹⁵⁻²⁰ risk

of dysphotopias, and decrease in contrast sensitivity associated with the plurality of foci formed by any presbyopia-correcting diffractive IOLs.²¹⁻²³ The combination of both sources of potential disturbances makes the implantation of presbyopia-correcting diffractive IOLs a controversial issue in patients who previously underwent laser corneal refractive surgery^{23,24}

The AcrySof IQ Vivity IOL (Alcon Laboratories, Inc) is a new  extended depth-of-focus (EDOF) IOL, which uses proprietary wavefront-shaping technology aiming to extend the range of vision and reduce photic phenomena compared to presbyopia-correcting diffraction-based IOLs. The few clinical studies

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conducted to date seem to indicate that this new IOL meets the objective of providing a good visual quality from distance to intermediate distance with functional near visual acuity and without significant visual disturbances.²⁵⁻³¹ However, as with all new IOL designs, the clinical studies have only been conducted in patients with normal untreated corneas.²⁵⁻²⁸ With these findings in mind, a question arises as to whether this IOL could also be a good option for patients who have had corneal refractive surgery.³²

Pre-clinical studies in the optical bench represent a helpful tool for evaluating the performance of an IOL combined with different simulated corneas, which allows assessment of the potential benefits and drawbacks before conducting clinical studies that obviously would require IOL implantation in patients.

The current study aimed to develop a comprehensive pre-clinical analysis of optical performance and halo produced in the event the AcrySof IQ Vivity IOL is combined with corneas of long-range spherical aberration (SA), in particular of high positive SA as would be the case if they had undergone previous myopic laser ablations.

MATERIALS AND METHODS

IOL

The IOL studied was the AcrySof IQ Vivity. It is an EDOF IOL that uses a proprietary technology entitled wavefront-shaping (X-WAVE) by the manufacturer. The IOL's characteristics have been detailed in previous studies.²⁵⁻³¹ Briefly, the mechanism to produce a continuous extension of the focus in this IOL relies on the 2.2-mm center with a "plateau design," which creates a two-surface transition that would induce a "stretching and shift" of the wavefront. From this 2.2-mm central region outward, the IOL has a monofocal design. The lens is available from +15.00 to +25.00 D in 0.50-D increments. The optical bench analysis of this study was carried out with lenses of 20.0 D base power. For comparison purposes, we also evaluated a standard monofocal IOL (Clareon; Alcon Laboratories, Inc). The asphericity communicated by the manufacturer for both IOLs is -0.2 μm .

OPTICAL PERFORMANCE

The optical quality of the IOLs was assessed using the NIMO TEMPO device (Lambda-X). It is an interferometer optimized to measure IOLs, including diffractive designs. The instrument is controlled by the software TEMPO-MENTOR (Lambda-X). This device allows MTF measurements at various frequencies and focal planes. In the experimental set-up, the IOL must be inserted into a cuvette containing saline or deionized water. The cuvette is then placed in the object arm of the interferometer. Once the set of images is acquired and processed,

the system computes the corresponding MTF curves. The system simulates a model cornea, which must be placed in front of the IOL to measure the IOL imaging performance in a representative eye. The model cornea is free of any higher order aberrations other than the 4th-order spherical aberration. This capability to simulate a model eye allows us to compute the IOL imaging performance at multiple apertures or with different cornea models without additional data acquisition.

The optical quality of the IOLs was evaluated with three artificial corneas with different degrees of 4th-order SA for a 5.15-mm pupil at the IOL plane³³ (+0.135, +0.290, and +0.540 μm), which aimed to simulate the SA of a normal untreated cornea, and corneas that underwent laser refractive surgery for low and moderate myopia, respectively.³⁴⁻³⁶ We recall that in normal pseudophakic and schematic eyes, 5.15 mm at the IOL plane corresponds to exposing a 6-mm corneal zone.³³ For better readability throughout the article, each simulated cornea (+0.135, +0.290, and +0.540 μm) will be referred to as A, B and C, respectively. For this study, the modulation transfer function (MTF) was obtained for a 3- and 4.5-mm diameter of aperture at the IOL plane. The focus extension was assessed from the through-focus MTF curves scanning the image space between +2.00 and -5.00 D defocus in 0.10-D steps. For a given focus position within the through-focus range, two MTF curves in the X and Y directions of the image plane were obtained and averaged. Then, the through-focus area under the MTF (MTFa) curves was calculated according to previous studies.^{38,39} 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 (the latter corresponding, in an eye of 17-mm focal length, to 15 cycles per degree in the object space or 0.30 logMAR).

