

Optical Assessment and Expected Visual Quality of Four Extended Range of Vision Intraocular Lenses

Juan Antonio Azor, MSc; Fidel Vega, PhD; Jesus Armengol, PhD; Maria S. Millan, PhD

ABSTRACT

PURPOSE: To assess the optical performance of four extended range of vision (ERV) intraocular lenses (IOLs) and predict the visual quality of the average pseudophakic patient.

METHODS: Four ERV IOLs (LuxSmart, Bausch & Lomb; Vivity, Alcon Laboratories, Inc; Tecnis Eyhance, Johnson & Johnson Vision; and Isopure, PhysiOL) were inserted in an on-bench model eye. Their performance was assessed using through-focus modulation transfer function (MTF)-based metrics, through-focus point spread function, and halo analysis for three pupils (2.0, 3.0, and 4.5 mm). The expected visual acuity and the range of vision was estimated from the through-focus area under the MTF curve. A monofocal IOL (Tecnis ZCB00; Johnson & Johnson Vision) was included as reference.

RESULTS: The Tecnis ZCB00 showed the highest image quality at far for all pupil conditions, closely followed by the Tecnis Eyhance. The LuxSmart and Vivity performed similarly in the intermediate range (-1.00 to -2.00 diopters [D]) with a

3.0-mm pupil and showed better performance than the other ERV IOLs for that range. All ERV lenses presented pupil dependent performance. All lenses reached normal expected visual acuity (0.0 logMAR) at far distance. The Tecnis ZCB00, Tecnis Eyhance, and Isopure decreased their expected visual acuity with defocus (0.1 logMAR at 66 cm) faster than the LuxSmart and Vivity (0.0 logMAR at 66 cm). The LuxSmart and Vivity produced greater halos than the Tecnis ZCB00, but they showed little change with larger pupils. The Isopure lens showed a pupil-dependent halo.

CONCLUSIONS: The expected visual acuity decreased with the object distance differently, depending on the ERV design. The Vivity and LuxSmart lenses showed an expanded imaging capability (> 0.50 D) with respect to a monofocal lens that may benefit intermediate vision. The Tecnis Eyhance and Isopure lenses showed more modest extensions that mainly rely on pupil constriction.

[J Refract Surg. 2022;38(11):688-697.]

Monofocal intraocular lenses (IOLs) are effective to restore distance vision after cataract surgery, but do not provide functional vision at other distances. The increasing patient demand for functional vision at all distances has accelerated the development of presbyopia-correcting IOLs. From monofocal and multifocal IOLs, new extended range of vision (ERV) IOLs aim to extend a continuous axial range of the image space, known as depth of focus, to provide perceptual tolerance to focus errors. A depth of focus extension enlarges, in turn, the depth of field (ie, the space where objects placed at different distances would be imaged by the eye with

maximum sharpness). Such a depth of focus extension has drawn particular attention because intermediate vision is becoming essential as a result of the frequent use of computers and handheld electronic devices. In general, ERV designs are based on shaping the light wavefront through a fine control of the power and aberration within the lens aperture.¹⁻³ They are featured as refractive IOLs because of their relatively smooth aspheric profile at either lens side, differing from diffractive multifocal IOLs that typically show at least one surface with step ring profile. This way, the strong wavelength dependence and dysphotopsia that may accompany the diffractive IOLs are reported to be alle-

From Universitat Politècnica de Catalunya-BarcelonaTech, Grupo de Óptica Aplicada y Procesado de Imagen, Barcelona, Spain.

Submitted: June 27, 2022; Accepted: September 27, 2022

Supported by Bausch & Lomb, Inc.

Disclosure: The authors have no financial or proprietary interests in the materials presented herein.

Correspondence: Maria S. Millan, PhD, Universitat Politècnica de Catalunya-BarcelonaTech, Grupo de Óptica Aplicada y Procesado de Imagen, C/ Violinista Vellsolà, 37, 08222 Terrassa, Barcelona, Spain. Email: m.millan@upc.edu

doi:10.3928/1081597X-20220926-01

viated.^{4,5} However, the depth of focus extension often does not cover the needs of the patients, who might need to wear spectacles for near vision.⁶

The large variety of ERV IOLs launched in recent years has led to the proposal of different classification schemes^{5,7,8} to help surgeons understand the elusive technical distinctions between designs. As such, featuring the ERV IOLs as either enhanced monofocal or extended depth of focus lenses is increasingly gaining acceptance.

The criteria for extended depth of focus IOLs were first stated by a task force of the American Academy of Ophthalmology in 2017⁹ on the basis of clinical post-operative measurements, such as the defocus curve testing methodology. The extended depth of focus concept resided in the clinical range of focus extension achieved by the average patient with pseudophakia of at least 0.50 diopter (D) over the standard monofocal control group at 0.2 logMAR. The American National Standards Institute (ANSI) Z80.35 standard for extended depth of focus IOLs¹⁰ kept such criteria within a list of effectiveness requirements for the clinical evaluation of the lens. More interestingly, the ANSI Z80.35 standard stated the normative requirements for the optical characterization of the lens, including the expected visual acuity determined by using the through-focus modulation transfer function (MTF) values measured in an on-bench model eye with a 3-mm pupil (at the IOL plane). As reported by the ANSI Z80.35 standard, Alarcon et al¹¹ described an example method for calculating the expected visual acuity from MTF values integrated in a spatial frequency range, also termed area under the MTF (MTFa). Vega et al¹² subsequently refined the mathematical approach.

On the one hand, extended depth of focus IOLs are intended to provide functional vision over a range of distances (ie, visual acuity higher than a defined threshold that decreases monotonically from the best distance vision toward intermediate vision). On the other hand, enhanced monofocal IOL designs have been introduced¹³ to enhance intermediate vision while providing distance vision comparable to its aspheric monofocal partner. The subtle differences between the enhanced monofocal and extended depth of focus IOLs need to be proved in terms of optical characterization and clinical results. Optical bench testing is complementary to clinical assessments because it is objective and independent of the patient. Moreover, it is possible to accurately control factors that are difficult to address in clinical studies, such as the pupil size, which is of paramount importance in ERV IOL designs that rely on wavefront shaping across the lens aperture. Some recent

investigations have focused on the issue using either optical¹⁴ or clinical^{4,15} methods.

In this study, we investigated the optical performance of four commercial ERV IOL designs: LuxSmart (Bausch & Lomb), Vivivity (Alcon Laboratories, Inc), Tecnis Eyhance (Johnson & Johnson Vision), and Isopure (PhysIOL) using an on-bench model eye, through-focus MTF-based analysis, calculation of expected visual acuity, and axial point spread function (PSF). We compared the four ERV IOLs with each other and with a monofocal reference lens (Tecnis ZCB00; Johnson & Johnson Vision) in terms of the depth of focus extension in the range of vision, halos, and possible dependence on the pupil size. To the best of our knowledge, this comprehensive, objective optical characterization and comparative analysis of ERV IOLs is the first of its kind and has not been previously reported.

MATERIALS AND METHODS

IOLs

For the development of this study, we considered four ERV IOLs (LuxSmart, Vivivity, Tecnis Eyhance, and Isopure) and one monofocal IOL (Tecnis ZCB00). The lenses had refractive surfaces (ie, no diffractive step profiles) and a nominal power of +20.00 D, except for the Isopure with +21.00 D.

