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ORIGINAL RESEARCH

Ray Visualization and Through-Focus Optical Quality of Diffractive Enhanced Monofocal and Extended-Depth-of-Focus Intraocular Lenses

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Purpose: We compared two hybrid refractive-diffractive IOLs with enhanced depth of focus in an in vitro study with regard to optical quality in monochromatic and polychromatic light as well as their ray-propagation behavior.

Methods: The Mono-EDoF ME4 IOL (Santen Pharmaceutical, Osaka, Japan) and the Tecnis Symfony IOL (Johnson & Johnson Vision, USA) were assessed using the OptiSpheric IOL PRO 2 (Trioptics GmbH, Germany) to measure the through focus (TF) modulation transfer function (MTF) using monochromatic green (546 nm) and polychromatic light at different spatial frequencies. Ray propagation imaging was performed using monochromatic green light (520 nm) projected through each IOL, while submerged in a bath of fluorescein solution. The visual pathways were captured by a camera mounted on a microscope. Ray visualization was additionally performed for a monofocal control IOL (W60-R IOL, Santen Pharmaceutical).

Results: The Mono-EDoF IOL showed superior TF-MTF performance for defocus of up to −1.3D compared to the Symfony IOL in monochromatic and polychromatic light. For higher defocus values, however, the Symfony showed superior performance than the Mono-EDoF. Image quality in polychromatic light decreased for both IOLs compared to monochromatic light. Ray propagation imaging revealed one distinct focus for the monofocal IOL. The Mono-EDoF demonstrated an elongated focus area. The Symfony showed two focal points.

Conclusion: We found comparable deterioration of image quality in polychromatic light for both IOLs with improved intermediate range. The Mono-EDoF demonstrated an elongated focus and superior TF-MTF performance at lower defocus values, but it did not match the standard EDoF model at higher defocus.

Keywords: extended depth-of-focus IOL, presbyopia correction, optical bench evaluation

Introduction

In cataract surgery, monofocal IOLs are still most commonly used to correct aphakia.[1] This usually results in the need to use reading glasses postoperatively as patients will be pseudo-presbyopic. Although numerous alternatives are available that allow simultaneous correction of presbyopia, these are offered to only a small proportion of patients. One of the reasons for this is that the correction of presbyopia can be associated with side effects such as dysphotopsia and reduced contrast sensitivity. New IOL technologies are constantly being developed to reduce these potential side effects while at the same time limiting the need for spectacles.

Extended depth of focus (EDoF) IOLs are a heterogenous group of IOLs that extend the visual range from far to intermediate distance. As EDoF IOLs use different optical principles to enhance the depth of focus, different performances and side effects have to be expected with different IOL models.[2] Another group of recently introduced IOLs are “enhanced monofocal” IOLs that are designed to provide similar distance visual acuity and superior intermediate visual acuity compared to a monofocal IOL while inducing only a low level of side effects.[3,4] Comparing different IOLs in the laboratory can improve our understanding of the differences between IOL models and allow us to refine IOL selection according to a patient’s visual demands. Individual visual

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requirements can be evaluated in a standardized way using various questionnaires. This enables a standardized query of various activities in order to gain a comprehensive picture of the habits of the respective patient requiring functional near, intermediate and far visual acuity.[5]

Chromatic aberrations can influence the performance of an IOL, and therefore, some manufacturers do take them into account in their IOL designs. However, data on the chromatic aberration effects of some IOL models are still sparse and when measurements are performed under different conditions the results are not directly comparable to each other.

In this laboratory analysis, we compared an EDoF IOL, the Tecnis Symfony ZXR00 (Johnson & Johnson Vision, USA), to an enhanced monofocal, the Mono-EDOF ME4 (Santen Pharmaceutical, Japan) with regard to optical quality in monochromatic and polychromatic light as well as their ray propagation behavior.

Methods

Intraocular Lenses

We studied the Mono-EDoF ME4 IOL (Santen Pharmaceutical, Japan) and the Symfony ZXR00 (Johnson & Johnson Vision, USA). Both are refractive-diffractive IOLs designed to extend the depth of focus.

