



Optical imaging properties and predicted visual resolution of two presbyopia-correcting intraocular lenses

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Dedicated to Prof (Dr) Daniel Malacara-Hernández

This study compared the *in vitro* optical quality of a trifocal (OptiFlex Trio) intraocular lens (IOL) and an extended-depth-of-focus (EDOF) (Asqelio) IOL to predict post-cataract surgery visual acuity. Through-focus modulation transfer function (TF-MTF) was measured using an eye model with two pupil diameters: 3.0 mm and 4.5 mm (at the IOL plane). Visual acuity and range of vision were estimated from the area under the TF-MTF curve. For a 3.0 mm pupil, both IOLs predicted sustained visual acuity better than 0.2 logMAR from distance to -3.0 D (33 cm) vision. The EDOF IOL performed slightly better for distance and intermediate vision, while the trifocal IOL provided an additional 1D range, extending to near vision. Unwanted photopic side effects (halos) were analysed from pinhole image intensity. © Anita Publications. All rights reserved.

doi: [10.54955.AJP.33.12.2024.805-814](https://doi.org/10.54955.AJP.33.12.2024.805-814)

Keywords: Cataract surgery, Intraocular lens, Multifocal lens, Extended depth of field, Modulation transfer function, Visual acuity.

1 Introduction

After cataract surgery with intraocular lens (IOL) implant, pseudophakic patients lose accommodation or their ability to correctly focus nearby objects. Presbyopia-correcting IOLs are designed to enhance vision at intermediate and near distances, reducing or eliminating the postoperative need for spectacles. These lenses can be classified into two main groups, multifocal intraocular lenses (MIOLs), which use distinct optical powers for emphasized far vision with improved intermediate and near vision, and extended depth of focus (EDOF) lenses, which aim to provide a continuous range of vision from far to intermediate distances.

A MIOL typically splits a collimated light beam into two (bifocal) or three (trifocal) focal points. While a MIOL design provides functionally useful visual acuity levels at far and closer vision distances, it can lead to a decrease in contrast sensitivity and an increase in unwanted photic phenomena such as halos and glare, which affect visual quality [1,2]. The extended focus technology was introduced in IOL design to reduce the photic phenomena. The basic principle of EDOF IOLs is to create a focal spot to improve the depth of focus, and hence, the expectation for an optimized distance and intermediate vision [3]. However, according to some studies, EDOF lenses worked less efficiently for near vision than did trifocal IOLs [2].

Given the wide range of IOLs available, it is necessary to evaluate the optical performance of the lens designs to help surgeon's choice. Objective evaluations use on-bench model eyes whose features

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are listed in standards [ISO-2024, ANSI]. These objective measurements are a necessary preliminary step, complementing the subjective assessments of monocular or binocular visual acuity (VA) defocus curves, which are a primary clinical measure. High contrast VA charts, consisting of lines of scaled optotypes in logMAR units, are utilized to assess the postoperative visual resolution of pseudophakic subjects at different distances in the clinical practice [4]. Thus, optical bench measurements can be correlated with clinical defocus curves [5].

In this study, we compare the optical performance and imaging quality of two lenses available in the market: Optiflex Trio trifocal IOL and Asqelio™ EDOF IOL. We use a model eye implemented on an optical bench to measure modulation transfer function (MTF)-based metrics and calculate the expected postoperative VA. We follow an objective protocol, which has proven useful for IOL optical characterization [6,7], included in the current standards for IOL testing (ISO Standard 11979-2-2024 [8] and ANSI Z80.35-2018 [9]). The scarcity of reported results using an on-optical bench model eye with these IOLs underscores the novelty of this work. The limited inclusion of these lenses in current classifications [10,11] highlights the importance of supplementing clinical studies with the optical bench analysis presented here. This study aims to provide valuable guidance to surgeons by objectively assessing and comparing the performance of these IOLs.

2 Material and Methods

2.1 Intraocular lenses

The Asqelio™ EDOF IOL (AST Products, Inc., Billerica, MA, USA) is a soft hydrophobic IOL. This IOL has a bi-aspheric surface with posterior phase ring profile. The lens has a total diameter of 13.0 mm and is built in powers ranging from +5.00 to +34.00 D at the IOL plane in 0.50 D increments, with a C-Loop platform. It has a refractive index of 1.50, Abbe number of 50, and spherical aberration (SA) of -0.27 microns (for 6.0 mm aperture) to compensate for the positive SA of average human cornea [12]. For this study, the IOL has a base power of +19.00 D.