According to the specifications,¹⁶ the LuxSmart IOL has a 2-mm central area where the combination of fourth and sixth orders of spherical aberration (SA) of opposite sign is intended to increase the subjective depth of field¹⁷ to approximately 1.50 D. A patented transition aims to smoothly decrease the optic vergence from the center to the periphery. A monofocal aspheric design provides an aberration-free lens periphery.¹⁸

The Vivivity IOL is a biconvex aspheric lens intended to extend the depth of focus by means of a patented wavefront-shaping technology, consisting of a slight plateau (1- μ m high) on the central 2.2-mm optical aperture at the anterior surface.¹⁹ The lens has a spherical posterior surface. The anterior surface is designed with a negative SA of -0.20 μ m for a 6-mm pupil to compensate for the positive SA of the natural human cornea.²⁰

The Tecnis Eyhance IOL features a higher order aspheric anterior surface, which is designed to produce a continuous power increase from the periphery to the center of the lens. A central plateau with the highest power occupies approximately 15% of its surface, targeting the intermediate vision. The posterior surface is spherical. Overall, the lens geometry is designed to induce -0.27 μ m SA (6-mm pupil) to compensate for the average corneal SA of the human eye.^{1,4,21}

The Isopure IOL is a refractive aspheric lens. Both surfaces are based on a polynomial higher order aspheric design, which results in a power change across the lens aperture and a central area of increased power for intermediate vision.^{2,22} Additionally, the Isopure has a more negative SA than its counterpart monofocal lens (Micropure; PhysiOL).²³ These two properties, increased power and larger SA, enhance the focus extension.

The Tecnis ZCB00 IOL is a monofocal biconvex IOL with a 6-mm optical zone. Its anterior aspheric surface provides a negative SA of $-0.27 \mu\text{m}$ to compensate for the average corneal SA.^{1,4}

EXPERIMENTAL SET-UP

An artificial model eye was used to evaluate the performance of the IOLs. In brief, this model consists of an artificial cornea with a SA of $+0.27 \mu\text{m}$ [Z_4^0] for a 6-mm diameter, an iris diaphragm, and a wet cell with saline solution where the IOL is immersed. A 10× microscope objective focuses the aerial image formed by the model eye on a charge coupled device camera, which acquires the final digital image. The microscope and camera were assembled on an on-axis translation holder for through-focus image acquisition. The model eye was placed on an optical bench and aligned with the other components of the set-up (**Figure A**, available in the online version of this article) as previously described.^{24,25}

The set-up was compliant with the International Organization for Standardization 11979-2 (2014) recommendations.²⁶ The light source was a green light-emitting diode with an emission centered at 530 nm and a full-width at half-maximum spectral bandwidth of 32 nm. We used two object tests in this study: a four-slit pattern for MTF measurements and a 200- μm pinhole object for axial PSF and halo characterization. The test was placed at the front focal plane of a collimator lens (200-mm focal length). An iris diaphragm allowed us to control the effective pupil diameter in the IOL plane, and, hence, the intensity of light and the amount of the corneal SA involved in the image formation. Hereinafter, all pupil diameters are referred to the IOL plane.

The 8-bit digital image acquisition system (microscope and camera) was diffraction limited with a cut-off frequency at 675 cycles/mm. For the through-focus analysis, we scanned the image space to cover an image vergence range of 5.00 D (from +2.00 to -3.00 D) around the best far focus in approximately 0.08-D steps.

METRICS

The optical quality metrics are mainly based on the MTF, which describes the amount of contrast transmitted through the model eye with an IOL immersed as a

function of the spatial frequency and pupil size. The MTF represents the normalized magnitude response of an optical system in the imaging process, expressed in cycles/degree in the object space or cycles/mm in the image plane on the retina.²⁷ The MTF can be derived from the Fourier transform of the line spread function imaged by the model eye and averaged for a number of directions.²⁸ We used the test presented in **Figure A** (b, right) to obtain the MTF experimentally.

The MTFa results from the integration of MTF function in a range of spatial frequencies; it can be seen as the area under the MTF curve versus the spatial frequency. We used MTFa calculated for spatial frequencies ranging from 0 to 50 cycles/mm, as proposed in previous studies^{11,12}:

$$MTF_a = \int_0^{50} MTF(f) \cdot df \quad (1)$$

MTFa is a useful objective metric that has been proved to correlate strongly with the expected visual acuity obtained after surgery.¹¹ Vega et al¹² hypothesized an asymptotic limit (ideal best value) in the visual acuity achievable with IOL implants of exceedingly large MTFa. They refined the non-linear function that fits the optical bench MTFa values measured under green light with clinical visual acuity to provide the expression:

$$VA(MTF_a) = A \exp \left\{ -\frac{MTF_a}{B} \right\} + c \quad (2)$$

where $A = 5.06 \pm 1.32$, $B = 3.03 \pm 0.35$, and $c = 0.00$ logMAR. The calculation of MTFa in a range of defocus positions along the optical axis indicates that through-focus MTFa can be used as a preclinical estimation of postoperative defocus curves.

The PSF can be obtained in practice by imaging a point source or a pinhole object through the model eye with the IOL undergoing testing and a given pupil size. The image depicted in **Figure A** (b, left) was used for the halo analysis. A sequence of such images at different defocus positions was used to calculate the axial PSF.

RESULTS

MTF OF FAR AND INTERMEDIATE IMAGE PLANES IN THE MODEL EYE

Figure 1 shows the MTFs of the four ERV IOLs and the Tecnis ZCB00, for the 3.0-mm pupil, at the far image plane (0.00 D), corresponding to distance vision, and at an intermediate image plane (-1.50 D), corresponding to vision at 66 cm.

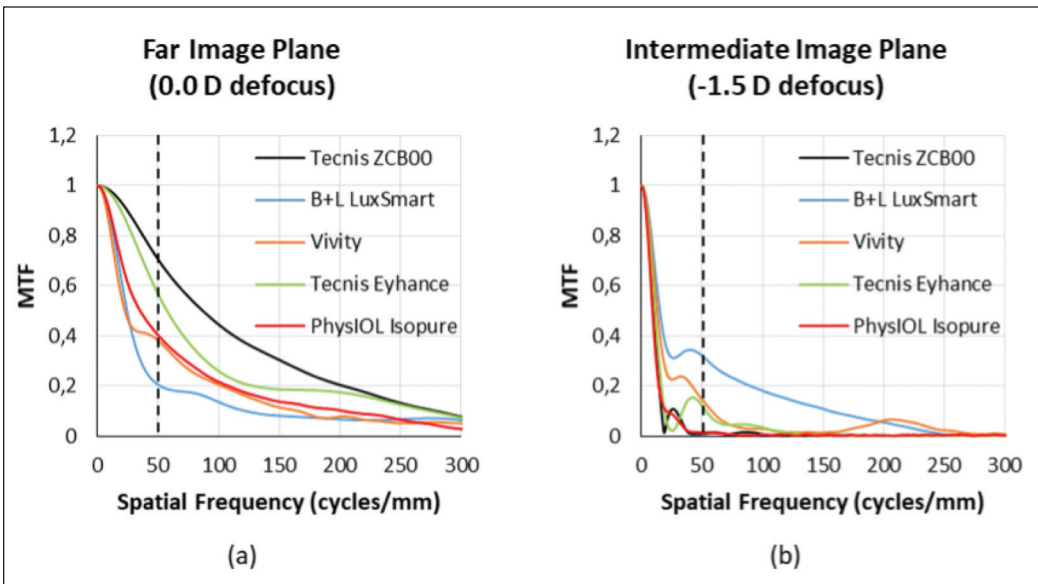


Figure 1. Modulation transfer function (MTF) at the (A) far and (B) -1.50 diopters (D) intermediate image planes for the set of extended range of vision intraocular lenses (IOLs) (LuxSmart, Bausch & Lomb; Vivity, Alcon Laboratories, Inc; Tecnis Eyhance, Johnson & Johnson Vision; and Isopure, PhysiOL) and the reference monofocal IOL (Tecnis ZCB00; Johnson & Johnson Vision). A vertical dashed line cuts the MTF plots at 50 cycles/mm. Pupil diameter = 3.0 mm.