The Mono-EDoF ME4 is a bi-convex single-piece IOL with an overall diameter of 12.5 mm and optic diameter of 6.0 mm. It is a hybrid refractive-diffractive enhanced monofocal IOL with an aspheric surface and four diffractive rings within a 3.2 mm diameter. The IOL features a spherical aberration (SA) correction of −0.13μm. The ME4 IOL is manufactured from a hydrophobic acrylic material with a refractive index of 1.540 and an Abbe number of 39.4. It features a blue light filter.

The Symfony ZXR00 IOL is a refractive-diffractive EDoF IOL with nine diffractive rings. The IOL is designed to correct 0.27μm of SA and additionally features correction of chromatic aberrations. Symfony's material is a hydrophobic acrylic with a refractive index of 1.47 and an Abbe number of 55. Figure 1 shows drawings of both models as well as surface images of both IOLs.

While the Symfony IOL is marketed as an EDoF IOL, the xact Mono-EDoF is classified as an enhanced monofocal IOL.

Five samples of each IOL model were measured, each with a dioptric power of +20.00 diopters (D).

For the ray propagation visualization, the W60-R IOL (Santen Pharmaceutical, Japan) served as a monofocal control.

Optical Metrology

The Laboratory's OptiSpheric IOL PRO2 (Trioptics GmbH, Germany) was used for optical quality measurements. The measurements were performed in accordance with the ISO 11979 standard.[6] The IOLs were placed in a model eye containing a balanced salt solution (BSS). A reticle was illuminated by a collimator and imaged by the IOL under test onto a CCD camera.

This setup was used to measure the effective focal length (EFL) and the modulation transfer function (MTF). A 3-mm aperture was used for the MTF measurements.

The EFL was measured in monochromatic green light using the magnification method described in the ISO 11979–2 standard without a model cornea and with a 3-mm aperture.[6]

Two different spectral filters were used for MTF measurements. One passes monochromatic-green light (wavelength 546 nm), and the other weighs the light spectrum according to the photopic-eye sensitivity. To achieve a more realistic simulation of in vivo conditions, we implemented polychromatic testing in our study. The IOL Pro 2 device we used has expanded capabilities for testing IOLs in polychromatic light. Based on information from the manufacturer of the IOL Pro 2 device detailing the spectral transmission, we determined that the filter's central wavelength is 531 nm with a full width of half maximum of 143 nm.

Furthermore, two different model corneas were used. Measurements of the Mono-EDoF IOL were performed using a model cornea with a SA correction of 0.13μm and for measurements of the Symfony IOL, a model cornea with SA correction of 0.27μm was used. To acquire the through-focus MTF (TF-MTF) the CCD was moved along the focal planes