HALO ASSESSMENT

The halo induced by the AcrySof IQ Vivity and monofocal IOLs were assessed in vitro with a test bench of the Grupo de Óptica Aplicada y Procesado de Imagen (GOA-PI, Universitat Politècnica de Catalunya BarcelonaTech, Terrassa, Spain) that incorporates a model eye specifically designed to get closer to a physiological eye⁴⁰ in combination with an adaptive optics system.⁴¹ This way, the higher order aberrations of the cornea (and specifically, the SA) could be modified accordingly, and then the halo formation and its characteristics were evaluated with the same corneal SA values (A: +0.135 μm , B: +0.290 μm , and C: +0.540 μm for a 5-mm pupil at the IOL plane) as those used for the MTF analysis.

Figure A (available in the online version of this article) shows a sketch of the optical bench with the adaptive optics system used for halo assessment. The adaptive op-

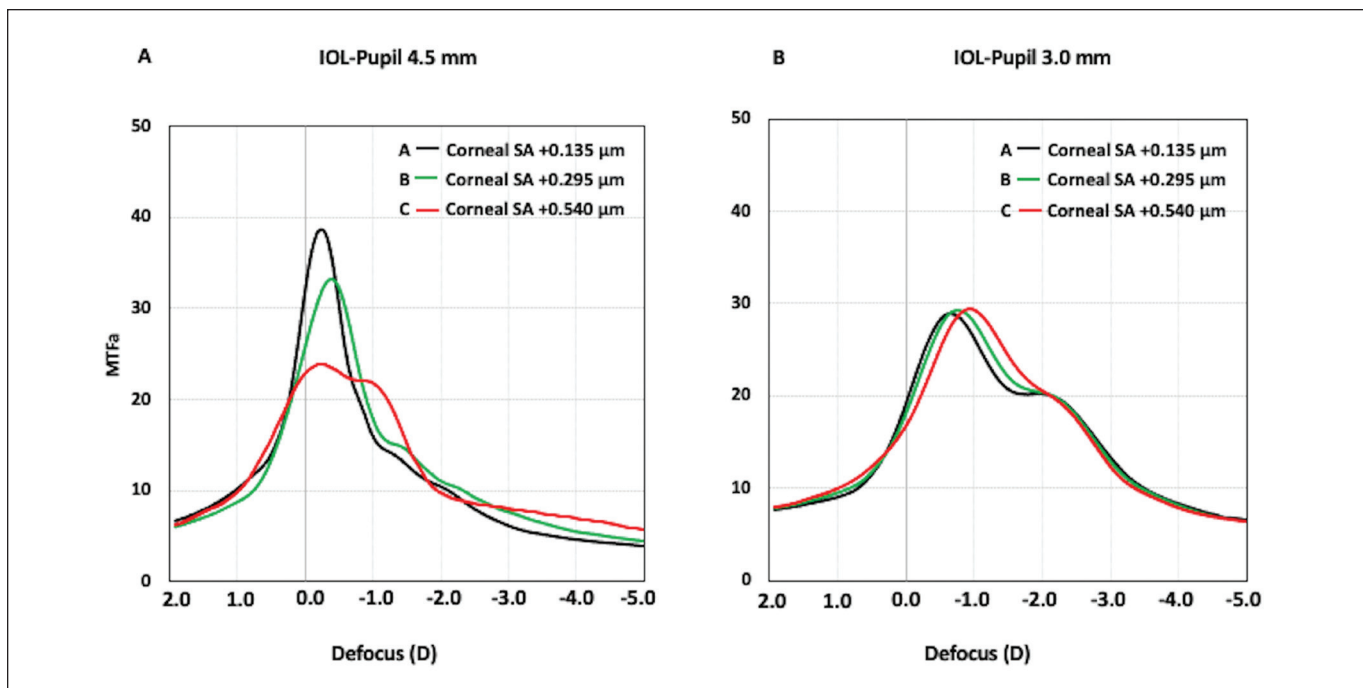


Figure 1. Through-focus modulation transfer function area (MTFa) curves obtained with the AcrySof IQ Vivity IOL (Alcon Laboratories, Inc) with a (A) 4.5- and (B) 3-mm pupil for corneas A, B, and C. SA = spherical aberration

tics system allowed us to modify the corneal SA of the model eye to match the required values of corneas A, B, and C (normal untreated cornea and cornea that underwent prior laser refractive surgery for low and moderate myopia, respectively). Regarding the illumination system, a high-power green LED source ($530 \pm 20\text{nm}$) illuminated a pinhole test object. The test is optically set to infinite (0.00 D vergence) by placing it at the object focal plane of a high optical quality collimator (150-mm focal length). A customized model eye was fabricated with a meniscus shape cornea embedded at one side of the wet cell, next to an iris diaphragm and the IOL under test.