TABLE 1
MTFa Maximum Value and Its Position (D) on Defocus Axis

Pupil (mm)	Tecnis ZCB00		LuxSmart		Vivity		Tecnis Eyhance		Isopure	
	MTFa	D	MTFa	D	MTFa	D	MTFa	D	MTFa	D
2.0	40.60	+0.10	33.40	-0.90	26.30	+0.10	36.10	-0.20	38.50	-0.30
3.0	40.70	0.00	26.30	0.00	27.10	0.00	38.10	0.00	31.40	0.00
4.5	37.00	+0.10	24.80	-0.20	30.20	-0.10	36.00	0.00	20.10	+0.20

D = diopters; MTFa = area under the modulation transfer function

The LuxSmart is manufactured by Bausch & Lomb, the Vivity is manufactured by Alcon Laboratories, Inc, the Isopure is manufactured by PhysiOL, and the Tecnis ZCB00 and Eyhance are manufactured by Johnson & Johnson Vision.

For the spatial frequency 50 cycles/mm,¹⁰ the MTF values at far (**Figure 1A**) are different for the various IOLs: the Tecnis ZCB00 reached the highest value (0.70), followed by the Tecnis Eyhance (0.56). The Isopure and Vivity performed similarly (0.40 and 0.38, respectively), whereas a rather low value was obtained for the LuxSmart (0.20).

At the -1.50 D intermediate plane (**Figure 1B**), the MTF values at 50 cycles/mm are, in general for the ERV and monofocal IOLs, much lower than those reached at far except for the LuxSmart IOL (0.31). The Vivity followed with 0.16. The rest of the lenses showed cut-off frequencies lower than 50 cycles/mm.

THROUGH-FOCUS MTFa, EXPECTED VISUAL ACUITY, AND RANGE OF VISION

Figure B (available in the online version of this article) presents the through-focus MTFa of the four ERV IOLs at pupil diameters of 2.0 mm (left column), 3.0 mm (center column), and 4.5 mm (right column). The through-focus MTFa of the Tecnis ZCB00 (black line) was included in all cases for comparison. **Table 1** con-

tains the maximum MTFa value and its position on the defocus axis for each lens and pupil. A clear difference between two subgroups of ERV IOLs can be seen in **Figure B**, particularly for the 3-mm pupil; whereas LuxSmart and Vivity plots show an asymmetric plateau that extends up to approximately -2.00 D, the Tecnis Eyhance's and Isopure's show a single, symmetric peak that is similar to the Tecnis ZCB00's. The similarity between the Tecnis Eyhance and ZCB00 MTFa curves is almost complete for the 3- and 4.5-mm pupils.

With pupil reduction from 3 to 2 mm, the through-focus MTFa curves show broader peaks, which account for some depth of focus extension. However, the LuxSmart is an exception: the broad plateau shown with the 3-mm pupil changed to a broad, single, higher peak that shifted to -0.90 D with the 2-mm pupil. The broad MTFa peaks of the Tecnis Eyhance and Isopure also shifted their maxima toward the negative defocus with the pupil reduction, but to a much lesser extent.

With pupil enlargement, moving from 3.0 to 4.5 mm, the through-focus MTFa curves show narrower, single, lower peaks, which account for some general

TABLE 2

Expected VA (logMAR) at Various Defocus (Object Distance) for IOLs With a 3.0-mm Pupil

Defocus (D) (Distance)	Tecnis ZCB00	LuxSmart	Vivity	Tecnis Eyhance	Isopure
0.00 (infinite)	0.0	0.0	0.0	0.0	0.0
-1.00 (100 cm)	0.0	0.0	0.0	0.0	0.0
-1.50 (66 cm)	0.1	0.0	0.0	0.1	0.1
-2.50 (40 cm)	0.4	0.2	0.1	0.4	0.5

D = diopters; IOL = intraocular lens; VA = visual acuity

The LuxSmart is manufactured by Bausch & Lomb, the Vivity is manufactured by Alcon Laboratories, Inc, the Isopure is manufactured by PhysIOL, and the Tecnis ZCB00 and Eyhance are manufactured by Johnson & Johnson Vision.

depth of focus reduction. However, the Vivity is an exception because it did not experience a decrease in its MTFa maximum, but in fact a slight increase, shifting from 27.1 to 30.2. Slight shifts toward negative defocus were noticed in the maxima of both the LuxSmart (-0.20 D) and Vivity (-0.10 D) through-focus MTFa curves with a 4.5-mm pupil. These results are consistent with a positive residual SA, which is more evident when opening the pupil because the Vivity and, in particular, the LuxSmart do not fully compensate for the corneal SA. The Isopure showed the largest degradation with a broad, low MTFa peak that shifted toward positive defocus (+0.20 D) when considering the 4.5-mm pupil. This result is consistent with a negative residual SA caused by overcompensation of the positive corneal SA for a 4.5-mm pupil.²³

On the whole, the LuxSmart and Vivity performed similarly in the intermediate range (-1.00 to -2.00 D) with a 3-mm pupil and showed superior quality to the other IOLs in this range. Performance of all ERV IOLs presented pupil dependence.

We calculated the expected visual acuity (logMAR) from the through-focus MTFa values of each lens (**Figure B**) using Equation 2. **Figure C** (available in the online version of this article) depicts the results (expected visual acuity versus defocus) obtained for a 3-mm pupil. In the first approach, the depth of focus can be translated to the defocus range with expected visual acuity values better than 0.2 logMAR.¹⁰ However, because part of this range falls in the positive side of defocus (virtual object distances), such a section is no longer useful in corrected distance visual acuity. Thus, the useful range of vision predicted for each lens is limited to the negative part of the defocus range. With best expected visual acuity (better than 0.01 logMAR), the ranges of vision were: -1.50 D for LuxSmart, -0.91 D for Vivity, -0.85 D for Tecnis Eyhance, -0.86 for Isopure, and -0.75 for Tecnis ZCB00. With the criterion of the ANSI Z80.35 standard (0.2 logMAR or better),¹⁰ the ranges of vision were -2.40 D for LuxSmart, -2.60 D for Vivity, -2.00 D for Tecnis

Eyhance, -1.70 D for Isopure, and -1.80 D for Tecnis ZCB00. **Table 2** contains further numerical results.

The visual acuity, as shown in **Figure C**, reached normal expected visual acuity (0.0 logMAR) at far for all IOLs included in this study. As the negative defocus magnitude increases from 0.00 to -2.50 D, meaning the object test moves from infinity to 40 cm away from the model eye, the expected visual acuity tends to decrease. The IOL design makes the difference in such a decrease. The Tecnis ZCB00, Tecnis Eyhance, and Isopure reduced their expected visual acuity with defocus (0.1 logMAR at 66 cm) faster than the LuxSmart and Vivity (0.0 logMAR at 66 cm). As for the useful range of vision, the LuxSmart and Vivity slightly exceeded -2.00 D (object distance closer than 50 cm), the Tecnis Eyhance just reached -2.00 D, and the Isopure and the Tecnis ZCB00 stayed slightly below -2.00 D.

HALO AT FAR FOCUS FOR 3.0- AND 4.5-MM PUPILS

Figure 2 shows the best images of the pinhole object obtained at the far focus of each lens for the 3.0- and 4.5-mm pupils. The images are presented in logarithmic scale of intensity for a better visualization of the halo around the pinhole image. From a qualitative comparison, the Tecnis ZCB00 formed the sharpest images with both pupils, followed by the Tecnis Eyhance. The image formed by the Isopure changed markedly with the different pupil sizes, ranging from a rather small halo with the 3.0-mm pupil to the largest halo with the 4.5-mm pupil.

The LuxSmart and Vivity produced greater halos than the monofocal reference but remained constant when the pupil was changed. A more detailed observation reveals that the halo produced by the Vivity reduced slightly in size with the pupil enlargement. No other lens in this study showed such a singular characteristic.