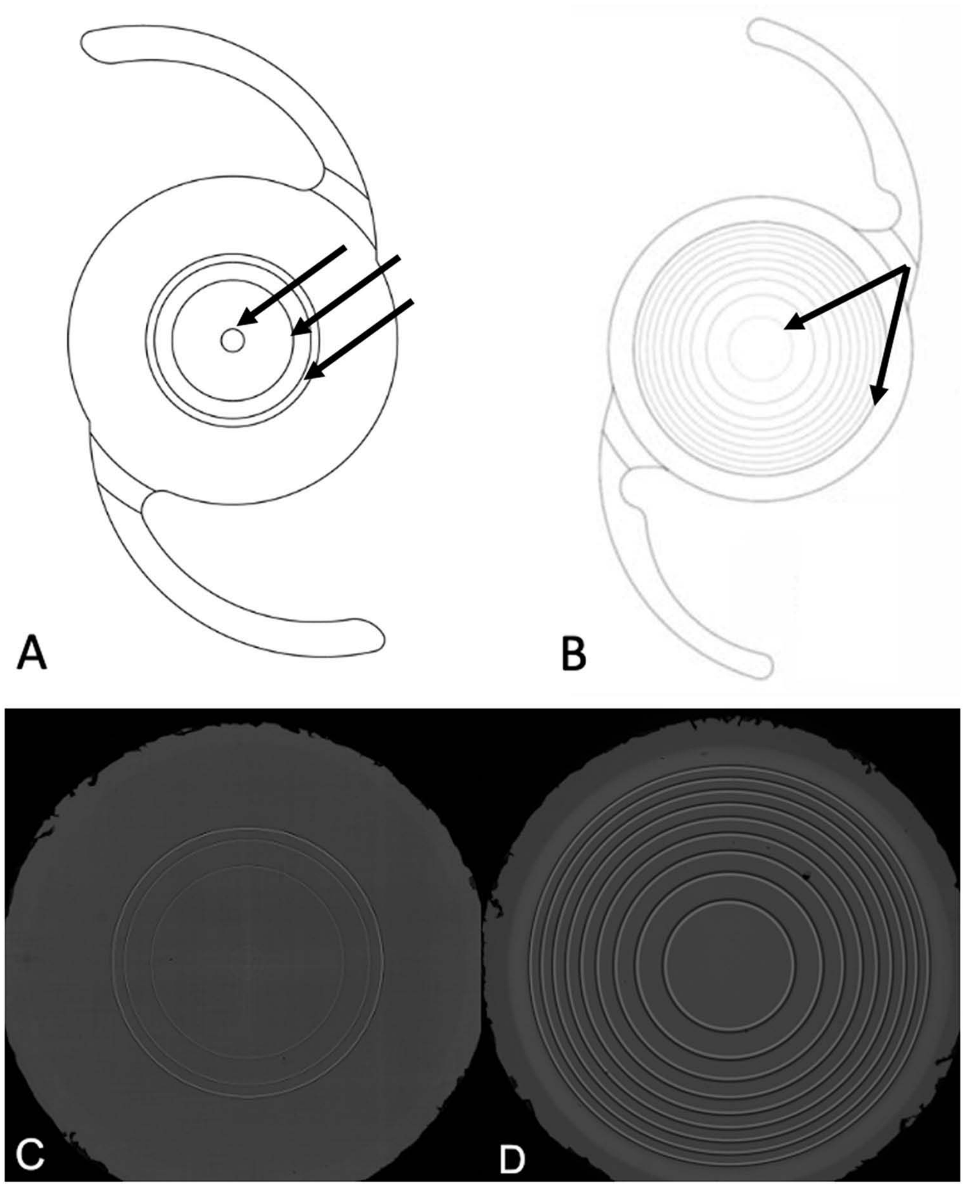

Figure 1 (**A**) Shows drawings of the xact Mono-EDoF IOL and (**B**) of the Symfony IOL. The arrows indicate the diffractive rings of each IOL model. (**C**) shows a surface image of the xact Mono-EDoF and (**D**) a surface image of the Symfony IOL.

of the optical axis with a defocus range from +0.5 to −2.5 diopters. MTF values were calculated at 25 lp/mm, 50 lp/mm and 100 lp/mm for monochromatic and polychromatic light.

The analysis of optical-quality data was performed with routines written in MATLAB (MathWorks, USA).

Ray-Propagation Visualization

The experimental setup we used was described in detail in our previous studies.[2,7] In brief, the IOL under test was placed in a lens holder and submerged in a water bath (1000 mL) which was stained with 1mL of a 10%-fluorescein solution. A green laser light source (wavelength 532nm) was projected through a model cornea and the IOL under test. A digital camera mounted onto a surgical microscope (Leica, Wetzlar, Germany) was used to capture the visualization of the light distribution. ImageJ was used to obtain pixel intensity values along the IOL's optical axis.

Table 1 The Detailed Results of EFL Measurement for the Different Samples for Both IOL Models

	Xact Mono-EDoF ME4	Symfony ZXR00
Sample 1 nominal power Sample 1 add power	20.08±0.012 0.63±0.005	20.36±0.013 1.74±0.005
Sample 2 nominal power Sample 2 add power	20.08±0.001 0.63±0.006	20.11±0.035 1.70±0.004
Sample 3 nominal power Sample 3 add power	20.08±0.019 0.64±0.009	20.19±0.018 1.71±0.006
Sample 4 nominal power Sample 4 add power	20.20±0.002 0.63±0.002	20.30±0.040 1.74±0.003
Sample 5 nominal power Sample 5 add power	20.14±0.003 0.60±0.012	20.13±0.034 1.73±0.003
Average nominal power Average add power	20.12±0.053 0.63±0.016	20.21±0.103 1.72±0.019

Notes: The table shows mean values ± standard deviations.

