

1 INTRODUCTION

2 Today, trifocal intraocular lenses (IOL) are becoming more popular among surgeons
3 who intend to provide spectacle independence ^{1,2}. Through the creation of three foci ³, these
4 designs have overcome the main limitation of bifocal IOLs, which is the gap between the
5 optical quality peaks for near and far vision. As a result of this gap, the optical quality
6 provided by bifocal IOLs for intermediate vision is low ^{4,5}.

7 Extended depth of focus (EDoF) IOL designs have also appeared on the market
8 recently as an alternative to bifocal IOLs. The EDoF theoretical principle is to increase the
9 depth of focus of the distance vision focal point by optimizing the interactions between
10 higher-order spherical aberration and diffractive patterns^{6,7,8,9}. Therefore reducing the gap
11 between the peak performance for far and near. Despite a lower addition power, some
12 studies have reported less photic phenomena when compared to classical diffractive or
13 refractive bifocal and trifocal IOLs ^{10,11}.

14 The great majority of current multifocal IOLs include aspheric designs attempting to
15 neutralize the positive asphericity of the cornea. Conversely, myopic corneal refractive
16 surgeries induce positive values of spherical aberration on the corneal surface ¹²⁻¹⁴. Therefore,
17 it would be of great clinical interest - a huge number of patients have undergone myopic
18 corneal refractive surgeries in the last decades last few decades worldwide - to know how the
19 asphericity of multifocal designs interacts with the described changes on corneal asphericity.

20 In addition, it is well known that visual axis misalignments after IOL implantation
21 have an impact on the final visual quality of the patients ¹⁵. Also, it has been shown that the
22 eye's aberrations can interact with the optical design of the lens and produce both positive
23 and negative synergies ^{16,17}. Therefore, the presence of tilt and decentration after IOL
24 implantation is of utmost importance when evaluating the final optical quality provided by an
25 IOL. The aim of the present study is to analyze and compare the optical performance of both

26 a trifocal and novel EDoF IOL designs as a function of varying levels of tilt and decentration
27 in eyes with a previous corneal myopic procedure. For the purpose of this study, we have
28 chosen an optical bench to represent the above-mentioned conditions with a non-invasive and
29 reproducible technique ¹⁸.

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METHODS

Intraocular lenses analyzed

The novel lens considered for the study was the hydrophilic XACT Mono-EDoF ME4® (Santen Pharmaceutical, Japan). This is a biconvex design with a C-loop platform. 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 diffractive rings are placed in the central 3.0mm of the optical zone diffracting light toward far and intermediate foci (from 1.0D to 1.9D of addition power). The overall diameter of the lens and optical zone are 12.5mm and 6.0mm, respectively. The base power of the EDoF lens evaluated in the current study was 18.5D. At the same time, it incorporates a UV and blue-light blocker.¹⁹

The trifocal IOL analyzed was the hydrophilic version of the FineVision IOL (PhysIOL; Liège, Belgium). This IOL presents an apodized diffractive trifocal design that combines two bifocal diffractive patterns for far/near and far/intermediate vision, respectively.^{3,20,21,22} The IOL presents intermediate near additions of +1.75D and +3.50D, respectively. The lens has a biconvex-aspheric optics with a posterior asphericity of -0.11 μm 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 base power of the trifocal lens analyzed in the study was also 18.5D. The FineVision IOL incorporates a UV and blue-light blocker.

Analysis of the optical quality

The image quality of the IOLs was assessed 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 and it comes with additional lenses for an aberration-free model cornea. It allows modulation transfer

function (MTF) measurements at various frequencies and at different focal planes (through-focus). The experimental setup was assessed according to previous investigations^{3,23,24}. Before each measurement, the optical device was calibrated to guarantee the precision of the MTF values.

In order to simulate post-myopic corneal procedures, the aberration-free cornea model was modified and an increment of +0.29 μm for 4.5mm of pupil aperture was introduced in the optical system. This positive increment of spherical aberration intends to simulate low-moderate myopic ablations²⁵.

At the same time, both lenses with and without an increment of positive spherical aberration were analyzed for three positions: 1. Centered (reference measurement); 2. With 0.4 mm of vertical decentration; 3. With 4 degrees of tilt.

Image quality metrics

Through-focus modulation transfer function (MTF) curves comprising 11 different focal points (steps of 0.5D) were calculated for a discrete spatial frequency of 50 cycles per millimeter^{3,23,24}. This spatial frequency could approximately correspond to an optotype for 0.5 Snellen-equivalent visual acuity (VA) in white light (30 cpd). The higher MTF value in the curve, the better optical quality the lens has at this focal point.

RESULTS

Figure 1 and figure 2 present the through-focus MTF of the EDoF IOL and the trifocal IOL, respectively. In both images, the blue line presents the curve for the centered situation, while the green line and the red line present the optical performance of the IOL through 0.4mm of decentration and 4 degrees of tilt, respectively.