Table 1. Specifications of Asqelio EDOF and Optiflex Trio intraocular lenses. D: Diopters. N/A: Not applicable.

Brand Name	Asqelio™ EDOF	Optiflex Trio
Technology	EDOF	Trifocal
Optic design	Bi-aspheric surface with posterior phase-ring profile	Diffraction zone in the center (4 mm) and a refractive zone in the periphery in the anterior surface
Optical diameter	-	6 mm
Overall diameter	-	13 mm
Refractive index	1.5	1.48
Abbe number	50	49
Spherical aberration for 6 mm corneal plane	-0.27 microns	-0.20 microns
IOL power	19.00 D	22.00 D
Add power	N/A	Intermediate +1.85D, Near +3.5D
Light energy distribution	N/A	45% for far, 27% for intermediate, and 28% for near vision.

Optiflex Trio trifocal IOL (Biotech Healthcare Holding GmbH, Luzern, Switzerland) is a single piece, hydrophobic IOL. Its anterior surface combines a diffractive profile in the central region of the lens aperture (4.0 mm diameter) with a refractive zone in the periphery. The diffractive profile produces

intermediate and near add powers of +1.85 D and +3.5 D, respectively (at the IOL plane). It has a total diameter of 13.0 mm. Its power ranges from +7.00 to +30.00 D at the IOL plane in 0.50 D increments. The optic zone of the lens is aspheric with negative SA (-0.20 microns for 6.0mm aperture) to compensate for the positive SA of the cornea. With a distribution of light energy of 45% for far, 27% for intermediate, and 28% for near, the lens is designed to provide good vision at all distances [13]. The IOL has 22.00 D of base power. Table 1 contains the main specifications of the IOLs for the present study.

2.2 Experimental Set-Up

The optical image quality of the IOLs was measured *in vitro* using an optical bench according to ISO 11979 2:2014 and ANSI Z80.35 2018 standards [8,9]. The setup, schematically shown in Fig 1 and described in more detail elsewhere [7,14], is formed by an illumination system, a model eye and an image acquisition system.

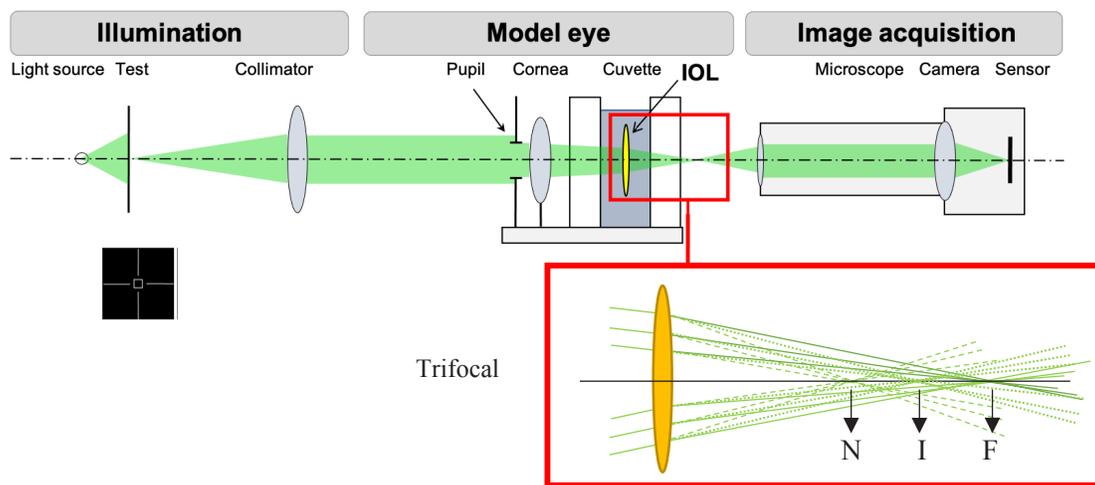


Fig 1. Scheme of the optical setup. Inset: Trifocal IOL with focus for N = near, I = intermediate, F = far vision.