Results

EFL Measurement

EFL measurements confirmed the labeled power of the studied models. The exact results are shown in Table 1.

MTF Measurement

Figure 2 shows the averaged TF-MTF curves for both IOL models studied at 25 lp/mm, 50 lp/mm and 100 lp/mm. The data labelled as "Mono-EDoF" refer to the xact Mono-EDoF ME4 and the data labelled as "Symfony" refer to the Symfony ZXR00 IOL.

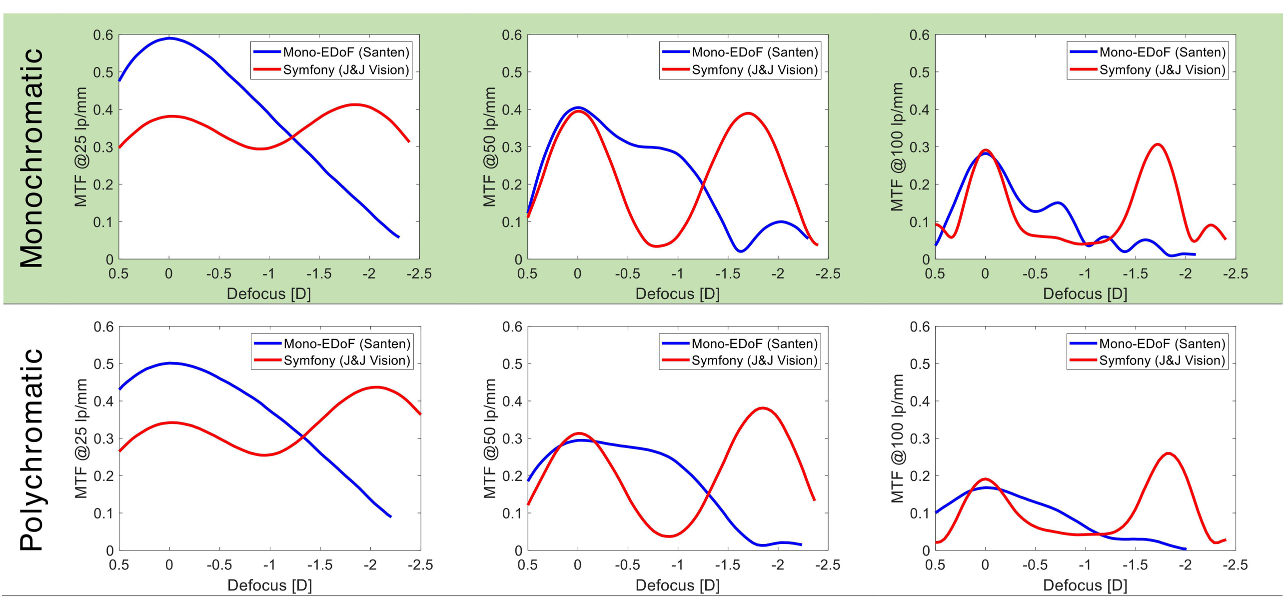

Figure 2 Through-focus MTF curves of the Mono-EDoF and the Symfony IOL under monochromatic and polychromatic light conditions at different spatial frequencies. The data labelled as "Mono-EDoF" refers to the xact Mono-EDoF ME4 and the data labelled as "Symfony" refer to the Symfony ZXR00 IOL.