Figure 1.A illustrates the through-focus MTF curves for the EDoF itself and 1.B shows the through-focus MTF curves with the positive increment of spherical aberration that simulates corneas with prior low-moderate myopic treatments. For the EDoF IOL itself (1.A), the curve shows two peaks at 0.0D (distant) and around -1.00D/-1.50D of object vergence (intermediate) with significant overlap between them. When decentration (green line) or tilt (red line) were induced, the far vision peak was shown to perform better for -0.5D of vergence and both peaks showed to be less overlapped.

When positive spherical aberration was induced (1.B) the centered EDoF lens showed a -0.50D negative shift of the whole through-focus curve (blue line). For this centered situation, there is a drop of the intermediate peak and the overall curve shows only an elongated far distance peak. For the decentered situation, both far and intermediate peaks are differentiated, and the curve shows an overall negative shift of -1.0D. For the tilted situation, both peaks are also differentiated, and the through-focus curve showed a significant negative shift of -1.5D. In fact, the far distance peak is placed at the intermediate focal point and the intermediate peak is placed at a near focal point.

Figure 2.A. shows the results of the trifocal IOL itself and the through-focus curves show three differentiated peaks for far, intermediate and near vision. When decentration (green line) or tilt (red line) were induced, the trifocal IOL showed similar results if

compared to the centered position (blue line). Therefore, the trifocal IOL standing alone showed a noticeable tolerance to misalignments.

Figure 2.B. illustrates the curves for the trifocal IOL with the positive increment of spherical aberration. In general, with the spherical aberration increment, the IOL maintained the three differentiated peaks of vision but the optical quality of the far distance peak decreased if compared to the IOL standing alone (figure 2.A). For the centered position (blue line), the spherical aberration increment induced a -0.50D negative shift of the curve. When the lens was decentered (green line) and tilted (red line), the curves showed a negative shift of -1.0D and both intermediate and near peaks were placed in nearer object vergences that correspond to shorter distances of vision.

DISCUSSION

Millions of patients have undergone corneal refractive surgeries in the last decades and it is of interest to analyze how these patients will perform with current multifocal designs. Considering that clinical studies are not able to analyze different situations in the same eye once the lens is implanted, in the present study we objectively analyzed the optical performance of a trifocal and a novel EDoF design with an optical bench. For a more complete analysis, the lenses were analyzed standing alone and with a certain amount of positive spherical aberration that intended to simulate prior corneal myopic ablations. Potential misalignments after IOL implantation were analyzed and compared to a control situation, that is, for a visual axis centered position.

The results of the EDoF IOL (figure 1) were divided in the analysis of the lens itself (1.A) and the lens with a certain amount of positive spherical aberration (1.B). The results of the lens itself in a centered position showed two overlapped peaks at distance and intermediate vision. The intermediate peak was placed between -1.0 and -1.5D of object vergence. Beyond the intermediate peak, optical quality decreased steeply. As in previous studies that analyzed similar EDoF designs, this EDoF lens actually performed a bifocal design with an intermediate addition power^{26,27}.

When the EDoF lens was decentered and tilted, it performed better at an object vergence of -0.50D and both peaks were not overlapped such as in the centered position. Despite this gap, the EDoF still performs a theoretical addition of around 1.5D. Then, when decentered or tilted, the EDoF IOL maintained an intermediate peak of vision but performed better at an object vergence of -0.50. This could decrease the optical quality at distance vision and provide an intermediate peak of vision actually performing at nearer distances.

With a certain amount of spherical aberration (1.B), the centered EDoF lens IOL was shown to perform better at -0.50D and maintained its optical quality for the far distance peak.

However, there is a slight drop of the intermediate distance peak that reduce the addition to $\approx 1.0\text{D}$. When decentration (green line) and tilt (red line) were induced, the shape of the curves changed but maintained far and intermediate peaks of vision. For the decentered situation, the peaks showed an overall negative shift of $\approx -1.0\text{D}$. For the tilted situation, the through-focus curve showed an even higher negative shift. In fact, for this situation, the distance vision peak is placed at an intermediate object vergence and the intermediate vision peak is placed at the near object vergence. This situation would improve intermediate and near vision, but the degradation of the distance peak would be considerable.

Then, summarizing the results of the EDoF IOL curves, they suggest that this IOL shows a certain tolerance to misalignments in terms of optical quality because they do not significantly affect the optical quality of far and intermediate peaks and the distances between them. However, the correct positioning of the lens is important because some degree of tilt and decentration may induce a negative shift in the overall through-focus curve of the lens. In addition, when a positive amount of spherical aberration is added to the IOL system, there is a myopic shift of the curve, but the lens maintains the optical quality. This suggests that for cases with a positive increment of spherical aberration (post-myopic ablations), a less positive IOL should be calculated in order to compensate for this myopization^{28,29}. At the same time, if some amount of positive spherical aberration is induced and the lens is tilted or decentered, these misalignments induce a stronger negative shift that could decrease the visual quality of the patients significantly. Then, it is always important to achieve a proper positioning of the IOL, but in cases of patients with higher amounts of positive spherical aberration this alignment seems to be more important. Related to these results, previous studies have also reported that the combination cornea-IOL aberrations could reduce the optical properties of aspheric IOLs if the cornea-IOL system is misaligned³⁰ and that these

misalignments could have a higher impact on eyes with previous myopic corneal refractive surgeries³¹.