The image acquisition system is formed by an infinity corrected microscope (10X Mitutoyo Plan Apo Infinity objective plus 200 mm focal tube lens) that magnifies and projects the images of the pinhole test formed by the model eye with the IOL, onto a photometric matrix array sensor ($1,920 \times 1,440$ pixels, Westboro Photonics P280SU). All optical elements in the set-up were mounted in high-precision mechanical holders with three axis (x, y and z) micrometers precision adjustments.

The image provided by the photometric array sensor (Figure BA [available in the online version of this article], linear scale of luminance) 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 BB). The luminance of the

halo and core regions were computed and normalized to the total luminance of the image.

The halo induced by the EDOF AcrySof IQ Vivity and monofocal Clareon IOLs was evaluated in the best focus plane (0.00 D defocus) for 4.5-mm pupil diameter with the A, B, and C artificial corneas. Additionally, to assess the effect of a hypothetical postoperative refractive error of 0.50 D on the halo induced by the EDOF AcrySof IQ Vivity, the measurements were also taken for +0.50 and -0.50 D defocus.

RESULTS

OPTICAL PERFORMANCE

We analyze the effect of an increase in corneal SA on the optical behavior of the EDOF IOL under study through the through-focus MTFa curves of the EDOF IOL for each simulated cornea for 3- and 4.5-mm of pupil aperture (Figure 1). For the 4.5-mm pupil (Figure 1A), the peak of maximum MTFa, and thus the maximum optical quality, decreases as the corneal SA increases (38.6, 33.1 and 23.8 units, for corneas A, B, and C, respectively). Furthermore, with corneas A and B, the shape of their MTFa curves is similar, showing a single highlighted peak, and then a monotonous MTFa decay for both lower (hyperopic) and higher (myopic) powers. However, the shape of the MTFa curve is significantly different for cornea C: the peak of maximum MTFa is lower and the shape of the curve widens toward the myopic powers. For the 3-mm pupil (Figure 1B), the increase in corneal SA did not seem to af-