Table 2 Mean MTF Values and Standard Deviations

	Xact Mono-EDoF ME4	Symfony ZXR00
MTF at far focus under green light (25lp/mm)	0.59 ± 0.006	0.38 ± 0.011
MTF at far focus under polychromatic light (25lp/mm)	0.50 ± 0.005	0.35 ± 0.011
MTF at far focus under green light (50lp/mm)	0.40 ± 0.022	0.39 ± 0.017
MTF value under polychromatic light (50lp/mm)	0.29 ± 0.011	0.32 ± 0.017
MTF at far focus under green light (100lp/mm)	0.28 ± 0.014	0.29 ± 0.019
MTF value under polychromatic light (100lp/mm)	0.17 ± 0.005	0.19 ± 0.011

Abbreviations: MTF, Modulation transfer function; lp/mm, line pairs per mm.

At 25lp/mm, the MTF values for the far focus were 0.59 for the ME4 and 0.38 for the Symfony in monochromatic green light. In Polychromatic light, the ME4 also showed a higher MTF value of 0.50 compared to 0.35 for the Symfony at 25 lp/mm. At 50 lp/mm and 100 lp/mm, the ME4 exhibited minimally higher monochromatic-MTF values at the far focus and comparable far-focus performance in polychromatic conditions. Figure 2 also indicates that the mono-EDoF IOL showed better MTF values at lower defocus of up to 1.3 diopters than the Symfony IOL under both monochromatic and polychromatic light. For higher defocus values, however, the Symfony showed superior performance with a secondary peak of the TF MTF at 1.72 diopters of defocus. At this level, ME4's MTF was close to zero. The Symfony demonstrated intermediate dominance at all spatial frequencies and spectral conditions, with the secondary peak showing higher TF MTF values than the primary peak at no defocus.

The bottom row of Figure 2 shows the MTF values at different spatial frequencies under polychromatic light. The images of the upper row obtained with monochromatic green light correspond to the images of the bottom row obtained using polychromatic light, while the other testing conditions remained unchanged. The use of polychromatic light led to a decrease in MTF values at the far focus. At 25, 50 and 100 lp/mm the reduction of MTF value was 15%, 27% and 40% for the ME4 and 9%, 20% and 35% for the Symfony IOL. These MTF measurement results are also shown in Table 2.

Ray Propagation

Figure 3 shows the light pathways and light intensity profiles from left to right of the standard-EDoF, enhanced-monofocal and standard-monofocal IOLs for comparison. We found a distinct focus for the monofocal IOL corresponding to the far focal point. The Mono-EDoF IOL demonstrated an elongated focus area. For the Symfony, we found two focal points, with one corresponding to the intermediate focus and the other one corresponding to the far focus of the IOL.

Discussion

As different optical principles can be used to create the EDoF effect, it may be difficult to predict the exact performance of an IOL labeled as "EDoF". In an attempt to standardize the requirements for an IOL labeled as 'EDOF' the American Academy of Ophthalmology published criteria for clinical evaluation of EDoF IOLs. These include a monocular depth of focus at the 0.2 logMAR level of at least 0.5 diopters (D) greater than a monofocal control. Furthermore, monocular distance corrected intermediate visual acuity at 66 cm should be superior to the monofocal control, and at least 50% of eyes should achieve a DCIVA of 0.2 logMAR (Snellen 6/9.6) or better. Monocular DCVA is required to be noninferior to the monofocal IOL.[8] Although the classification as 'EDoF' IOL is not possible from optical bench parameters alone, the through-focus assessment of the IOLs' optical quality can help to compare different EDoF IOLs and to better understand the differences between various IOL models.[2] It was a primary focus of this study to highlight the differences between the lens models, as distinguishing enhanced monofocals from standard EDoF lenses has always been challenging. To properly validate the EDoF designation on the optical bench, a monofocal control lens would be required, which was not