AXIAL PSF

From the through-focus sequence of pinhole images, we computed the normalized energy distribution in a meridian plane (ie, a cross-section that contains

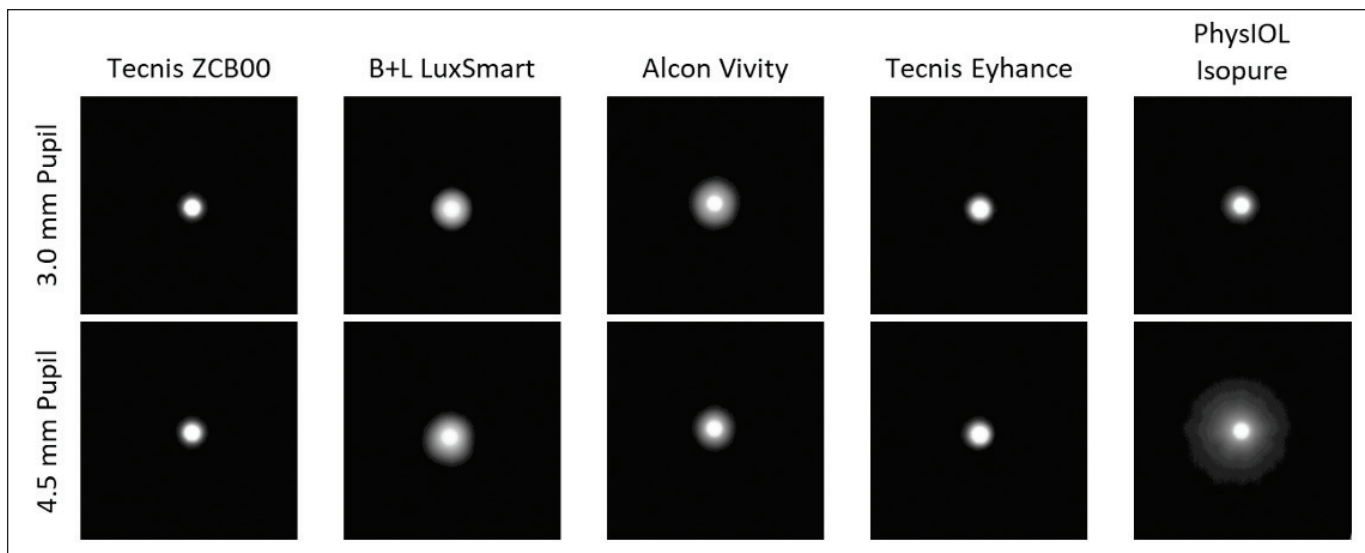


Figure 2. Halo images at distance focus for the 3.0-mm pupil (top row) and the 4.5-mm pupil (bottom row). The images are presented in logarithmic scale of intensity. The LuxSmart is manufactured by Bausch & Lomb, the Vivity is manufactured by Alcon Laboratories, Inc, the Isopure is manufactured by PhysIOL, and the Tecnis ZCB00 and Eyhance are manufactured by Johnson & Johnson Vision.

the optical axis). **Figure 3** displays the experimental results, in logarithmic scale and pseudocolor, for the four ERV IOLs and the Tecnis ZCB00 with the 3-mm pupil. Zero defocus corresponds to the best far focus in the retina (distance vision) and negative defocus to intermediate and near vision. The color palette, as it ranges from blue to yellow, indicates increasing light intensity. As a rule of thumb, the thinner, longer, and more uniform line-shaped the figure, the better the optical quality of the depth of focus segment. According to this, the Tecnis Eyhance and Isopure showed an axial PSF similar to the Tecnis ZCB00 (ie, symmetric and centered at 0.00 D defocus). The LuxSmart and Vivity showed longer axial PSFs, yet with high intensity at 0.00 D, but somewhat shifted to the negative defocus, both characteristics revealing a depth of focus extension translated to the useful range of vision.

The results shown in **Figure 3** are in good agreement with those previously obtained from MTFa (**Figure C**), but it must be stressed that they are not the same concept. The axial PSF is illustrative of the through-focus energy spread in a meridian plane and across the optical axis. For this reason, it is used in studies, reports, and technical brochures to graphically show the continuity of the depth of focus segment in ERV IOLs in contrast to the light intensity dips existing between the multiple foci in diffractive multifocal IOLs.^{3,19} However, special care must be taken when using axial PSF for precise comparison between ERV IOLs. First, it is worth recalling that each figure is normalized to the maximum PSF value obtained for a specific lens. Therefore, the color scale is valid

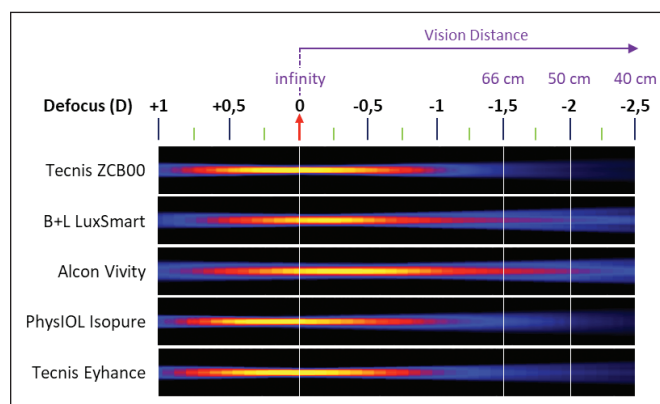


Figure 3. Axial point spread function of the intraocular lenses (3.0-mm pupil). The color palette, as it ranges from blue to yellow, indicates increasing light intensity. The LuxSmart is manufactured by Bausch & Lomb, the Vivity is manufactured by Alcon Laboratories, Inc, the Isopure is manufactured by PhysIOL, and the Tecnis ZCB00 and Eyhance are manufactured by Johnson & Johnson Vision. D = diopters

for intraclass comparisons (ie, for different vision distances of a given IOL), but not for comparison between different lenses. Second, we must not confound the length of these lines with the depth of focus extension depicted in **Figure C**. We emphasize that not only is the length important, but also the thickness of the line. Thus, a thick line crossing the far focus would imply a relatively spread PSF and, consequently, a rather low MTFa value and expected visual acuity. This effect is sometimes difficult to evaluate from the direct observation of the axial PSF figure. For this reason, we must stress that the MTFa, not the A-PSF shown in **Figure 3**, is the metric that has proved to strongly correlate with the expected visual acuity.

DISCUSSION

The American Academy of Ophthalmology task force⁹ and the ANSI standard¹⁰ have developed consensus statements and procedures for the optical and clinical assessments of extended depth of focus IOLs. However, there is still a need to clarify the existing terminology to aid surgical decision making, particularly in the overwhelming scenario that currently exists, with approximately 100 IOLs available on the market.⁵ In vitro testing is strongly recommended in parallel with clinical testing of IOLs because it provides an objective assessment independent of the patient and can control factors such as pupil size, corneal aberrations, and lens alignment, which are difficult to address in routine clinical work. We investigated the optical properties of four ERV IOLs using an on-bench model eye^{24,29} that fulfilled the standard recommendations.^{10,26} Three of these IOLs (Vivity, Tecnis Eyhance, and Isopure) are classified as enhanced monofocal in Rampat and Gatinel's proposal for theoretical extended depth of focus nomenclature, although with different designs and features.⁵ The classification does not include the fourth lens, LuxSmart, which was launched (May 2020) after Rampat and Gatinel's article submission. We also included a monofocal reference (Tecnis ZCB00).

The studied lenses had different aspheric designs, with distinct compensation for the corneal SA.^{30,31} Thus, for example, both Tecnis IOL designs (Tecnis ZCB00 and Eyhance) fully compensated for corneal SA ($-0.27\text{ }\mu\text{m}$ for the 6-mm pupil), which might give them some advantage with respect to the Vivity, which only compensated for corneal SA in part ($-0.20\text{ }\mu\text{m}$, for the 6-mm pupil). In contrast, the Isopure overcompensated for the corneal SA,²³ which may result in a pseudophakic eye with residual negative SA. The aberration neutral platform of the LuxSmart produced the least favorable testing conditions: the lack of compensation for the positive corneal SA had an effect on its optical quality outcomes. In any case, the damage caused by the remaining corneal SA on the optical quality results is expected to be more important for the largest pupil (4.5 mm), mild for the intermediate pupil (3 mm), and likely negligible for the smallest pupil (2 mm).