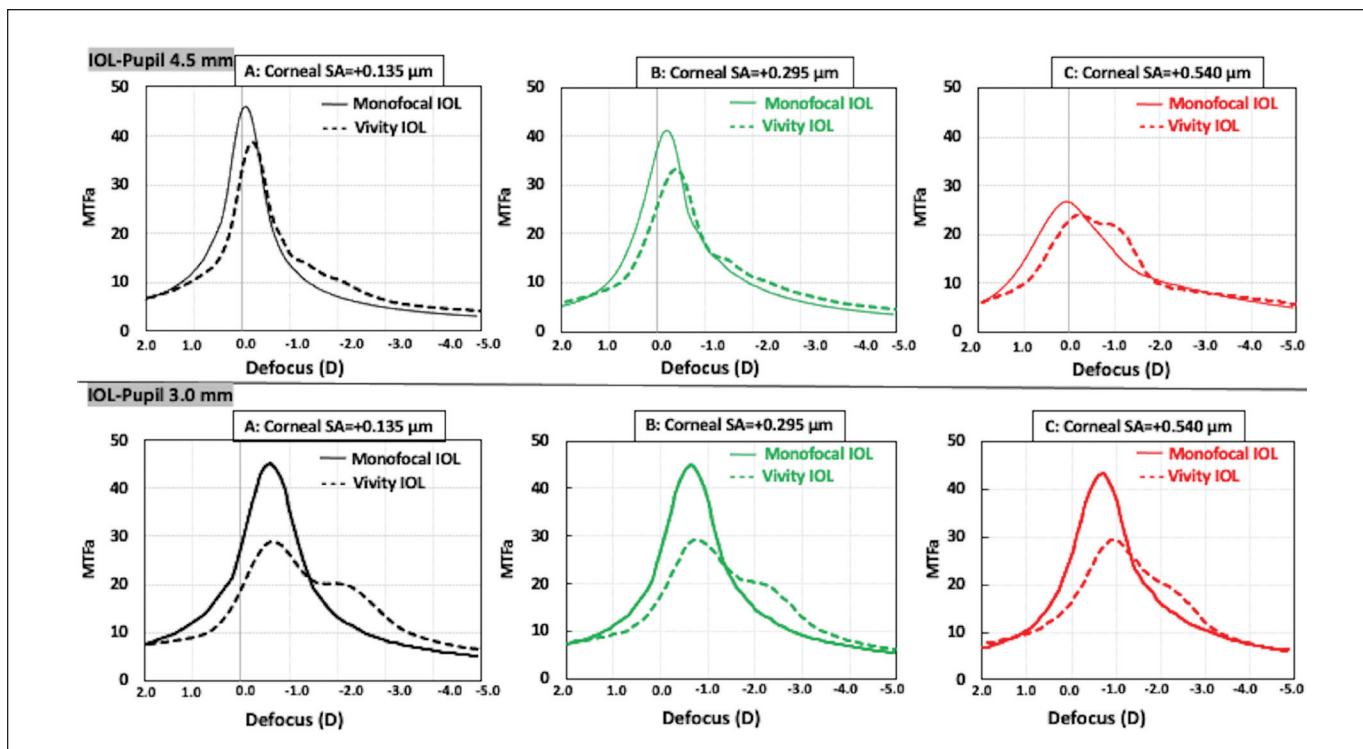


Figure 2. Through-focus modulation transfer function area (MTFa) curves obtained with the AcrySof IQ Vivity IOL (Alcon Laboratories, Inc) (dashed lines) and the standard monofocal Clareon IOL (Alcon Laboratories, Inc) (solid lines) with a 4.5- and 3-mm pupil for corneas A, B, and C. D = diopters

fect either the maximum MTFa value or the curve shape. Of note, as the SA increased the maximum peak position shifted toward higher myopic defocus (-0.70, -0.80, and -1.00 D for corneas A, B, and C, respectively).

For the sake of comparison, **Figure 2** shows the through-focus MTFa curves of the EDof IOL and reference monofocal IOL for each corneal situation. For the 4.5-mm of pupil size, the optical quality of the monofocal IOL also worsened as the SA of the simulated cornea increased. Thus, we measured a decrease in the peak of maximum MTFa value provided by the EDof IOL with respect to the monofocal IOL with the three simulated corneas (45.9 vs 38.6 units with cornea A; 41.1 vs 33.1 units with cornea B, and 26.9 vs 23.8 units with cornea C). For the 3-mm pupil, however, the increase in the corneal SA did not significantly affect the optical behavior of both IOLs designs. More in detail and in contrast with the single peaked curve of the monofocal design, the EDof IOL had a lower peak value, and the shape of the MTFa curve widened towards the myopic powers with a plateau of MTFa of approximately 20 that reaches defocus values of -2.20 D. From this point onward to nearer distances (-2.20 to -5.00 D), the MTFa curve significantly declines.

HALO ASSESSMENT

The images formed by the EDof and the monofocal IOLs of the pinhole object test with a 4.5-mm pupil are

shown in **Figure 3**. The images were recorded at the best focus for distance vision with both IOLs, and with defocus of ± 0.50 D in the case of the EDof lens. We recall that the images are displayed on a logarithmic scale only for the sake of better visualization. The horizontal bars below each figure account for the energy in the core (green) with respect to the halo regions (red) (relative to the total energy of the image). In the best focus with corneas A and B, the EDof IOL induced slightly larger halo than the monofocal IOL, meaning that, in both situations, the EDof IOL correctly focused a high fraction of energy on the core. Overall, the halo features of both IOL designs were comparable in A and B situations. However, with cornea C, which induces a larger amount of SA, the halo produced with the EDof IOL was almost twice as big and energy as the halo produced by the monofocal IOL. Cornea C (**Figure 3**, bottom row) led to clearly worse haloes with both EDof and monofocal IOLs in comparison with the other two simulated corneal profiles.

To show the impact of defocus on the halo formed by the EDof IOL, **Figure 3** also displays the results obtained with -0.50 and +0.50 D defocus. Compared to the best focus, a defocus of +0.50 D (hyperopic defocus) or -0.50 D (myopic defocus) induced a somewhat larger halo with corneas A and B. For cornea C, the halo at the best focus was so large and intense that those values of defocus barely influenced on the halo formed.