The illumination system is composed by a high-power green LED (SOLIS 565C, Thorlabs GmbH, Bergkirchen, Germany) with a narrow bandpass filter with transmission peak at 550nm and full width at half maximum of 10nm that illuminates a test object with four slits, two along horizontal axis X and two along vertical axis Y. The width of the slits is $10\mu\text{m}$. The test is located at the front focal plane of a collimator (200 mm focal length). The model eye is conformed to the ANSI Z80.35–2018 Type 2 specification (i.e., with an artificial cornea with SA = $+0.27\ \mu\text{m}$ for 5.15 mm aperture at the IOL plane) [15]. All the pupil diameters mentioned in this work are referred to the IOL plane.

A microscope and a CCD camera were used to acquire the images formed by the model eye with the IOL immersed. To this end, a through-focus (TF) scan was carried out in the image space (in mm) and eventually converted to power change or defocus (in diopters, D), which can be related either to the IOL plane or the spectacle one. Although manufacturers refer lens power features (such as add power and astigmatism) to the IOL plane, clinicians usually prefer to represent clinical outcomes versus defocus referred to the spectacle plane, which approximates the object vergence. This magnitude is defined as the inverse of the observer's distance (in meters) to the object. In eyes with ocular biometric parameters in the normal range, a difference of about 0.75 D between defocus at the spectacle plane and power variation at the IOL plane has been approached [16,17]. Thus, the add powers +1.85 D (Intermediate) and +3.5 D (Near) for Optiflex Trio (Table 1) correspond to +1.37 D and +2.59 D, respectively at the spectacle plane. From now on, in this study, the defocus range will be referred to the spectacle plane.

2.3 Optical-Quality metrics

MTF-based metrics were used to evaluate experimentally the optical quality of the two presbyopia-correcting IOLs under study. These metrics describe contrast transmission through the model eye as a function of spatial frequency and pupil size. The average MTF was computed from the four-line spread functions (LSF) obtained from the image of the four-slit test (Fig 2). The best focus plane for distance vision (0.0 D defocus) was determined, in accordance with the ANSI standard guidelines, at the position where the 50 cycles/mm spatial frequency (equivalent to 15 cycles/deg in a normal human eye [18]) achieved maximum MTF with a 3.0-mm aperture.

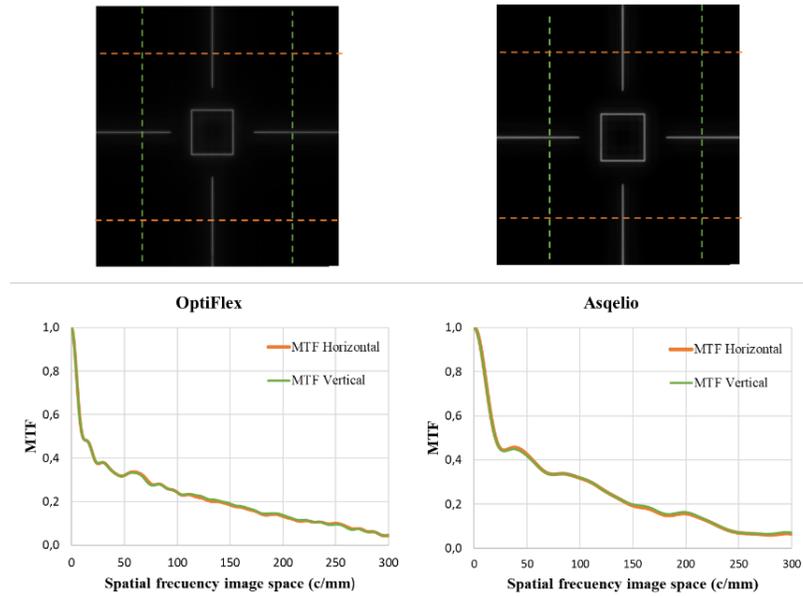


Fig 2. Top: Images of the four-slit test acquired in the far focus of either IOL (3 mm pupil): OptiFlex (left), Asqelio (right). Bottom: MTF curves obtained from the respective top image. Green plot: average of the two MTFs measured in the vertical direction (see green lines overlaid to the top image); Orange plot: idem. in the horizontal direction (see orange lines overlaid to the top image).