Thus far, few on-bench studies using these IOLs have been conducted and reported. Interestingly, however, Schmid and Borkenstein¹⁸ analyzed higher order aberrations in three of them (Vivity, LuxSmart, and Tecnis Eyhance) and the contrast function of two (Vivity and LuxSmart).³² They explained the expected extended depth of focus effect of both the Vivity and LuxSmart from the magnitude and type of SA modification.¹⁸ They used the OptiSpheric IOL Pro 2 device

(Trioptics GmbH), with a model cornea ($\text{SA} = +0.28\text{ }\mu\text{m}$) and a polychromatic light-emitting diode, to measure the MTF curves of the Vivity and LuxSmart (22.00 D power) using different pupil sizes, centration, and misalignment.³² Overall, they did not find that any of them presented a clearly superior performance but, in fact, reported similar measurements, particularly for the 3-mm pupil and centered condition. This result is in fairly good agreement with our findings for these two lenses, the Vivity and LuxSmart, which show the closest performances for the 3-mm pupil among the four studied lenses. We must state, however, that in Schmid and Borkenstein¹⁸ and Borkenstein et al's³² work and in ours, corneal asphericity was not compensated for by the LuxSmart and, therefore, the operating conditions for this lens were less favorable than those for the Vivity.

Labuz et al³³ analyzed 20.00 D base power lenses (Tecnis ZCB00, Tecnis Eyhance, and Isopure, among others) with the OptiSpheric IOL Pro 2 device. Concerning the MTF curves obtained using a 3-mm pupil, they found that the Tecnis ZCB00 obtained the highest MTF values of all of the enhanced monofocal IOLs studied, particularly at higher spatial frequencies. This result is in full agreement with ours, although we measured a larger difference between the Tecnis Eyhance and Isopure MTF values at 50 cycles/mm, 0.16 in our study with respect to -0.05.

The results of the through-focus MTFa (**Figure B**) are more interesting in terms of their relationship with the expected visual acuity (**Figure C**). They illustrate the differences between the various IOL designs in terms of maximum optical quality and depth of focus, determined by the height and width of the MTFa curve, respectively, as well as their dependence on the pupil size.

The MTFa peak position of the LuxSmart IOL showed pupil dependence (**Figure B**), with a myopic shift of approximately -1.00 D for the 2-mm pupil, thus benefiting near vision along with the pupil constriction (miosis) experienced by patients in this viewing condition. The range of MTFa values of 20 or greater (expected visual acuity = 0.0 logMAR) remained wide for the 2- and 3-mm pupil. This effect seems to indicate that the central part of the lens, with the combination of fourth and sixth orders of SA of opposite signs, still has a noticeable effect when the pupil widens to 3 mm. As the pupil enlarges further, the aberration neutral periphery of the lens takes part, which may explain the shorter focus extension for a 4.5-mm pupil.

The Vivity performed similarly to the LuxSmart for the reference 3-mm pupil (**Figure B**), showing a plateau of enlarged depth of focus. This plateau was also

present with the 2-mm pupil, but vanished with the 4.5-mm pupil, likely due to the involvement of the lens periphery. The MTFa peak position of the Vivity remained centered or minimally displaced from the 0.00 D defocus for all of the pupils.

Both the Tecnis Eyhance and Isopure behaved similarly to the monofocal Tecnis ZCB00 for the 2-mm pupil (**Figure B**), with one broad MTFa peak, slightly shifted toward negative defocus. The Tecnis Eyhance demonstrated a performance even closer to the Tecnis ZCB00 with larger pupils. This behavior was expected because they have the same platform and equal corneal SA compensation. The results are in agreement with earlier studies reporting on-bench comparison between the Tecnis Eyhance and the standard monofocal Tecnis ZCB00.^{1,14} In contrast, the Isopure reduced its MTFa height when employing the 3- and 4.5-mm pupils and its peak shifted slightly toward positive defocus (hypermetropic). This lens produces a more negative SA that overcompensates for the corneal SA, leaving the model eye with residual negative SA. This fact may explain a decrease in the optical quality for larger pupils and accounts for the hyperopic shift observed in the MTFa peak. Unless the patient presents with a small pupil, which is not rare after cataract surgery, such behavior would affect visual acuity with low illumination.

Moreover, because the pupil constricts for near vision tasks, it will be beneficial to reach high MTFa values in the negative defocus zone. This property is mostly featured by the LuxSmart and Vivity and, to a lesser extent, by the Tecnis Eyhance.

Several studies have compared the visual acuity outcomes after implantation of the Tecnis ZCB00 and Eyhance IOLs. Mencucci et al³⁴ found at 0.00 D defocus a binocular corrected distance visual acuity (mean $\pm$ SD) of 0.02 ± 0.04 and 0.01 ± 0.03 logMAR ($P = .554$) for the Tecnis ZCB00 and Eyhance groups, respectively, which is in close agreement with the expected visual acuity (0.0 logMAR) obtained in our calculations (**Table 2**). In contrast, Auffarth et al⁴ reported better corrected distance visual acuity in both groups (-0.06 ± 0.01 logMAR for Tecnis ZCB00 and -0.02 ± 0.01 logMAR for Eyhance). Interestingly, their results align well with the predicted visual acuity for these IOLs reported by Łabuz et al³³ using the approach proposed in Alarcon et al.¹¹ Regarding the defocus curves, Huh et al³⁵ obtained binocular through-focus visual acuity after 4 weeks, similar to our predicted visual acuity for both IOLs. The same lenses were analyzed by Unsal et al³⁶ 1 month after surgery. Their visual acuity graphs are in good agreement with ours, although they decline slightly faster.

The through-focus MTFa results we obtained for the Vivity are consistent with the results provided by the manufacturer,²⁰ although the expected visual acuity obtained in our calculations slightly overestimated the clinical visual acuity outcomes reported in their defocus curves (6 months after surgery in patients with previous astigmatism < 1.00 D).

Other factors may have an influence on the visual acuity of implanted eyes, such as light scattering, misalignments, individual amount of preoperative corneal SA, pupil size, neural pathway, and processing of the retinal image. We have not taken chromatic aberrations into account either because our study used green light.

The analysis of halos is important considering that ERV IOLs are intended to induce a dysphotopsia comparable to that of a monofocal IOL and lower than that of a multifocal IOL.³⁷ From our results (**Figure 2**), only the halo of the Tecnis Eyhance was similar to the monofocal Tecnis ZCB00, whereas the other three IOLs produced larger halos. The LuxSmart and Vivity had the greatest halos for the 3-mm pupil, whereas the Isopure had the largest halo for the 4.5-mm pupil. Isopure performance showed strong pupil dependence. Vega et al¹⁴ and Łabuz et al³³ found similar results for the monofocal Tecnis ZCB00, Tecnis Eyhance, and Isopure. Overall, the halo characteristics accounts for the residual SA of the eye implanted with a specific ERV IOL and becomes more evident as the pupil diameter increases.

Taken collectively, our study has highlighted objective differences in the optical performance of four ERV IOLs. The LuxSmart and Vivity IOLs showed, for a 3-mm pupil, a plateau in their through-focus MTFa curves that extend toward myopic defocus. In comparison with a standard monofocal IOL, such a depth of focus extension should benefit intermediate vision as predicted by the calculated expected visual acuity. For instance, the expected visual acuity at -1.50 D defocus was Vivity 0.0 logMAR; LuxSmart 0.0 logMAR, and Tecnis ZCB00 0.1 logMAR. In contrast, the Tecnis Eyhance and Isopure rely on a modest myopic shift of the MTFa peak, on pupil constriction, to extend their range of vision. This strategy leads to a good optical quality for far vision, but more limited extension of the range of vision. The pupil size has a strong influence on the optical behavior of the four ERV IOLs, with the Isopure being the lens that results in the largest halo and reduction in optical quality with a 4.5-mm pupil.