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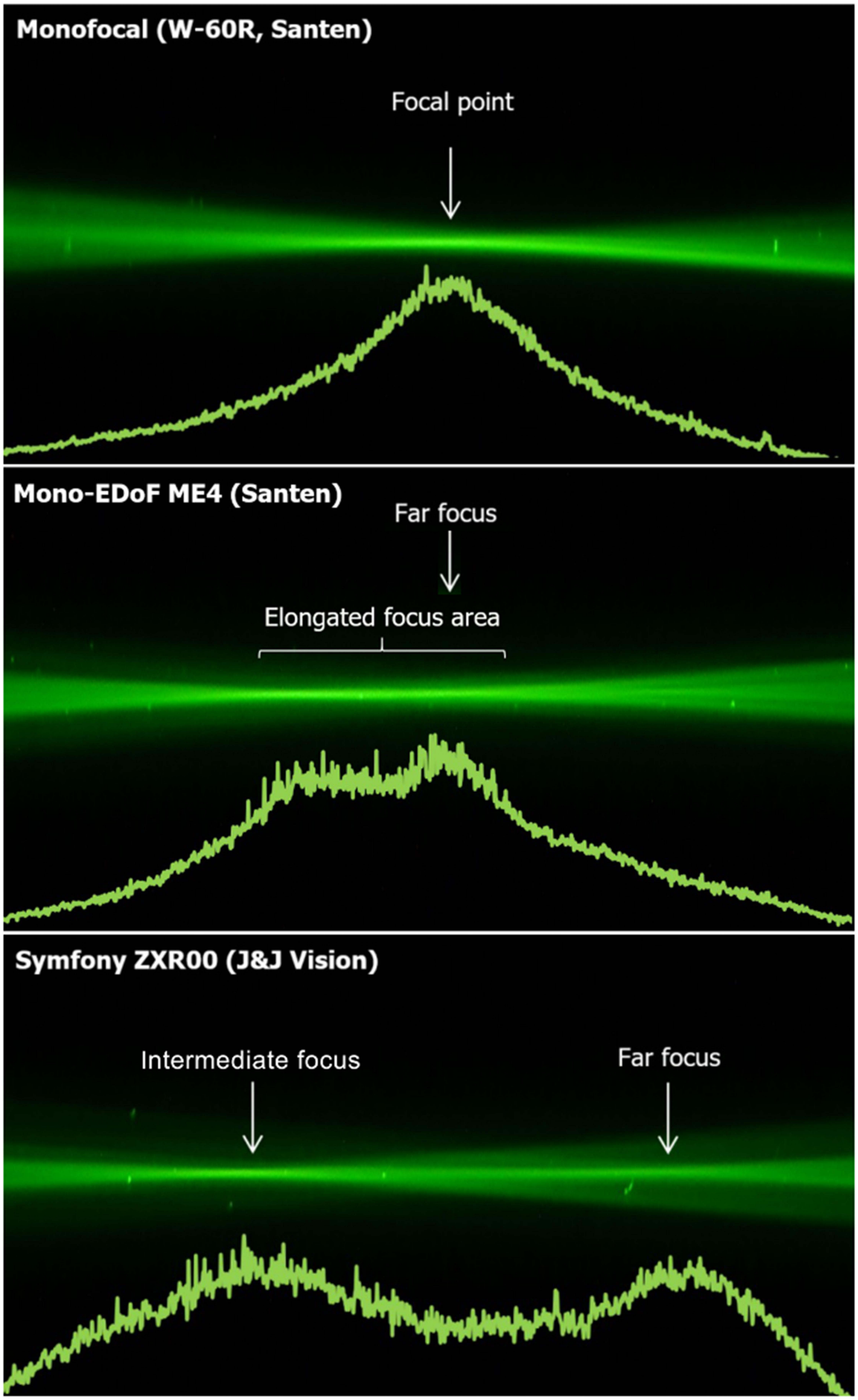

Figure 3 Ray propagation and light intensity profiles of a monofocal IOL (upper row), the Mono-EDoF (middle row) and the Symfony (bottom row).

included in this case. Nevertheless, based on our through-focus MTF results, the MTF value at −1.5 D is close to zero while achieving a visual acuity better than 0.2 logMAR at 67 cm – a criterion for EDoF classification as mentioned above – appears unlikely according to our measurements.

We found an elongated focus for the Mono-EDoF ME4 and two foci for the Symfony IOL using ray propagation imaging (Figure 3). These findings are consistent with the results of the TF MTF testing, which also showed an extended focus for the ME4 IOL and two peaks for the Symfony IOL (Figure 2).