The area under the MTF curve (MTFa) was calculated by integrating the MTF function from 0 to 50 cycles/mm for each image plane. This process was repeated across a defocus range of +1.00 to -3.00 D in 0.10 D steps to obtain the through-focus MTFa (TF-MTFa), as described previously [7,19]. The TF-MTFa was measured for 3.0- and 4.5-mm aperture diameters.

MTFa is an objective metric that can be used to estimate the expected mean VA obtained after surgery. To this end, the ANSI standard in Annex C recommends using the formula of Eq (1) [9] that was first published by Alarcon *et al* [6].

$$VA(MTFa) = \alpha * \left(\frac{1}{MTF_a} \right) + c \quad (1)$$

where, $\alpha = 0.085$ and $c = -0.21 \log MAR$.

The study of halo is based on the intensity analysis of the image of a pinhole object. From the pinhole diameter (200 microns) and the collimating lens of focal length (200 mm), it follows that the pinhole diameter subtends a visual angle of 3.44 arc minute, thus fulfilling the standard ANSI Z80.35:2018 requirements.

3 Results

Figure 3 shows the images formed by the model eye with each IOL at the different foci. A gamma correction of 0.4 was applied to all the images to enhance the visualization of the weak background details.

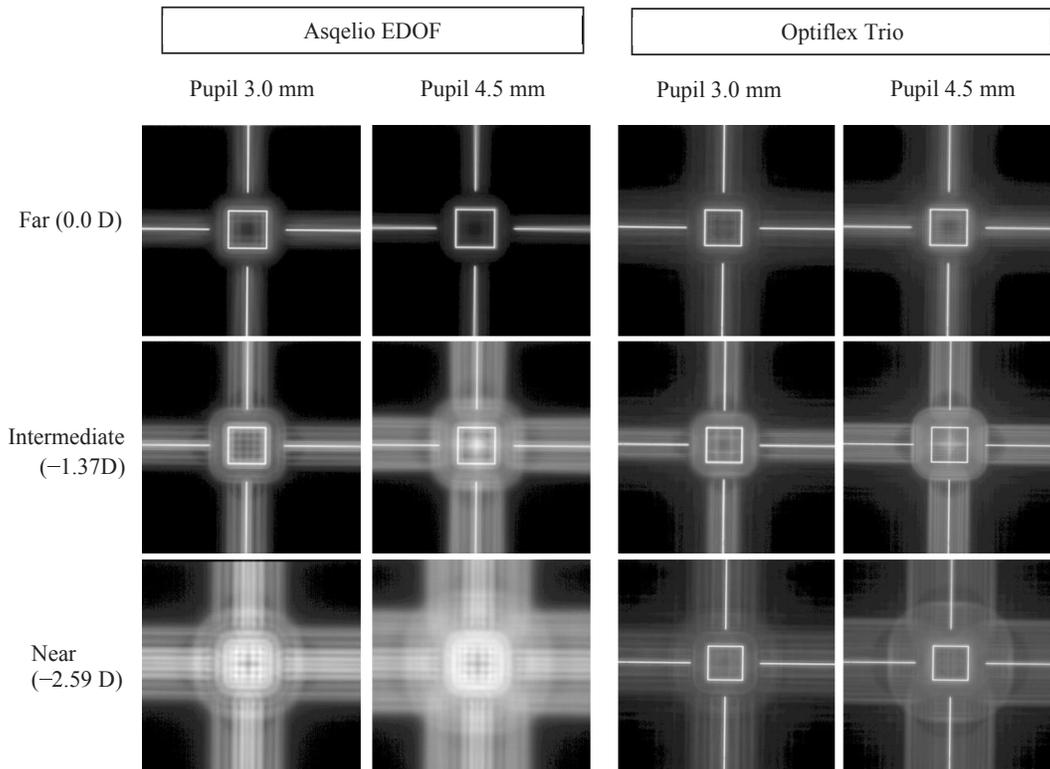


Fig 3. Test image quality with gamma correction (0.4) for far, intermediate and near distance.

In general, both the EDOF and trifocal lenses show better image quality with 3.0 mm pupil than with 4.5 mm pupil, except for the far focus of the EDOF IOL. The EDOF IOL provided better contrast at far distance (particularly with the 4.5 mm pupil) than the trifocal IOL and comparable contrast at the intermediate distance (tested at -1.37 D). At near distance, the EDOF IOL's image quality worsened clearly due to defocus, while the trifocal IOL still provided a distinct image in the near focus.