In the context of the four ERV IOLs evaluated in this study, we highlight two clear groups among them, with the Vivity and LuxSmart considered to be different from the Tecnis Eyhance and Isopure. The first two

lenses showed a depth of focus extension (≥ 0.50 D) that may benefit intermediate vision with better optical quality than a monofocal IOL. The latter two lenses showed a more modest depth of focus extension that mainly relied on pupil constriction. The pupil size and the existence of a possible residual SA had an influence on the optical behavior of the four ERV IOLs. This comparative assessment reinforces the importance of attending to the individual characteristics of each patient when selecting an IOL for implantation.

AUTHOR CONTRIBUTIONS

Study concept and design (FV, MSM); data collection (JAA, FV); analysis and interpretation of data (JAA, FV, JA, MSM); writing the manuscript (JAA, MSM); critical revision of the manuscript (JAA, FV, JA, MSM); administrative, technical, or material support (JA); supervision (JAA, FV, JA, MSM)

REFERENCES

- Alarcon A, Cánovas C, Koopman B, Weeber H, Auffarth GU, Piers PA. Enhancing the intermediate vision of monofocal intraocular lenses using a higher order aspheric optic. *J Refract Surg.* 2020;36(8):520-527. <https://doi.org/10.3928/1081597X-20200612-01> PMID:32785725
- Fernández Gutiérrez D, inventor; Barbero Briones S, inventor; Dorronsoro Díaz C, inventor; Marcos Celestino S, inventor; Consejo Superior de Investigaciones Científicas (CSIC), assignee; Refractive Multifocal Intraocular Lens With Optimised Optical Quality In A Range Of Focus And Method To Produce It. WO 2014/102352 A1. July 3, 2014. <http://hdl.handle.net/10261/124923>
- Schwiegerling JT, Carson DR, Choi M, Lee S, Milanovic Z, Lane S. Optical simulation and bench data of a non-diffractive intraocular lens designed to extend depth of focus and minimise visual disturbances. Presented at the 37th Congress of the European Society of Cataract & Refractive Surgeons; September 14-18, 2019; Paris, France.
- Auffarth GU, Gerl M, Tsai L, et al; Quantum Study Group. Clinical evaluation of a new monofocal IOL with enhanced intermediate function in patients with cataract. *J Cataract Refract Surg.* 2021;47(2):184-191. <https://doi.org/10.1097/j.jcrs.000000000000399> PMID:32932369
- Rampat R, Gatineau D. Multifocal and extended depth-of-focus intraocular lenses in 2020. *Ophthalmology.* 2021;128(11):e164-e185. <https://doi.org/10.1016/j.ophtha.2020.09.026> PMID:32980397
- Böhm M, Petermann K, Hemkepler E, Kohnen T. Defocus curves of 4 presbyopia-correcting IOL designs: diffractive panfocal, diffractive trifocal, segmental refractive, and extended-depth-of-focus. *J Cataract Refract Surg.* 2019;45(11):1625-1636. <https://doi.org/10.1016/j.jcrs.2019.07.014> PMID:31706517
- Breyer DRH, Kaymak H, Ax T, Kretz FTA, Auffarth GU, Hagen PR. Multifocal intraocular lenses and extended depth of focus intraocular lenses. *Asia Pac J Ophthalmol (Phila).* 2017;6(4):339-349. <https://doi.org/10.22608/APO.2017186> PMID:28780781
- Fernández J. Functional classification of multifocal IOLs. *Cataract & Refractive Surgery Today Europe.* February 2021. Accessed May 13, 2022. <https://crstodayeurope.com/articles/feb-2021/functional-classification-of-multifocal-iols/>
- MacRae S, Holladay JT, Glasser A, et al. Special report: American Academy of Ophthalmology Task Force consensus statement for extended depth of focus intraocular lenses. *Ophthalmology.* 2017;124(1):139-141. <https://doi.org/10.1016/j.ophtha.2016.09.039> PMID:27743644
- The Accredited Committee Z80 for Ophthalmic Standards; American National Standards Institute. ANSI Z80.35-2018, "Extended depth of focus intraocular lenses." Published online 2019.
- Alarcon A, Canovas C, Rosen R, et al. Preclinical metrics to predict through-focus visual acuity for pseudophakic patients. *Biomed Opt Express.* 2016;7(5):1877-1888. <https://doi.org/10.1364/BOE.7.001877> PMID:27231628
- Vega F, Millán MS, Garzón N, Altemir I, Poyales F, Larrosa JM. Visual acuity of pseudophakic patients predicted from in-vitro measurements of intraocular lenses with different design. *Biomed Opt Express.* 2018;9(10):4893-4906. <https://doi.org/10.1364/BOE.9.004893> PMID:30319910
- Alarcon A, Koopman B, Canovas C, Domingo J, Piers P. Optical and predicted visual performance of the next generation TECNIS monofocal intraocular lens. Presented at the Winter European Society of Cataract & Refractive Surgeons meeting; February 15-17, 2019; Athens, Greece.
- Vega F, Millán MS, Gil MA, Garzón N. Optical performance of a monofocal intraocular lens designed to extend depth of focus. *J Refract Surg.* 2020;36(9):625-632. <https://doi.org/10.3928/1081597X-20200710-01> PMID:32901831
- Corbelli E, Iuliano L, Bandello F, Fasce F. Comparative analysis of visual outcome with 3 intraocular lenses: monofocal, enhanced monofocal, and extended depth of focus. *J Cataract Refract Surg.* 2022;48(1):67-74. <https://doi.org/10.1097/j.jcrs.0000000000000706> PMID:34054077
- Bausch & Lomb. LuxSmart Preloaded-Premium Hydrophobic IOL. Accessed June 16, 2022. <https://www.luxsmartiol.com/wp-content/uploads/2021/11/Brochure.pdf>
- Benard Y, Lopez-Gil N, Legras R. Optimizing the subjective depth-of-focus with combinations of fourth- and sixth-order spherical aberration. *Vision Res.* 2011;51(23-24):2471-2477. <https://doi.org/10.1016/j.visres.2011.10.003> PMID:22019797
- Schmid R, Borkenstein AF. Analysis of higher order aberrations in recently developed wavefront-shaped IOLs. *Graefes Arch Clin Exp Ophthalmol.* 2022;260(2):609-620. <https://doi.org/10.1007/s00417-021-05362-2> PMID:34370067
- Kohnen T. Nondiffractive wavefront-shaping extended range-of-vision intraocular lens. *J Cataract Refract Surg.* 2020;46(9):1312-1313. <https://doi.org/10.1097/j.jcrs.0000000000000247> PMID:32898097
- U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED). AcrySof™ IQ Vivity™ Extended Vision Intraocular Lens. Published 2020. Accessed November 24, 2021. https://www.accessdata.fda.gov/cdrh_docs/pdf/P930014S126B.pdf
- Johnson & Johnson Vision. Delivering Intermediate Vision: The New TECNIS Eyhance Monofocal IOL. *The Ophthalmologist.* 2019. https://theophthalmologist.com/fileadmin/top/subspecialties/2019_April/0419-900_J_J_Supplement__1_.pdf
- Fernández D, Barbero S, Dorronsoro C, Marcos S. Multifocal intraocular lens providing optimized through-focus performance. *Opt Lett.* 2013;38(24):5303-5306. <https://doi.org/10.1364/OL.38.005303> PMID:24322243
- Marcos S. Isofocal intraocular lens concept. Presented at the International Society of Presbyopia Congress; September 13, 2019; Paris, France.
- Vega F, Alba-Bueno F, Millán MS. Energy distribution between distance and near images in apodized diffractive multifocal intraocular lenses. *Invest Ophthalmol Vis Sci.* 2011;52(8):5695-5701. <https://doi.org/10.1167/iovs.10-7123> PMID:21659312

