Optical performance of a trifocal and a novel extended depth of focus (EDoF) intraocular lenses combined with different corneal profiles

Authors: Javier Ruiz-Alcocer PhD[1], Amalia Lorente-Velázquez PhD[1]; José Luis Hernández-Verdejo PhD[1]; Pablo De Gracia, OD, PhD[2], David Madrid-Costa PhD[1]

1. Faculty of Optics and Optometry. Universidad Complutense de Madrid, Madrid, Spain.

2. Chicago College of Optometry, Midwestern University, USA

Corresponding Author: Javier Ruiz-Alcocer, PhD
Optics and Optometry Department
Faculty of Optics and Optometry
Universidad Complutense de Madrid
C/ Arcos de Jalón, 28037, Madrid, Spain
Telf: +34913946887
e-mail: jruizalcocer@ucm.es

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ABSTRACT

Purpose: To assess the effect of prior myopic ablations in the optical performance of a trifocal diffractive intraocular lens (IOL) and a novel extended depth of focus (EDoF) diffractive design.

Methods: The novel XACT Mono-EDoF ME4 diffractive IOL with an extended depth of focus and the trifocal diffractive FineVision IOL were analysed standing alone and combined with a simulated myopic corneal ablation. The optical quality of the IOLs in both situations was evaluated with the PMTF optical bench. The through-focus modulation transfer function (MTF) curves and the MTF at three different focal points (+0.50, 0.0, -0.50 D) were recorded.

Results: The through-focus MTF curves showed three differentiated peaks for the trifocal IOL and two overlapped peaks for the EDoF IOL. The presence of simulated myopic corneal ablations induce a -0.50 D shift on the overall through-focus curves and softens the multifocal properties of both lenses by decreasing the variations through focus of the MTF. For the analysis of the lenses standing alone, the highest MTF values were obtained for an object vergence of 0 D. For a simulated myopic corneal ablation, both IOLs showed better optical quality results at -0.50 D.

Conclusion: The trifocal IOL provides better optical quality at far and near distances when analysed standing alone. The EDoF IOL optical properties are more stable when a myopic ablation is introduced. Preoperative calculations of both lenses should consider that prior myopic corneal ablations induce a -0.50 D shift on their far peak quality.

INTRODUCTION

Multifocal intraocular lenses (IOL) were developed to offer patients high optical quality at near distances after cataract surgery and thus providing spectacle independence. Initially, the great majority of multifocal IOLs were bifocal, that is, they provided a near and far foci with a gap in between for intermediate vision.[1-4] To overcome this limitation, trifocal IOLs were designed to distribute incoming light to three foci[5] improving intermediate vision and achieving higher spectacle independence.[6,7]

At the same time, in the last few years, "extended depth of focus" (EDoF) designs of IOLs are becoming more popular among surgeons. The EDoF theoretical concept of these IOLs is based on achieving good vision at different distances by means of appropriate interactions of higher-order spherical aberration and diffractive patterns that elongates the focal zone.[8-10] As it is commonly described by EDoF IOLs manufacturers, this optical approach intends to increase the depth of field of patients while the visual disturbances induced by classical diffractive or refractive multifocal designs (such as halos and/or glare) are minimized.

Still regarding spectacle independence, it should be taken into account that in the last two decades a massive amount of patients have undergone corneal refractive surgeries to eliminate myopia worldwide.[11,12] Obviously, if these patients were looking for spectacle independence for far distance, they will also look for being spectacle independence in near tasks. It is important to note that myopic corneal refractive surgery induces an increase of positive SA compared to patients with virgin corneas.[13-16] Then, given the mentioned global situation, it would be interesting to analyse how the current designs of IOLs perform with corneas with an increased amount of positive spherical aberration.

The current study assesses and compares the optical quality performance of a widespread implanted trifocal IOL and a novel EDoF IOL. At the same time, the optical performance of both IOLs with a simulated post-myopic LASIK cornea was analysed.