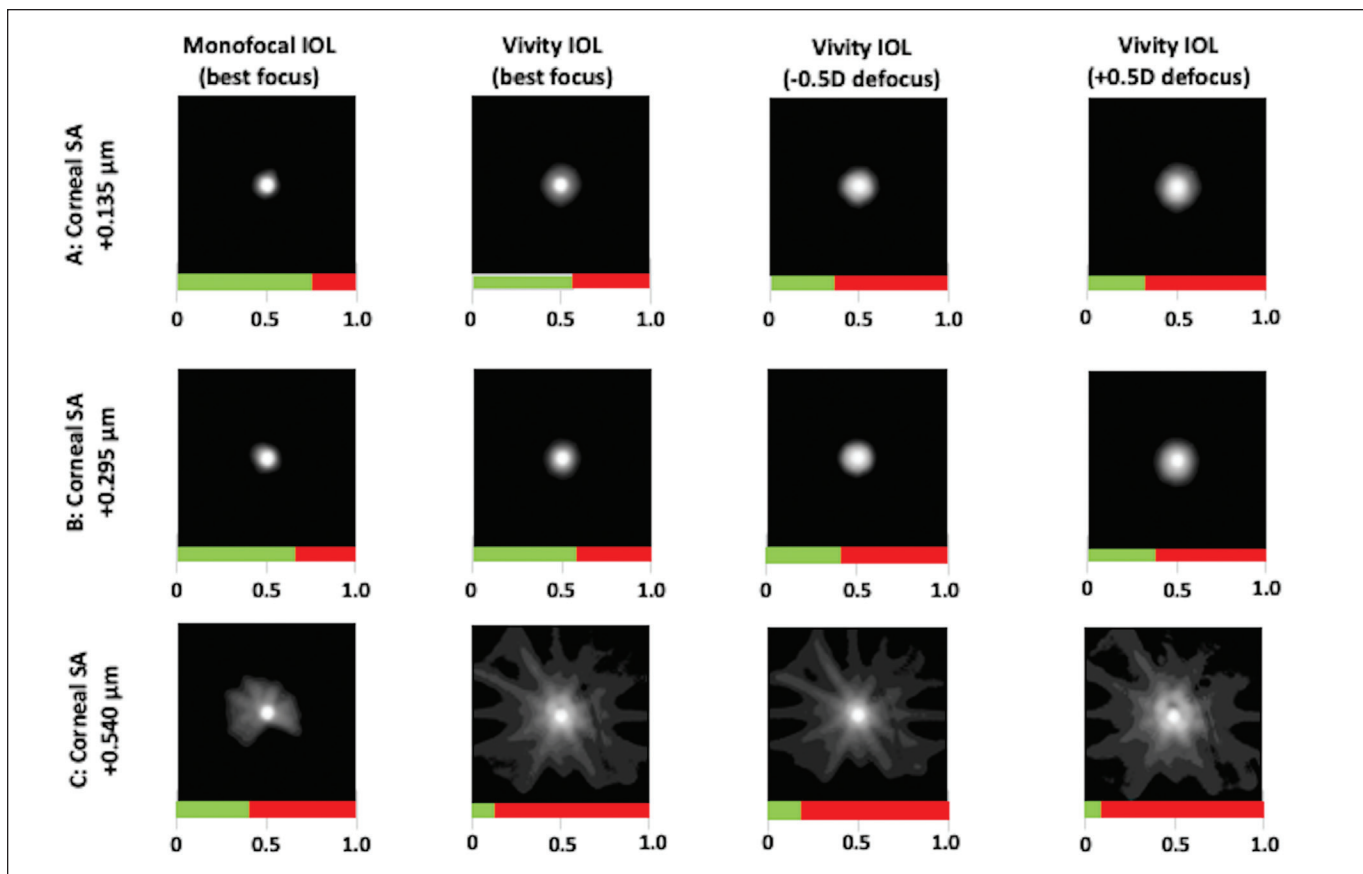


Figure 3. Best focus images of the pinhole object test formed by the [Clareon](#) and AcrySof IQ Vivity intraocular lenses (Alcon Laboratories, Inc) with a 4.5-mm pupil in corneas A, B, and C. The figure also shows the images of the pinhole formed with defocus of -0.50 and +0.50 diopters by the AcrySof IQ Vivity with a 4.5-mm pupil and in each situation evaluated. The images are in logarithmic scale of intensity. The horizontal bars show the energy in the core (green) and halo (red) regions relative to the total energy of the image. SA = spherical aberration

DISCUSSION

In a previous study by our research group, we reported the optical behavior of the EDOF IOL with an artificial cornea that was intended to simulate, in terms of its higher order aberrations, a normal untreated cornea.²⁶ This analysis is also repeated in the current study for the sake of comparison and corresponds to the results obtained with cornea A (SA = +0.135 μm for 5.15-mm IOL pupil). Considering the pupil dynamic, which involves larger pupils for distance activities and a progressive pupil constriction at intermediate and near vision due to the accommodation reflex, our previous work showed that this IOL would have a behavior comparable to a monofocal IOL for distance vision and an extended range of focus up to approximately 2.00 D. From such a defocus onward to closer distances, the optical quality would significantly decline. Furthermore, we found that the halo induced was low intensity.²⁶ These outcomes in the optical bench correlated well with the clinical results reported in several studies, which concluded that the range of vision, from distance to near, significantly improved with the EDOF IOL compared to the monofocal IOL while maintaining

a similar low visual disturbance.²⁵⁻³¹ These clinical findings, along with the features of optical IOL design, led to researchers postulating that this new beam-shaping EDOF design might be a good approach for patients with a previous myopic corneal refractive surgery.³² However, no previous clinical or experimental studies have analyzed how this IOL performs with corneas with increased amounts of positive spherical aberration, which is the case of corneas that underwent a myopic ablation. This study addresses how an increasing positive corneal SA may affect the optical performance and the halo formed by this beam-shaping EDOF IOL.