Analyzing the through-focus curves of the trifocal IOL standing alone (without induced positive spherical aberration) (figure 2.A), it is possible to observe that the lens performs the classical three peaks of vision that correspond to the addition powers mentioned in the methods section. These peaks have been reported in previous investigations and are related to good visual quality results at far, intermediate and near distances³². The through-focus curves, when decentration and tilt are induced, show that the lens is highly robust to these misalignments, achieving similar results compared to the control situation and better results if compared to the EDoF IOL. The fact that the trifocal IOL is more robust to tilt and decentration than the EDoF lens could be due to the trifocal IOL presenting a lower amount of negative spherical aberration. As was suggested in a previous study, this lower amount of negative spherical aberration would compensate less positive corneal spherical aberration, but it could make the IOL more tolerant to misalignments³³.

When a positive amount of spherical aberration was induced in order to simulate a previous myopic ablation (figure 2.B – blue line), the overall curve maintained the three peaks of vision but showed a myopic shift of -0.50D. These results are similar to those obtained for the EDoF IOL and agree with other authors who analyzed patients with previous myopic corneal refractive surgeries that were implanted with multifocal IOLs²⁸. These results suggest a less positive IOL calculation to compensate for the myopic shift induced under these conditions. Besides, the far distance peak was shown to be attenuated if compared to the situation without induced spherical aberration. On the other hand, when the lens was decentered and tilted, the through-focus curves also showed the three peaks but an overall negative shift of $\approx -1.0\text{D}$. Therefore, despite the fact that the lens can offer three peaks of vision, if it is misaligned, the overall dioptric change suggests that a proper alignment is

strongly recommended for patients with previous myopic corneal refractive surgeries. As in the case of the EDoF lens, the results also suggest that misaligned aspheric trifocal IOLs combined with significant increments of positive spherical aberration induce a noticeable worsening of the optical quality of the cornea-IOL system.

Then, in terms of optical quality tolerance, the EDoF lens was shown to be more robust to positive spherical aberration increments. However, if the lens is misaligned, it undergoes refractive changes (myopic shift) that are higher with previous corneal myopic procedures. Conversely, the trifocal IOL was shown to be robust to misalignments when the lens was analyzed standing alone and the optical quality at the far distance peak was shown to be significantly better if compared to the EDoF lens. Nevertheless, when a positive amount of spherical aberration is induced, the far distance peak decreased remarkably. As with the EDoF lens, the overall curve showed a myopic shift of -0.50D. The actual clinical impact of a -0.50D refractive shift should be determined in future studies, however, it could be suggested that the higher refractive shift induced by misalignments would significantly impair the visual quality of patients implanted with these lenses. In general, the induced amounts of tilt and decentration showed a similar impact on the optical quality of both lenses (excepting the trifocal IOL standing alone). It would be also interesting to analyze whether a combination of both situations (decentration and tilt) may have a proportional impact (or not) on the optical quality of the lenses.

As far as the authors know, this is the first time that these situations are induced and analyzed by an objective method for these two multifocal IOLs. Therefore, future studies should address and correlate the clinical impact of the results obtained in this study. At the same time, it should be interesting to perform future similar studies with different amounts of spherical aberration in order to analyze these combinations and the impact on the optical

quality of multifocal IOLs. With the same objective, simulating corneal ablations of different sign (i.e., previous hyperopic corneal refractive surgeries) will be also valuable.

In conclusion, the optical quality provided by the trifocal IOL was more stable under the presence of decentration and tilt than the one provided by the EDoF IOL. The changes in optical quality induced by the presence of tilt and decentration (for both lenses) were higher when a significant amount of positive spherical aberration was present. Surgeons should always aim for very good visual axis centration of the IOL and to minimize lens tilt in all procedures but more even so in cases with patients who have undergone a previous corneal myopic procedure that wish to be implanted with a trifocal IOL design.

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FIGURE LEGENDS

Figure 1. Through-focus MTF curves for centered, decentered and tilted situations of the XACT Mono-EDoF ME4 intraocular lens itself (A) and when a positive amount of spherical aberration was induced (B). The curves were calculated for a spatial frequency of 50 cycles per millimeter (cycles/mm).

Figure 2. Through-focus MTF curves for centered, decentered and tilted situations of the trifocal FineVision intraocular lens itself (A) and when a positive amount of spherical aberration was induced (B). The curves were calculated for a spatial frequency of 50 cycles per millimeter (cycles/mm).