METHODS

Image quality metrics

The modulation transfer function (MTF) is a measure of the attenuation of each spatial frequency when light passes through a given optical system. Therefore, it offers a characterization of the image degradation caused by the optical system. Diffraction due to the aperture size and optical low and high optical aberrations of the optical system decrease MTF values. As a general rule, the higher the spatial frequency the larger the drop in contrast caused by the optical system**.** In addition, MTF measurements based on eye models are currently an international standard method to analyse the image quality through an IOL (or other optical systems such as contact lenses) and several investigations have followed this methodology.[17-22]

For the current work, the MTF was analysed for an aperture of 4.5mm. In order to assess the tolerance to defocus at the far distance focal point, data were recorded for three different focal points from the base power of the lens (+0.50 D, +0.0 D, -0.50 D). At the same time, to compare the MTF value of the IOLs we followed a previously described methodology[22-24] where the value of each MTF was considered as the average modulation value, which is the modulation averaged across all frequencies within the 0.0-to-100.0 cycles-per-millimetre range. The average modulation value is proportional to the area under the MTF curve between 0.0 cycles/mm and 120.0 cycles/mm.

Finally, through-focus MTF curves comprising 11 different focal points (steps of 0.5D) were calculated for 4.5mm and for a discrete spatial frequency of 50 cycles per millimetre.

This spatial frequency could approximately correspond to an optotype for 0.5 Snellen-equivalent VA in white light (30 cpd). The higher MTF value in the curve the better optical quality the lens has at this focal point.

Optical quality analysis

The image quality of the IOLs was performed with the PMTF optical bench (LAMBDA-X, Belgium) with Software version: 1.13.6. The device complies with International Standard Organization (ISO) 11979-2 and 11979-9 requirements; that is, it comes with additional lenses for an aberration-free model cornea. It allows MTF measurements at various frequencies and at different focal planes (through-focus). The experimental setup was assessed according to previous investigations in which other IOLs were analyzed by the same optical bench.[5,24,25] Similarly, before each measurement, the optical device was calibrated to guarantee the precision of the MTF values.

The optical quality assessment of a certain IOL is related to the ISO 11979-2, in which it is specified the use of a model eye including an aberration-free model cornea. At the same time, in order to simulate post-myopic LASIK procedures, the aberration-free model cornea was modified and an increment of +0.29 μm was introduced in the optical system. This positive increment of spherical aberration intends to simulate LASIK for low myopia.[26] In addition, pupil size modifies the optical performance of multifocal lenses and their depth of focus, the smaller the pupil size, the larger the depth of focus. In the present study, we have used a 4.5 mm pupil to be a good compromise between habitual pupil sizes and an attempt to evaluate as much optical surface of the IOL as possible.

Intraocular lens designs studied

The first lens to be assessed was the XACT Mono-EDoF ME4® (Santen Pharmaceutical, Japan). This is a hydrophobic lens with a C-loop platform that presents a biconvex design. The lens shows diffractive rings in the anterior surface and a posterior asphericity designed to induce a negative Zernike 4th order spherical aberration coefficient of -0.17 microns for a 6.0 mm pupil. The anterior surface shows 4 diffractive rings inside the 3.0mm of the optical zone diffracting light mainly toward far and intermediate foci. This EDoF lens has an overall diameter of 12.5mm and an optical zone of 6.0mm. The lens is available from +10.0D to +30.0D in 0.5D increments. The base power of the EDoF lens evaluated in the current study was 18.5 D. At the same time, it incorporates a UV and blue-light blocker.[27]

The other IOL analyzed was the FineVision IOL (PhysIOL; Liège, Belgium) in its hydrophilic version. This IOL has a trifocal design that has been properly described in previous investigations.[5,28-30] In summary, for obtaining three foci the lens combines two bifocal diffractive patterns for far/near and far/intermediate vision, respectively. The IOL presents two addition powers: +1.75D for intermediate and +3.50D for near vision. Moreover, this lens shows an apodized design in which the step height decreases toward the periphery with increasing amount of light directed to distance vision. The lens has a biconvex-aspheric optics that generate -0.11 microns of negative spherical aberration for a 6.0 mm pupil. The diameter of the lens is 10.75 mm and the optic zone's diameter is 6.15 mm. The optical power of the lens goes from +10.0 to +30.0D in steps of 0.50 D. As in the previous case, the base power of the trifocal lens was 18.5D. Finally, the FineVision IOL incorporates a UV and blue-light blocker.