25. Alba-Bueno F, Vega F, Millán MS. Design of a test bench for intraocular lens optical characterization. *J Phys Conf Ser*. 2011;274:012105. <https://doi.org/10.1088/1742-6596/274/1/012105>
26. International Organization for Standardization. Ophthalmic Implants–Intraocular Lenses–Part 2: Optical Properties and Test Methods. Published 2014. <https://www.iso.org/standard/55682.html>
27. Atchison DA, Smith G. Retinal image quality. In: Atchison DA, Smith G. *Optics of the Human Eye*. Butterworth-Heinemann; 2000:194-210. <https://doi.org/10.1016/B978-0-7506-3775-6.50022-5>
28. Boreman GD. *Modulation Transfer Function in Optical and Electro-Optical Systems*. SPIE Press; 2001. <https://doi.org/10.1117/3.419857>
29. Vega F, Millán MS, Vila-Terricabras N, Alba-Bueno F. Visible versus near-infrared optical performance of diffractive multifocal intraocular lenses. *Invest Ophthalmol Vis Sci*. 2015;56(12):7345-7351. <https://doi.org/10.1167/iovs.15-17664> PMID:26562168
30. 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;17(10):1697-1702. <https://doi.org/10.1364/JOSA.17.001697> PMID:11028517
31. Wang L, Dai E, Koch DD, Nathoo A. Optical aberrations of the human anterior cornea. *J Cataract Refract Surg*. 2003;29(8):1514-1521. [https://doi.org/10.1016/S0886-3350\(03\)00467-X](https://doi.org/10.1016/S0886-3350(03)00467-X) PMID:12954298
32. Borkenstein AF, Borkenstein EM, Luedtke H, Schmid R. Optical bench analysis of 2 depth of focus intraocular lenses. *Biomed Hub*. 2021;6(3):77-85. <https://doi.org/10.1159/000519139> PMID:34950668
33. Labuz G, Son HS, Naujokaitis T, Yildirim TM, Khoramnia R, Auffarth GU. Laboratory investigation of preclinical visual-quality metrics and halo-size in enhanced monofocal intraocular lenses. *Ophthalmol Ther*. 2021;10(4):1093-1104. <https://doi.org/10.1007/s40123-021-00411-9> PMID:34689301
34. Mencucci R, Cennamo M, Venturi D, Vignapiano R, Favuzza E. Visual outcome, optical quality, and patient satisfaction with a new monofocal IOL, enhanced for intermediate vision: preliminary results. *J Cataract Refract Surg*. 2020;46(3):378-387. <https://doi.org/10.1097/j.jcrs.0000000000000061> PMID:32050218
35. Huh J, Eom Y, Yang SK, Choi Y, Kim HM, Song JS. A comparison of clinical outcomes and optical performance between monofocal and new monofocal with enhanced intermediate function intraocular lenses: a case-control study. *BMC Ophthalmol*. 2021;21(1):365. <https://doi.org/10.1186/s12886-021-02124-w> PMID:34656091
36. Unsal U, Sabur H. Comparison of new monofocal innovative and standard monofocal intraocular lens after phacoemulsification. *Int Ophthalmol*. 2021;41(1):273-282. <https://doi.org/10.1007/s10792-020-01579-y> PMID:32893321
37. Schallhorn JM. Multifocal and extended depth of focus intraocular lenses: a comparison of data from the United States Food and Drug Administration premarket approval trials. *J Refract Surg*. 2021;37(2):98-104. <https://doi.org/10.3928/1081597X-20201111-02> PMID:33577695

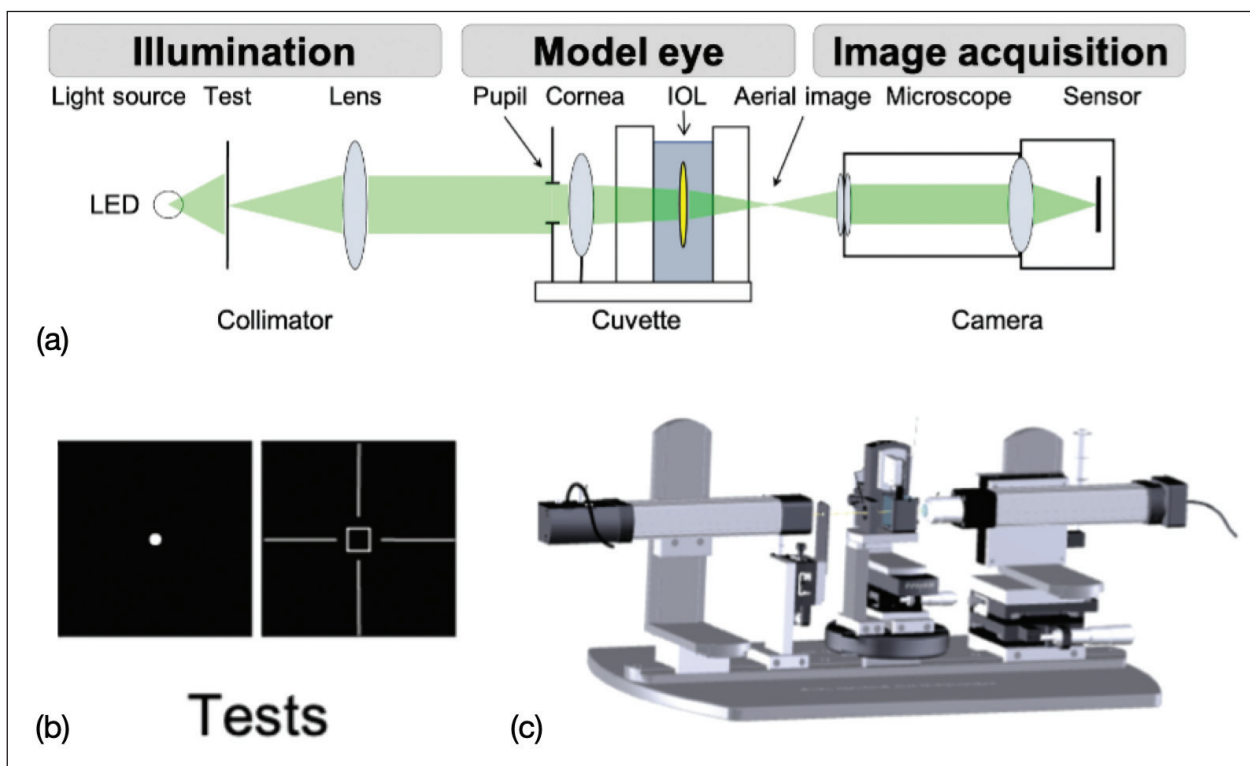


Figure A. Schemes of the optical bench testing set-up: [A] components, [B] object tests, and [C] opto-mechanic depiction. IOL = intraocular lens