In **Figure 1A** for a 4.5-mm IOL pupil, the comparison between corneas A and B yielded that an increase in corneal SA up to +0.295 μm (5.15 mm IOL pupil), which could represent a low to moderate myopia ablation³⁴⁻³⁶ did not significantly modify the optical performance of the IOL, beyond the slight decrease in the maximum MTFa. However, with cornea C (which simulates the SA induced by a high myopic ablation³⁴⁻³⁶), there was a significant deterioration in the optical performance.

The joint analysis of the three situations shown in **Figure 1** (considering the pupil dynamic previously noted) would suggest that in patients who had a previous corneal refractive procedure for low to moderate myopia, this beam-shaping EDOF IOL would provide similar visual performance as in patients with normal untreated corneas (ie, those previously reported in clinical studies).²⁵⁻³¹ In contrast, in patients with a high myopic ablation, a significant deterioration in distance vision would be expected. It is worth noting that all of these considerations are formulated assuming a pupil size of approximately 4.5 mm for distance activities. The behavior would be noticeably different for patients with a pupil size of 3 mm or smaller. First, the maximum peak position is shifted toward myopic values in all three situations. Consequently, a further adjustment in the IOL power calculation should be performed to achieve emmetropia and place the best focus on distance vision (approximately 0.50 D less positive). However, that adjustment on the IOL power would induce a displacement of the curve as a whole toward the left, consequently shortening the extended range of vision. The second remarkable finding is that for a small pupil the increase in corneal SA would not significantly modify the optical performance of the IOL. It is well known that the smaller the pupil size, the more negligible the impact of the SA on the optical quality. Finally, it is worth emphasizing that, with corneas A and B, the maximum MTFa peak for a 3-mm pupil was lower than for a 4.5-mm pupil; thus, the optical quality of the IOL decreased when the pupil became smaller. This paradoxical finding has already been reported in previous experimental studies,^{26,42} and it has been proposed that it is inherent to the optical design of the lens and the space occupied by the plateau area.²⁶

The previous analysis is helpful to know the impact of increasing corneal SA on the optical behavior of the IOL on the reference situation (normal untreated cornea), that is, on what was previously reported. However, in patients undergoing corneal refractive surgery, their cornea profile and the associated high-order aberrations will be different. Hence, we considered it relevant to evaluate the benefits and drawbacks of implanting this EDOF IOL in a specific patient profile compared to a standard monofocal IOL. This is reported in **Figure 2** for the two IOL pupils analyzed, 4.5 mm (top row) and 3 mm (bottom row). The comparison of the MTFa curves obtained with corneas A and B led, as previously explained, to a behaviour comparable to a monofocal IOL for distance vision and an extended range of focus up to approximately 2.00 D (considering the pupil requirements previously detailed, which implies a larger pupil for distance vision and smaller for near). **Figure 2** also shows for the EDOF IOL and 4.5-mm pupil that the optical quality was

significantly worse with cornea C than with corneas A and B, albeit there was not a significant worsening of its optical quality compared to a monofocal IOL. Hence, similarly to the patients with normal untreated corneas (A corneal condition) or with previous low to moderate corneal ablation for myopia correction (B corneal condition), this beam-shaping EDOF IOL would provide a similar distance optical quality to a monofocal IOL, but with the advantage of extending further the depth of vision. Hence, as long as the patients had a pupil size for distance activities of up to 4.5 mm, this analysis allows us to conclude that independently of the SA induced, the EDOF IOL evaluated would provide a comparable distance optical quality to a reference monofocal IOL and extend the range of vision (note that for a pupil of 3 mm in distance vision it should be considered the worsening on the optical quality previously explained).