As explained above, we computed the MTF and MTFa from the raw data of the acquired images (i.e., before gamma correction). The TF-MTFa curves (Fig 4) allow establishing quantitative comparison between the optical performance of Asqelio EDOF and Optiflex Trio trifocal IOLs in the defocus range of interest (from 0.0 D defocus -far vision-, towards the negative defocus values -intermediate and near vision) and for both pupil sizes (3.0- and 4.5-mm).

The shape of the MTFa curves reflects the differences between the respective IOL's designs and its dependence on the pupil size. Thus, for a 3.0 mm pupil Asqelio EDOF reaches higher MTFa and consequently better optical image quality for far and intermediate vision up to about -1.50 D. For defocus ranging from -1.25 to -3.0 D (i.e., closer distances to the eye) the quality of the image formed by the Asqelio EDOF IOL decreases as anticipated by the images of Fig 3. In contrast, Optiflex Trio exhibits three MTFa peaks at 0.0 D (far), -1.37 D (intermediate) and -2.59 D (near). Among them, the highest peak corresponds to distance vision.

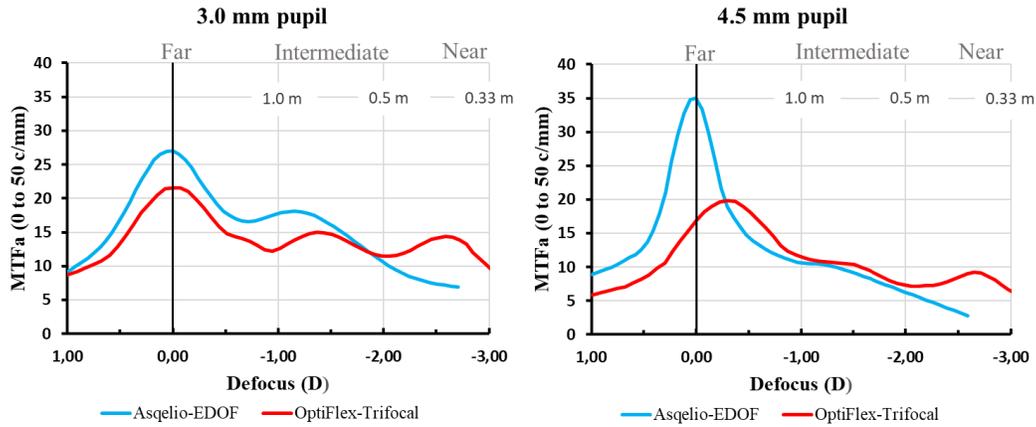


Fig 4. TF-MTFa curves obtained for both IOLs with 3.0 mm (left) and 4.5 mm (right) pupils. The abscissa axis represents defocus in diopters (D). Far, intermediate (1.0 m to 0.5 m) and near (up to 0.33 m) distances from the observer have been marked in grey (top) for clarity.

As pupil size increases to 4.5 mm, the optical behavior of both lenses changes. Asqelio EDOF maintains a single high MTFa peak for far vision. It is noteworthy the larger MTFa value obtained with this pupil (35 units) in comparison to the one reached with the 3.0 mm pupil (27 units). This result evidences improved optical performance of Asqelio EDOF at far with larger pupils. In return, there is a clear reduction of the MTFa, and consequently of the lens optical quality, at intermediate distances. With regard to Optiflex Trio, there is also a reduction of the MTFa for intermediate and near distances, resulting in a flatter curve where the peak for intermediate is barely discernible. Moreover, Optiflex Trio far focus shifts toward negative vergence (-0.5 D), likely due to an overall increase in uncompensated positive SA of the model eye.