RESULTS

Figure 1 illustrates the through-focus MTF curves for the EDoF (1.A) and the trifocal IOL (1.B), respectively, both without and with the positive increment of spherical aberration that simulates corneas with prior myopic LASIK. For the analysis of the IOL itself, the curves (black line) show the mean peak values of optical quality of both lenses, showing that the EDoF lens has two peaks with significant overlap and the trifocal lens has three peaks with less overlap (far, intermediate and near).

When the spherical aberration is introduced in the system (grey line of figure 1.A and 1.B) both lenses showed changes with respect to the case without induced spherical aberration. In this case the EDoF lens showed a -0.50D negative shift of the through-focus curve (grey line of figure 1.A). For the case of the trifocal IOL, also a negative shift of -0.50D and a drop in the three peak values is showed (grey line of figure 1.B).

In order to show the tolerance to defocus at the far distance focal point, figure 2 and figure 3 show the MTF curves of the EDoF and the trifocal IOL for the 0.00D, +0.50D and -0.50D focal points, respectively. At the same time, it is possible to see the results of both lenses in the two situations considered: without an increment of spherical aberration (left part of the figure - A) and with the increment of spherical aberration that simulates myopic LASIK ablations (right part of the figure - B). In each case, the figures show a dotted line that represent the far distance focus (0.0D) to better illustrate the optical quality of the lenses with a potential defocus of ±0.50D at far distance.

Finally, table 1 summarizes the average modulation values (which is proportional to the area under the MTF curve (the higher the area the better optical quality) between 0.0 cycles/mm and 120.0 cycles/mm) at these three focal points for both IOLs and for the situations previously mentioned.

DISCUSSION

In the present study, we assessed and compared the optical performance of the Physiol trifocal IOL and the novel XACT Mono-EDoF ME4 IOL in two situations: with and without a positive increment of spherical aberration that simulates a prior low-moderate myopic LASIK ablation.

Analizing the black line of figure 1A (analysis of the IOL itself), it is possible to observe that the EDoF IOL shows two peaks with significant overlap that elongate the far distance focus (0.0D vergence) to 1.5D of addition approximately. After the vergence of 1.5D, the optical quality of the EDoF lens decrease significantly which could be understood as an IOL with addition just for intermediate vision. This optical quality could be related to clinical outcomes that were observed in several studies with other EDoF IOLs.[9,10,31,32] However, no clinical studies have been performed with the IOL in our study and results should not be compared directly.

At the same time, the optical quality of the lens rapidly decreases toward positive vergences. Then, it could be suggested that a negative over-refraction after the surgery will be barely accepted for far distance. However, a slight negative over-refraction could improve somehow the near vision in patients with EDoF IOLs such the one analyzed in this study. Then, a combination of emmetropia in one eye and a slight myopia in the counterpart, previously called as mini-monovision, could offer higher addition ranges without a significant deterioration of distance vision under binocular conditions.[33]

On the other hand, the grey line of figure 1 A, which simulates post-LASIK corneal profiles, shows an overall negative shift of -0.50D of whole trough-focus curve and the elongated distance focus performs 1D of addition. Nonetheless, the profile of through-focus curve in this case showed to be quite similar to the case of the IOL without increment of spherical aberration (black line). Then, it could be suggested that the combination of aberrations (IOL + increased corneal spherical aberration) did not dramatically modified the optical performance at far and intermediate distance EDoF lens besides the slight increment of optical power and the consequent displacement of all distances of vision. Related to the myopic shift, there is a previous work in which the clinical outcomes of patients with presbyopia correcting IOLs after myopic LASIK were analyzed.[34] In that study, the authors found that the manifest refraction of these patients after the surgery showed a spherical equivalent of -0.6 D. It means that the effective power of the IOLs was ≈0.5D more positive and this totally agree with the results of our study. In other words, in order to reach an effective emmetropia for these patients, the calculated power of the IOL should be less positive (-0.50D).