Extending the range of vision while maintaining a similarly photic phenomena profile to the monofocal IOL is the great claim of this new beam-shaping EDOF IOL. With corneas A and B and considering the best focus plane, we found that the EDOF IOL induced a slightly larger halo than the monofocal IOL. In both cases, this EDOF IOL correctly focused a high fraction of energy on the core (**Figure 3**; green part of the horizontal bars). Hence, it seems to induce a halo with low energy, which could lead to providing few levels of photic phenomena, if any. Furthermore, increasing the corneal SA to +0.295 μm (5.15-mm IOL pupil) did not modify the halo features. These outcomes suggest that patients with a previous low to moderate myopia ablation should not experience a more bothersome halo than that reported in patients with normal untreated corneas. However, it is worth noting that, as shown in **Figure 3**, a slight postoperative residual refractive error caused a larger halo with more energy, which might increase the postoperative photic phenomena. This aspect is relevant from two perspectives. First, a slight postoperative residual refractive error might increase the photic phenomena. Second, the clinical studies aiming to evaluate the visual disturbances through subjective questionnaires should consider the postoperative residual refraction, analyzing the outcomes separately in emmetropic patients and those with a residual refractive error, which would allow knowing the effect of the IOL design on the halo induced and the cumulative effect of residual refractive error plus IOL design.

The features of the halo induced drastically changed when the EDOF IOL was tested jointly with cornea C (+0.540 μm of SA for 5.15-mm IOL pupil, which is intended to represent a high myopic ablation³⁴⁻³⁶). The halo was almost twice the size and intensity than that

produced by a monofocal IOL and in the other two simulated corneal profiles.

A limitation of the current study was that we just tested one sample of the two assessed IOLs. Nevertheless, different studies showed high repeatability in the design parameters and performance when different samples of a commercially available IOL were assessed with lenses of base power ranging from 19.00 to 23.00 D.⁴³⁻⁴⁵

The outcomes found in this experimental study in an optical bench should be considered as a pre-clinical study, the starting point. These results might be of great interest to designing future clinical studies to evaluate the efficacy and safety of implanting the beam-shaping EDOF AcrySof IQ Vivity IOL in patients who have had corneal refractive surgery. Our findings in this experimental study showed that this EDOF IOL performed similarly to normal untreated corneas and with corneas simulating the conditions after low to moderate myopic ablation (ie, an optical performance comparable to a monofocal IOL for distance vision and an extended range of focus up to approximately 2.00 D), whereas the halo produced is less intense. However, it is essential to note that a slight postoperative residual refractive error might increase the photic phenomena. Finally, for patients who had undergone a corneal ablation for high myopia, a significant worsening of the distance optical performance should be expected compared with the other two patients' profiles, although not significantly worse than a monofocal IOL. However, in this patient profile, the halo induced would be of considerable size and intensity.

AUTHOR CONTRIBUTIONS

Study concept and design (DM-C, LF-V-C, JAA-M, FV, MSM, JFA); data collection (DM-C, JAA-M); analysis and interpretation of data (DM-C, LF-V-C, FV, MSM, JFA); writing the manuscript (DM-C); critical revision of the manuscript (DM-C, LF-V-C, JAA-M, FV, MSM, JFA); supervision (MSM, JFA)

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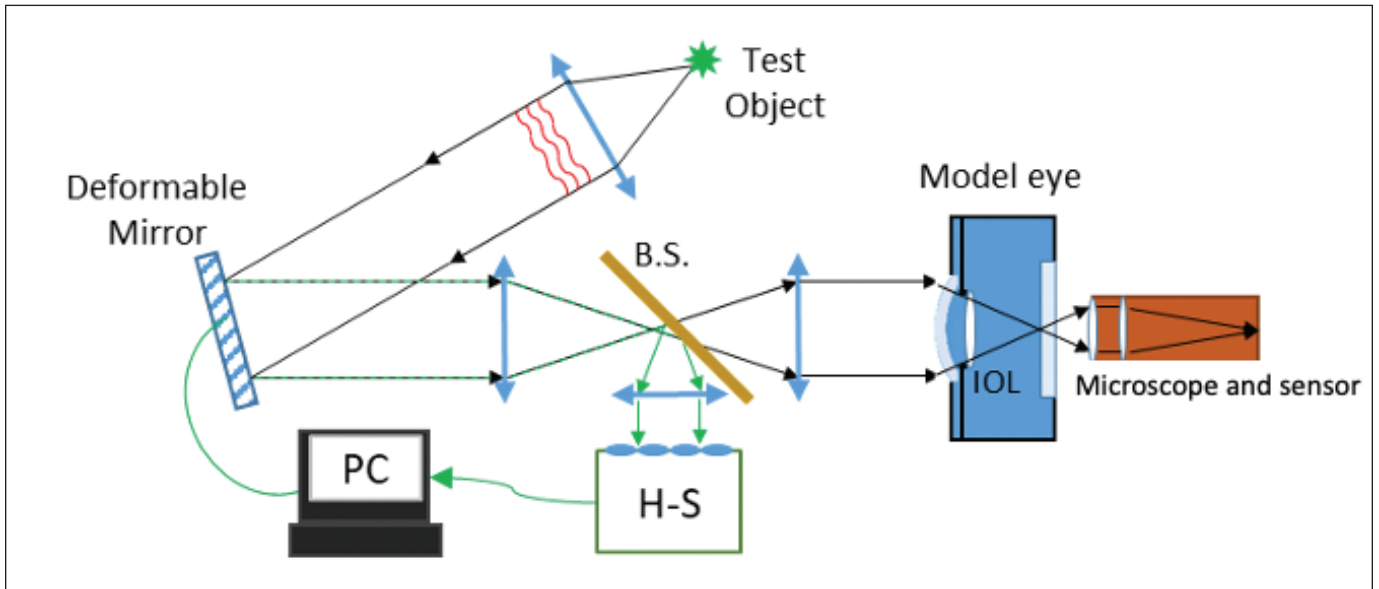