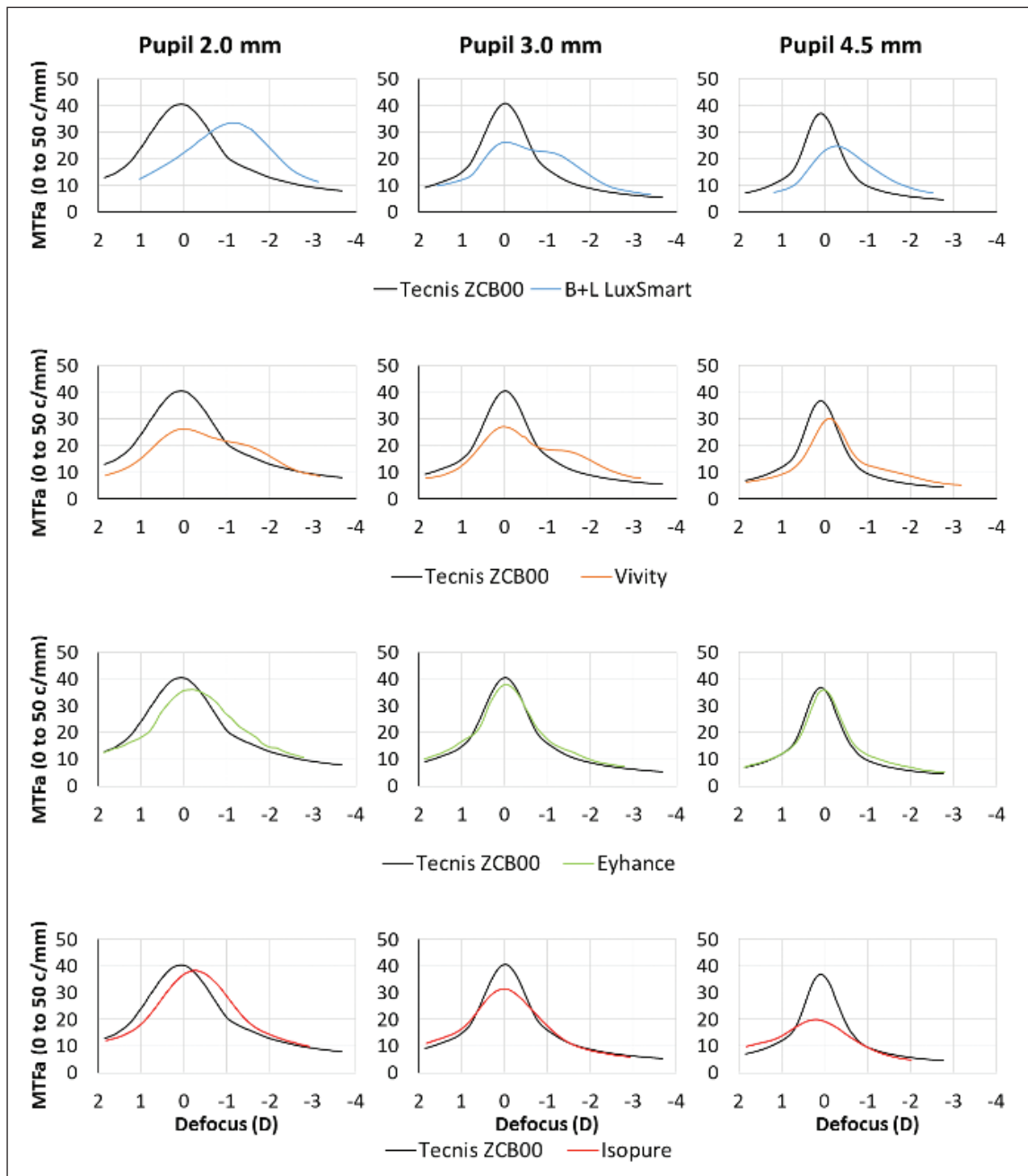


Figure B. Through-focus area under the modulation transfer function (MTFa) versus defocus for all four extended range of vision intraocular lenses (IOLs) and the reference monofocal IOL at 2.0-, 3.0-, and 4.5-mm pupil diameters. A 0.00 diopter (D) defocus corresponds to far distance vision and negative defocus corresponds to intermediate and near vision. The LuxSmart is manufactured by Bausch & Lomb, the Vivity is manufactured by Alcon Laboratories, Inc, the Isopure is manufactured by PhysIOL, and the Tecnis ZCB00 and Eyhance are manufactured by Johnson & Johnson Vision.

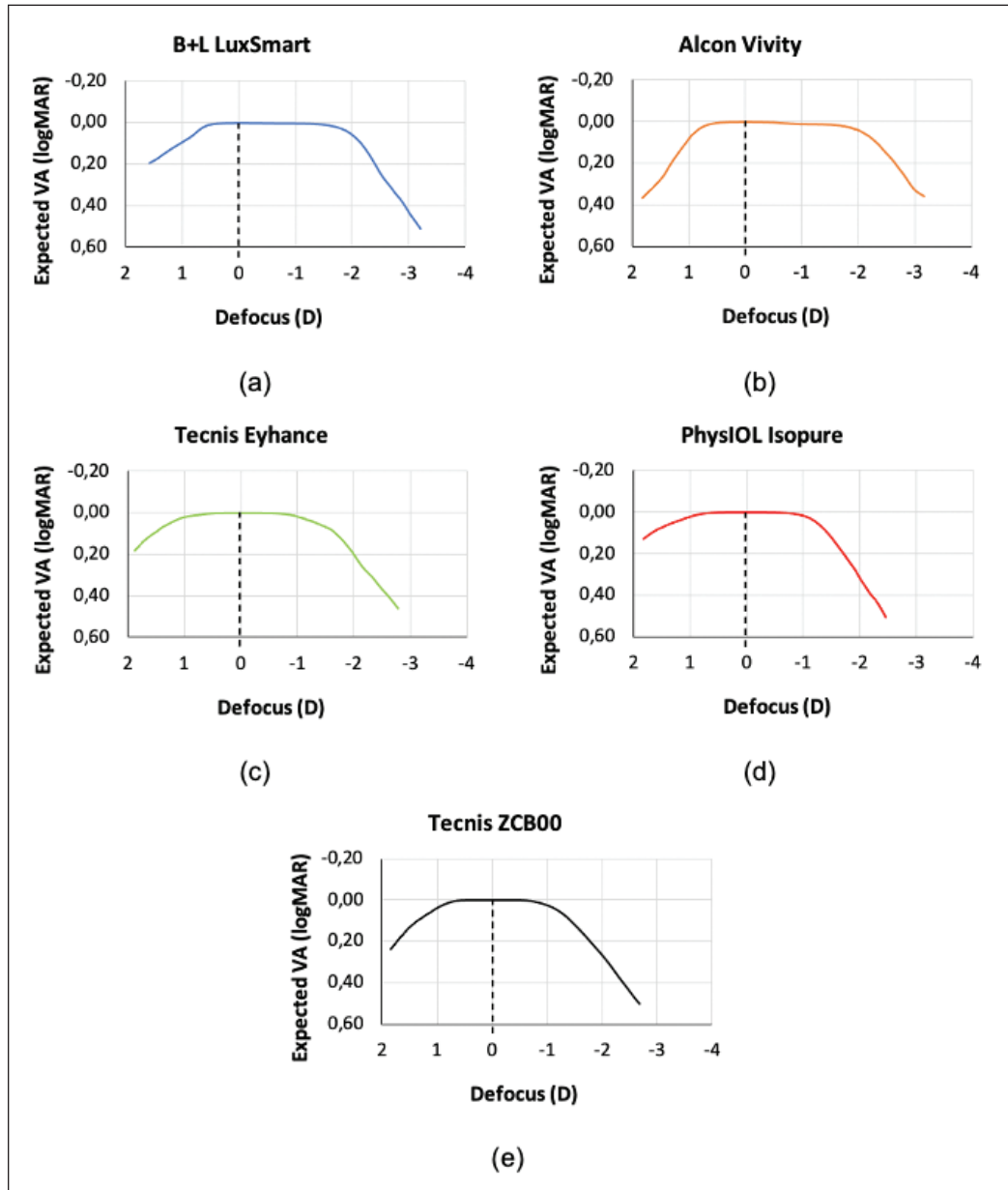


Figure C. Expected visual acuity in logMAR units as a function of defocus (D) for the extended range of vision intraocular lenses: (A) LuxSmart, Bausch & Lomb; (B) Vivity, Alcon Laboratories, Inc; (C) Tecnis Eyhance, Johnson & Johnson Vision; (D) Isopure, PhysIOL, and (E) the reference monofocal Tecnis ZCB00 IOL (Johnson & Johnson Vision). The pupil has a 3.0-mm diameter.