The through-focus curve of the trifocal IOL is showed in figure 1.B (bottom of the figure). As in the previous case, the black line of the figure corresponds to the optical performance of the IOL without the increment of positive spherical aberration. It reveals three peaks corresponding to far, intermediate and near focal points. These results have been reported in previous investigations that analysed the optical quality of this IOL.[5,28-30,35] At the same time, several clinical studies that assessed the visual performance of this IOL demonstrated that these focal points correspond to three zones with improved visual quality.[30,36] It should be mentioned that the trifocal IOL showed a significant better optical quality for the far distance focal point if compared to the EDoF IOL. However, the trifocal IOL decreases its optical quality rapidly out of the far foci while the EDoF IOL remains more stable. As it will be discussed below, it could be suggested that for achieving the best optical performance the IOL power calculation is more critical for trifocal IOLs.

As in the previous case, the grey line shows the through-focus curves of the IOL with the mentioned amount of spherical aberration. In this case, the curve of the trifocal IOL also showed an overall negative shift of -0.50D. These results follow the trend shown in the case of the EDoF IOL. Therefore, it should also be considered that post-myopic LASIK patients with this IOL could show a slight myopic refraction that should be compensated with less positive IOL power. [34] Finally, instead of the presence of the three peaks, which means that patients could achieve the aimed trifocality (far, intermediate, and near), the optical quality of the far distance peak is attenuated in comparison to a cornea without previous myopic ablation.

Moreover, positive or negative over-refractions after cataract surgery have important clinical implications for surgeons because they can deteriorate the distance vision and/or modify the distance at which near activities have to be performed by patients. This situation has clinical implications even for monofocal IOLs, but it is crucial for multifocal lenses. Hence, in order to assess the impact of a small amount of residual refractive error on the optical behavior at far distance of these IOLs, we have analyzed its tolerance to defocus by means of analyzing the MTF curves at 0.0 D, +0.50 D and -0.50 D.

For the case of the EDoF without increased spherical aberration (figure 2 A and table 1), the MTF showed to be better for the far distance focus, being the +0.5D focus the one that showed the worst optical quality. Despite a certain tolerance to hyperopic and myopic shifts, surgeons should achieve emmetropia in patients with normal corneas to obtain the better performance in distance vision. The simulation of prior low myopic LASIK ablation (figure 2B and table 1) showed a significant change in these values and it is possible to see that the better optical quality in this case is achieved for -0.50D, then leading to a myopic residual refraction and to a worsening at far distance focus. These results agree with the results presented in the through-focus curves. Therefore, surgeons should compensate this situation in patients with prior myopic ablations in order to achieve satisfactory far vision results. In addition, it should be mentioned that calculating IOL powers for patients with previous corneal ablations is challenging[37] and this issue should be accurately addressed if emmetropia want to be achieved.

Similarly, the trifocal IOL showed a significantly better MTF value for 0.0D focal point when a normal cornea is considered (figure 3A and table 1). Due to the steep change in the optical quality induced by $\pm$ 0.5D of defocus, surgeons should achieve emmetropia with high rates of accuracy for these patients in order to obtain satisfactory results in far vision. As previously explained, it seems that an accurate IOL power calculation is more important for trifocal than EDoF IOLs. On the other hand, the myopic LASIK ablation situation (figure 3B and table 1) showed a change in the order to the optical quality. In this case, better optical quality is achieved with -0.50D and it should be also taken into consideration at the moment of calculating the IOL power. However, it is interesting to note the differences regarding the tolerance to defocus between the situation of with and without increase of spherical aberration. The first difference is that the impact of a small residual refractive error on the optical quality was lower for the increased spherical aberration situation. The second one is that for the situation of corneas with a significant increase of positive spherical aberration, the IOL power calculation should target a less positive IOL power, whereas the target in the situation with a normal cornea should be emmetropia.

It should be considered that all the measurements of the present study were made through centered positions of the IOLs and it may do not represent all possible real world scenarios. In future studies the scope of the study should be extended to account for misalignments between cornea and the actual placement of the IOL.

In conclusion, the results of the present study show that the trifocal IOL provided three clearly differentiated peaks of vision with a high optical quality for the far distance focal point. Meanwhile, the EDoF IOL showed two peaks with significant overlap that reached an acceptable optical quality from far distance to intermediate. When myopic LASIK ablations were simulated, the EDoF IOL showed to be more robust than the trifocal IOL. Finally, the negative shift in the optical performance of both IOLs suggest that IOL calculations for patients with previous myopic ablations should consider less positive IOL powers in order to reach an effective emmetropia.

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