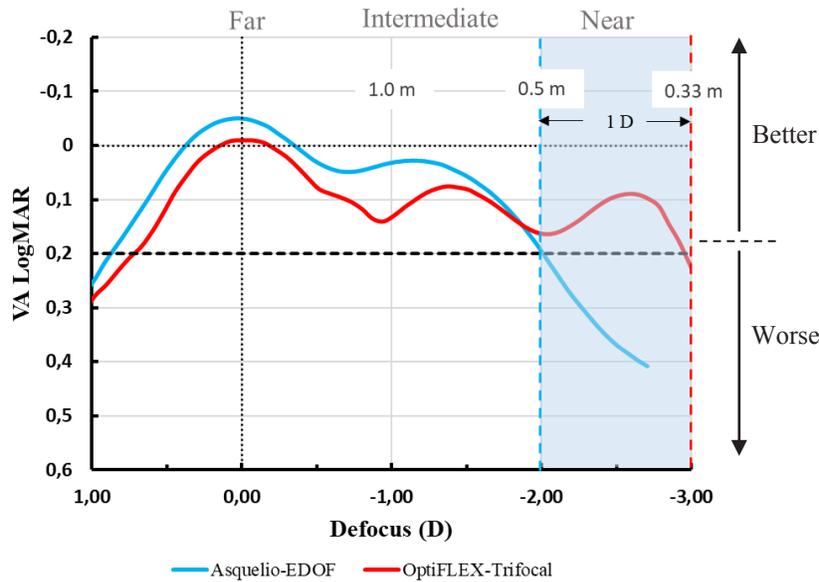


Fig 5. Expected VA (logMAR) defocus curves for Asqelio EDOF and Optiflex Trio IOLs. At the top, the distance values from the observer (in meters) equivalent to the defocus values (in diopters) at the abscissa axis.

We calculated expected VA (logMAR) from the TF-MTFa values for both IOLs using Eq (1). Figure 5 depicts the results, expected VA versus defocus, obtained for a pupil of 3.0 mm. Figure 5 shows that with both IOLs, the best expectation for VA is for 0.0 D defocus (far vision). Consistent with the MTFa differences obtained with 3.0 mm pupil (Fig 4, left), the Asqelio EDOF IOL is expected to provide slightly better VA than the Optiflex Trio trifocal IOL, at far distance with sustained performance at intermediate distances (-1.25 D) and 3.0 mm pupil. The difference for the expected far vision (Fig 5), however, is narrower than 0.1 logMAR, meaning differences smaller than 1 line in the optotype charts used for the clinical VA assessment. In remarkable contrast, the expected VA for near vision is much better with the trifocal Optiflex Trio IOL.

To account for the magnitude of the range of vision we followed the ANSI recommendation by establishing an absolute VA threshold of 0.2 logMAR [9] (in logMAR scale, 0.0 logMAR corresponds to normal vision). As it can be seen in Fig 5, part of this range falls in the positive part of the defocus curve (virtual object distances), so the useful visual range or depth of focus is limited from 0.0 D defocus (best distance vision) to the negative part of the defocus range (real object distances) with the VA equal or better than the 0.2 logMAR. With this definition, the expected depth of focus for the Asqelio EDOF is 2.0 D and for the Optiflex Trio is approximately 3.0 D.

We measured the intensity distribution of the pinhole image in the far, intermediate and near focus planes with 4.5 mm pupil in compliance with the ANSI standard for both IOLs (Fig 6). The analysis of the halo profile, i.e., its size and intensity distribution, is crucial to understanding how halos can affect a patient's VA, contrast sensitivity, and photic phenomena after IOL implantation. From the pinhole diameter (200 μm) and the collimating lens focal length (200 mm) in the optical setup, it follows that the pinhole object subtends a visual angle of 3.44 arc minute, thus fulfilling the standard ANSI Z80.35:2018 requirements. To illustrate this with an example, these conditions are visually equivalent to observing a car headlight (20 cm size) placed at 200 meters.

Figure 6 shows the intensity profiles and the images of the pinhole obtained in all the studied conditions. They are displayed on logarithmic scale for better visualization. Below each pinhole image, the intensity is plotted versus the visual angle in minutes of arc. The graphics include a central part with the highest energy (core) corresponding to the focused pinhole image. Around the core, all graphs show a lower energy pedestal corresponding to the surrounding halo.

From the results depicted in Fig 6, the intensity of the halos depends on the lens design (either trifocal or EDOF). At far distances, the EDOF lens produces smaller halos compared to the trifocal lens. However, at intermediate and near distances, with a 4.5 mm pupil size, the trifocal lens generates smaller halos than the EDOF lens, which was further affected by defocus.