Previous laboratory studies reported optical quality parameters for the Symfony IOL and Mono-EDoF IOL using monochromatic green light.[9–12] As chromatic aberrations can deteriorate image quality, it is important to also examine image quality in polychromatic light. A previous study by Lee et al found two distinct foci in the TF-MTF curves of the Symfony IOL in polychromatic light.[13] These findings are consistent with our results. We confirmed that the TF-MTF curve of the Symfony demonstrates two foci in polychromatic light and that the same was true for monochromatic green light. A study by Millán et al assessing the Symfony IOL in vitro also found two foci when using light of different wavelength,[14] which is in good agreement with our results demonstrating a bifocal-like behavior of this IOL. Miret et al also found two foci for the Symfony IOL in their study, comparing results with different model corneas. They found that image quality deteriorated when using a model cornea that did not match the IOLs approach to spherical aberration correction.[15] A study by Domínguez-Vicent et al compared the Symfony IOL to the MiniWell Ready (SIFI Medtech) and found similar results for the Symfony at the 3-mm aperture. Image quality decreased for both IOLs at the 4.5-mm aperture with the MiniWell showing far-dominance in this setting.[16] In a comparative study by our research group, various EDoF IOL models including diffractive and refractive optics were examined in polychromatic light. The MTF analysis at 50 lp/mm shows that the refractive models show a rather balanced energy distribution between the far and intermediate focus. In contrast, the diffractive EDoF IOL models showed a bifocal-like behavior producing 2 well-separated focal points.[17]

Ruiz-Alcocer et al examined the Mono-EDoF IOL in vitro and found two overlapping peaks in the TF-MTF curves.[9] We also found a slight drop in TF-MTF for the Mono-EDoF in monochromatic light at higher spatial frequencies corresponding to two peaks with considerable overlap. In polychromatic light and at lower spatial frequencies, the ME4 showed one broad focus without a clear separation of a secondary (intermediate) focus. This can be explained by two overlapping foci that are sufficiently close to each other so that no abrupt changes in TF-MTF are observed. Montagud-Martínez et al assessed the Mono-EDoF ME4 IOL in the laboratory and compared it to a diffractive trifocal IOL (FineVision POD F, PhysIOL, Liège, Belgium) and a diffractive EDoF IOL (AT LARA 829MP, Carl Zeiss Meditec, Jena, Germany).[18] They also found two overlapping peaks in the TF-MTF curves. The two peaks were broader than in the study by Ruiz-Alcocer et al which they explained by the different apertures used (3 mm in the work of Ruiz-Alcocer and 4.5 mm in that of Montagud-Martínez).[9,18] The latter group found that the chromatic aberrations of the Mono-EDoF ME4 contributed to the EDoF effect.[18]

The ME4 demonstrated superior TF-MTF than the Symfony at defocus values of up to approximately −1.3D but the opposite was observed for defocus greater than −1.3 D (Figure 2). This can be explained by the differences in IOL design. While the ME4 is an enhanced monofocal IOL that demonstrated an elongated far focus, it provides superior performance at lower defocus values. The Symfony's behavior was bifocal-like with a low near addition which allows a better performance at higher defocus values.

The use of polychromatic light leads to a decrease in MTF values at different spatial frequencies for both IOLs. Lee et al also reported decreased image quality with polychromatic light for different EDoF IOL models.[13] The diffractive IOLs assessed in the work of Lee et al, including the Symfony IOL, proved more resistant to chromatic aberration effects than a refractive EDoF IOL. They also found that chromatic aberrations affected the image quality of the Symfony more at the primary (far) focus than at the secondary (intermediate) focus.[13] This can be explained by the 1st and 2nd diffractive order design that employs longitudinal chromatic aberration (LCA) correction at both the far- and intermediate-focus with doubled LCA correction at the intermediate focus compared to the distance focus.[13,19] As the Symfony has a higher Abbe number than the Mono-EDoF, a higher dispersion and, thus, inferior polychromatic image quality could be expected for the latter. Besides, as mentioned above, the Symfony features chromatic aberration correction.[19] The similar decrease in polychromatic optical quality could be explained by the extended depth of focus of the Mono-EDoF without a distinct secondary peak that may attenuate the impact of the chromatic aberrations on image quality. Another contributing factor is the Mono-EDoF's diffractive design, which, per se, also counters the material's dispersion of light, but given its lower defocus range, the impact of such correction is limited.