Figure A. Schematic of the test bench, which includes an adaptive optics system. The set-up mainly consists of four parts: the illumination system, the adaptive optics system (formed by a deformable mirror plus a Hartmann-Shack [H-S] wavefront sensor), the model eye where the IOL is inserted, and the image acquisition system (microscope and sensor). B.S., beam splitter; PC, personal computer.

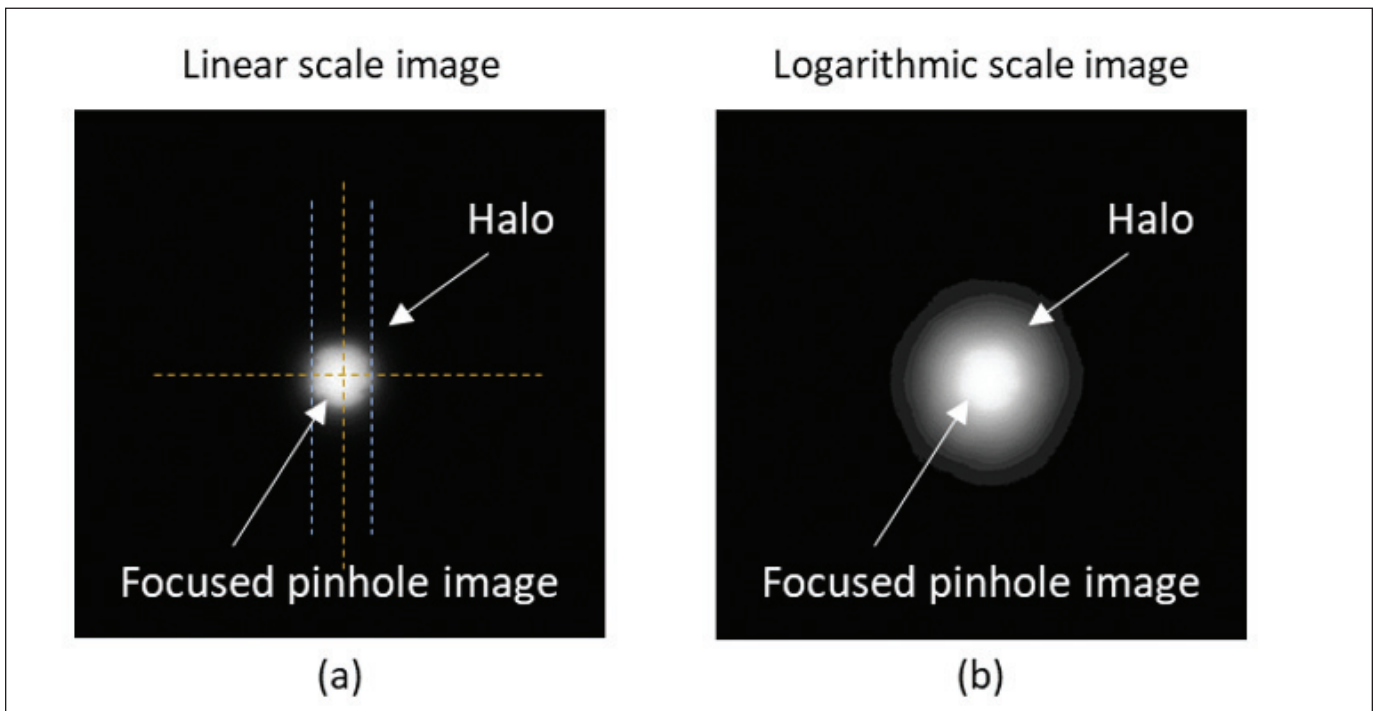


Figure B. Images of the pinhole object test formed by the AcrySof IQ Vivify IOL (defocus = 0.00 diopter, pupil = 4.5 mm): (a) in linear grayscale of intensity and (b) in logarithmic grayscale.