4 Discussion and Conclusions

In vitro testing provides a controlled environment to objectively evaluate the optical performance of IOLs under specific conditions such as pupil size, corneal aberrations, and lens alignment. These conditions are challenging to replicate in clinical settings. Moreover, given the significant number of intraocular lenses available on the market, it is crucial to be able to determine expected visual outcome trends and establish meaningful preclinical comparisons before the actual implantation of the lens [11,20].

In this laboratory study, we evaluated two IOLs: a trifocal IOL (Optiflex Trio) with a base power of 22.0 D and an EDOF IOL (Asqelio) with a base power of 19.0 D using an on-bench model eye following standardized recommendation. Given the limited research and lack of inclusion in current IOL classifications [10], a comprehensive characterization of these lenses is necessary to fully understand their performance and potential benefits and trade-offs. The Optiflex Trio IOL shows for a 3.0 mm pupil, good optical quality for distance, intermediate and near distances that translates into excellent expected VA for far vision (0.0 logMAR), and similar but slightly worse acuity for intermediate and near distances (≈ 0.1 logMAR). These results are in good agreement with a recent clinical evaluation of this lens, which shows very similar VA at

intermediate (-1.4 D, 70 cm) and near (-2.5 D, 40 cm) distances [21]. Compared to the optical quality of other trifocal lenses studied in vitro (e.g., [22]), the VA of the Optiflex Trio lens demonstrates satisfactory performance at all distances (above 0.2 logMAR). It is important to note that unlike the study by Yan *et al* [22], who used polychromatic light, we used (550nm) monochromatic light in our study. This difference might explain slightly superior optical quality of Optiflex Trio because optical quality tends to decrease with the use of polychromatic light, as demonstrated, for example, by Łabuz *et al* [17].