Millán et al found low values for longitudinal chromatic aberration (LCA) with the Symfony IOL and the highest energy efficiency span of all IOLs included in their study.[14] An increased spectral dependency of this IOL, which is associated with its approach to LCA correction, has been reported previously.[13,20] As mentioned above, in our study the Symfony did show a comparable reduction in image quality as the enhanced monofocal, which contrasts the results by Millán et al, but can be attributed to the properties of the Mono-EDoF IOL as explained above.

In vitro studies can only approximate the in vivo situation and should therefore be assessed in conjunction with clinical data.

In clinical research which we previously published, we assessed intermediate visual acuity in cataract patients with the ME4 IOL. We included visual acuity testing at 50 cm, 60 cm, 66 cm and 70 cm. At 50 cm distance binocular DCIVA was 0.30±0.16 logMAR, while binocular DCIVA at 70 cm was 0.13±0.11 logMAR.[3]

The Symfony was assessed in several clinical studies, and intermediate visual acuity was measured at different distances. Lubiński et al reported UIVA of 0.09±0.09 logMAR at 60 cm and of 0.15±0.08 logMAR at 80 cm.[21] Ruiz-Mesa et al reported DCIVA of 0.05±0.04 logMAR at 60 cm and DCNVA of 0.20±0.07 logMAR at 40 cm.[22] As expected from the in vitro results, the Symfony seems to provide better intermediate visual acuity at closer distances, but the Mono-EDoF also extends the depth of focus compared to what can be expected with a monofocal IOL. Tañá-Sanz et al found a depth of focus of approximately 1.25 diopters in their clinical report on the ME4 IOL.[23] In our clinical study, we found the same value for the functional defocus of 1.25 diopters for the Mono-EDoF ME4 IOL.[3]

Data on ray propagation of different IOL models are currently sparse. Mendroch et al report simulation-based data on ray propagation of the monofocal SN60WF (Alcon) and two EDoF IOL models, the Vivity (Alcon) and the LuxSmart (Bausch & Lomb) IOL. They found that both EDoF IOLs showed a far focus as well as a secondary focal region. With a larger aperture, both EDoF IOL models showed a more far-dominant behavior. When using polychromatic light, however, the focal positions became indistinguishable.[24] In contrast to this study, they did not measure ray propagation in a physical eye model, and therefore, results are only comparable to a limited extent. Overall, these results are in good agreement with our results: The monofocal IOL in our study also generated one clear far focus, whereas the EDoF IOL model generated an additional focal area. For the enhanced monofocal, however, there was no second focal area distinguishable, which could correspond to two overlapping peaks. Previous work of our group showed, that the light intensity curves obtained from ray propagation imaging are in good agreement with trough-focus-MTF curves.[7] Our previous studies on ray propagation included different diffractive EDoF IOL namely the Symfony IOL, AT Lara IOL (Carl Zeiss Meditec) and Proming IOL (Eyebright Medical Technology), all of which generated two distinct focal points, which confirms our results for the Symfony IOL in this work.[2,25]

A limitation of our study is that measurements were only performed at a 3-mm aperture. Future studies are needed to further evaluate the performance of the IOLs studied with different aperture sizes.

In conclusion, ray propagation of the Mono-EDoF revealed an elongated focus compared to a monofocal IOL. The ME4 IOL showed superior performance at lower defocus levels up to −1.3D, while Symfony's performance was superior at higher defocus values. Despite the differences in IOL design and their respective strengths at different defocus levels, both the Mono-EDoF and the Symfony IOL showed comparably reduced TF-MTF performance in polychromatic light compared to monochromatic green light. This suggests that, while the extended depth of field features offers notable benefits in real-world conditions, the optical performance of both lenses may still be compromised by the presence of chromatic aberrations and other factors that affect the perception of image contrast in polychromatic light.

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