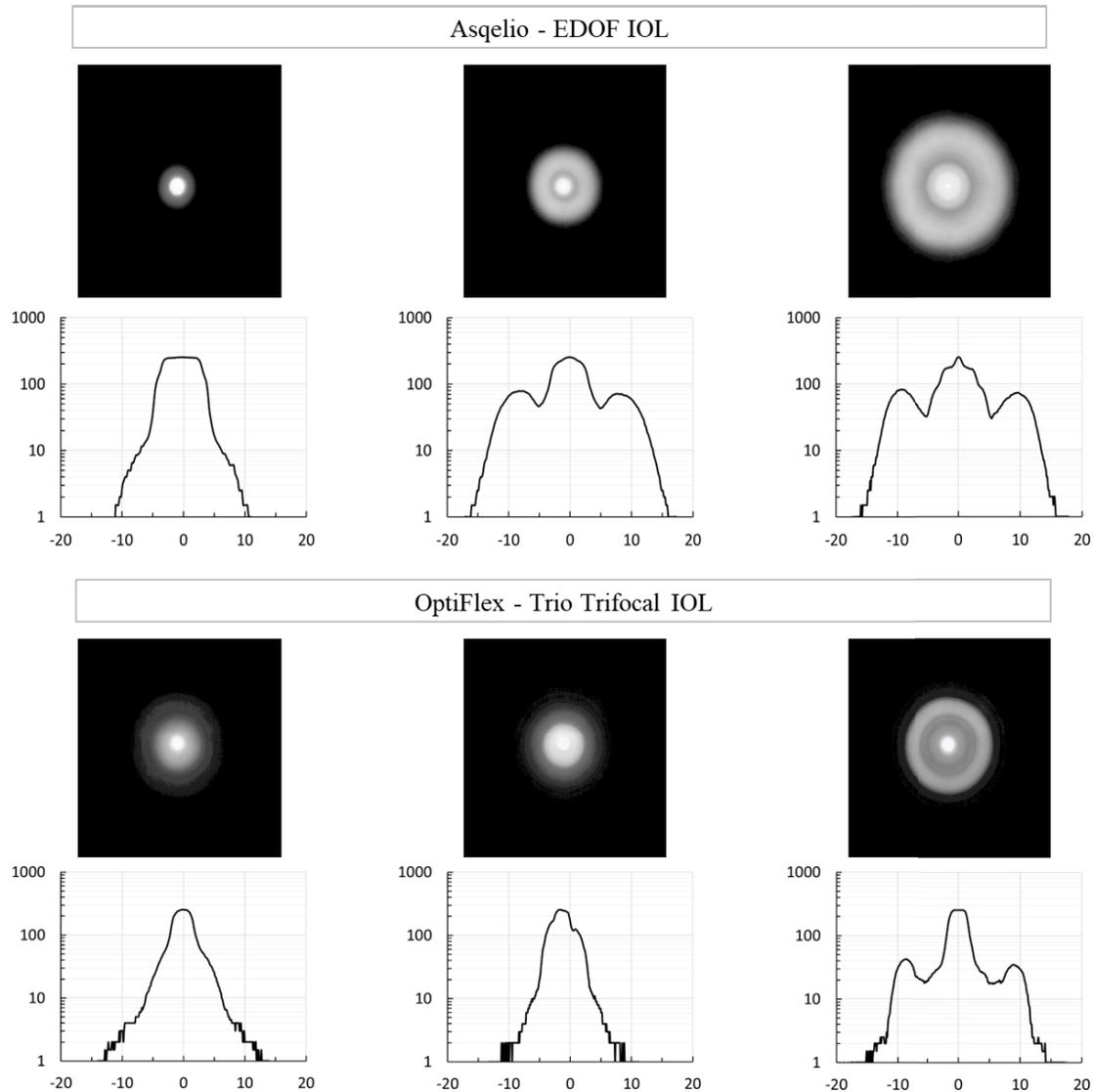


Fig 6. Halos formed by IOLs with 4.50 mm pupil size: Each pair represents the image of a pinhole (top) and its intensity profile (bottom). The intensity profile plots the normalized logarithmic value of the radial light intensity (vertical axis) versus the visual angle in arc minute (abscissa axis). Asqelio EDOF IOL (top row): (a) Far focus (0.00 D), (b) intermediate plane (-1.37 D), (c) near plane (-2.59 D); trifocal Optiflex Trio IOL (bottom row): (d) Far focus (0.00 D), (e) intermediate plane (-1.37 D), (f) near plane (-2.59 D).

Regarding the Asqelio-EDOF IOL only a few optical bench studies have been conducted. Cerviño *et al* [12] investigated the effects of lens misalignment (decentration and tilt) when using Asqelio-EDOF IOL and compared them with those caused by misaligning an Asqelio-Trifocal IOL. They observed that the EDOF IOL's intermediate-focus quality was worse than its far-focus quality for a 3 mm pupil, an observation that aligns with our study's findings. The Asqelio-EDOF exhibits behavior similar to that of the ALCON Vivity EDOF IOL, as reported by Azor *et al* [3], who analyzed various EDOF IOLs. Thus, with a relatively large pupil size (4.5 mm), a single high peak in the TF-MTFa curve (Fig 4, right) reveals better quality than with a smaller pupil (3.0 mm). Moreover, in the case of the ALCON Vivity lens, a myopic shift was also reported and explained in terms of residual spherical aberration.

We acknowledge that it would have been methodologically better to have studied IOLs with same base power. We think, however, this factor does not have an important influence on the analysis. In fact, several studies [23,24], analysing IOLs with 10 D to 30 D base power, showed that the optical quality was not significantly affected by large variations in power. In our study, the power difference between the two IOLs was only 3.0 D, further minimizing any potential impact on the optical performance.

In conclusion, with a 3.0 mm pupil, the trifocal lens provides a range of vision extended 1 D (negative) over the EDOF IOL, thereby providing better vision at near distances. An increase in pupil size causes a drop in the EDOF lens's optical quality at intermediate distances, while its performance at far distances is maintained. However, the trifocal's optical quality decreases with large pupils at all distances. The intensity of the halos is notably influenced by the lens design. At distance vision, with a relatively large pupil size (4.5mm), the EDOF lens produces smaller halo than the trifocal lens. In contrast, at intermediate and near distances, with the same pupil, the trifocal lens generates smaller halos than the EDOF lens, which is further affected by defocus.

Acknowledgements

Spanish Agencia Estatal de Investigación (PID2020-114582RB-I00/AEI/ 10.13039/501100011033). Fátima Cuéllar acknowledges a pre-doctoral contract (PRE2021-100674).

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[Received: 01.10.2024 ; rev recd: 28.12.2024; accepted: 29.12.2024]



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