Clinical Ophthalmology

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ORIGINAL RESEARCH

Objective Depth-of-Focus Estimation from Wavefront Measurements After Implantation of an Isofocal Intraocular Lens

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Purpose: To assess the objective depth-of-focus after implantation of isofocal intraocular lens (IOL) during cataract surgery based on VSOTF using ray tracing aberrometry.

Methods: In this prospective study, 40 eyes were implanted with the isofocal Isopure IOL (Beaver-Visitec International, Inc. [BVI], Waltham, USA). The patient assessments considered: refraction (sphere, cylinder and axis), uncorrected-distance visual acuity (UDVA), corrected-distance visual acuity (CDVA), uncorrected intermediate visual acuity (UIVA, at 60 and 80 cm), distance-corrected and uncorrected near visual acuity (DCNVA and UNVA), wavefront aberrations and objective depth-of-focus using ray-tracing optical technology from several percentages of degradation on the visual Strehl ratio based on the optical transfer function (VSOTF, 90%, 80% and 60%). Patients were assessed at 3 months post-surgery.

Results: Eyes implanted with the isofocal IOL showed good outcomes in terms of refraction and visual acuity at the last follow-up visit. Specifically, half a dioptre was obtained for the spherical equivalent and about 20/20 for CDVA, about 20/25 for UIVA at 80 cm, about 20/30 for UIVA at 60 cm, and about 20/25 for DCNVA. In relation to the objective depth-of-focus computed from the wavefront analysis in our cohort, we obtained mean values of 2.12 D, 3.16 D and 4.94 D at 90%, 80% and 60% of degradation, respectively.

Conclusion: Our study shows that the isofocal IOL provides high values of objective depth-of-focus based on the VSOTF using ray tracing optical technology when implanted after cataract surgery.

Keywords: intraocular lens, cataract, depth-of-focus, optical quality, wavefront aberrations

Introduction

A systematic review and meta-analysis based on 28 randomised controlled trials with 2465 subjects, have analysed the efficacy and safety of different intraocular lenses (IOLs), considering monofocal, bifocal, trifocal, extended depth-of-focus (EDOF) and enhanced monofocal IOLs.[1] This study indicates that binocular implantation of trifocal IOLs can give higher spectacle independence and good vision at intermediate and near distance, but needs to overcome the decrease of optical quality. This also reflects that EDOF and enhanced monofocal IOLs are also good choices if there are more activities at intermediate distances. EDOF IOLs have improved the visual performance at intermediate distances, while reduced some photic phenomena reported by multifocal IOLs.[2]

The isofocal (Isopure 1.2.3). IOL (Beaver-Visitec International, Inc. [BVI], Waltham, USA) is an aspherical lens designed to improve intermediate vision without diminishing high-quality distance vision.[3] A recent review of literature of articles published with this IOL concluded that this lens provides excellent visual performance for far vision and functional intermediate vision with an increased range of vision with few photic phenomena.[4] The author considered this IOL to be an effective option for providing functional intermediate vision and correcting aphakia. Laboratory studies, using several metrics,[5–8] have analysed this IOL and some reported that the IOL optical performance at –1 D was better

Received: 25 April 2025
Accepted: 27 August 2025
Published: 4 September 2025

than that of a monofocal IOL,[5] while others concluded that it shows a good balance between depth-of-focus (about 1.50 D) and optical quality under different conditions.[8] The in vivo wavefront aberrations were measured in several studies[9–11] showing that the optical aberrations were similar to those found in monofocal IOLs. The standard clinical measurement of the depth-of-focus is based on the defocus curve, which is a subjective assessment. It is also possible to obtain an objective measurement of the depth-of-focus based on a wavefront analysis, which calculates the dioptric range for which the image quality does not change appreciably.[12–14] A percentage of degradation on the visual Strehl ratio based on the optical transfer function (VSOTF) has been proposed as an objective depth-of-focus measurement.[12] Some publications have measured this metric using the ray tracing aberrometer (iTrace, Tracey Technologies, Houston, USA) on monofocal and presbyopia-correcting IOLs.[15–17] However, to the best of our knowledge, no studies have assessed the objective depth-of-focus of eyes implanted with the isofocal IOL.

Therefore, the main purpose of the present clinical study was to assess the objective depth-of-focus based on the VSOTF using ray tracing optical technology after implantation of the isofocal IOL after cataract surgery.

Methods

Patients, Surgery and Intraocular Lens

This was a single-centre, prospective, observational study conducted at the Dar El Oyoun specialized Eye Hospital (Cairo, Egypt). The study protocol was reviewed and approved by the Institutional Review Board following the tenets of the Declaration of Helsinki. All patients provided written informed consent. The inclusion criteria were patients submitted to cataract surgery using the Centurion Vision Gold with Active Sentry (Alcon Labs, Fort Wort, TX, USA) receiving the isofocal IOL implant. The exclusion criteria considered any retinal pathology, hyperprolate corneas with negative spherical aberration, any corneal opacity and corneal astigmatism more than 2 D.

The isofocal lens is a glistening-free IOL made of hydrophobic material (refractive index of 1.52). It has an ultraviolet and blue light filter and a 4-closed-loop haptics platform. The overall diameter of the IOL is 11.0 and the optical zone is 6 mm. The lens is based on an isofocal concept that extends the depth-of-focus compared to monofocal IOLs. The IOL power ranged from +10.00 to +30.00 D (0.50 D steps for preloaded systems) and from +31.00 to +35.00 D (1.00 D steps for non-preloaded systems). All the surgical procedures were performed by two expert surgeons (MH and MA), with the isofocal IOL being implanted in the capsular bag. Both did the same standard technique in all cases, which was a stop and chop phacoemulsification using only tortional phaco power and no longitudinal power. All cases had a 2.4 mm incision at 110 degrees and two 1.0 mm paracentesis at 3 and 9 o'clock for bimanual irrigation aspiration. All IOLs were implanted using the same disposable Lens injecting system by Medicel.

Outcome Measures

Preoperatively, optical biometry using the Haag Streit Lenstar 900 (Haag Streit, Köniz, Switzerland) was conducted to obtain the main parameters to calculate the IOL power. We used the Barrett True K formula, and emmetropia was the refractive target in all cases. Postoperatively, refraction (sphere, cylinder and axis), Snellen decimal uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected intermediate visual acuity (UIVA, 80 and 60 cm), uncorrected near visual acuity (UNVA, 40 cm), and distance corrected near visual acuity (DCNVA, 40 cm). We also recorded the optical quality of each eye using ray tracing aberrometer (Tracey Technologies, Houston, USA) for a 3-mm pupil diameter. Specifically, higher-order aberrations and spherical aberration, and depth-of-focus from several percentages of the VSOTF (90%, 80% and 60%). All the variables were represented by their mean, standard deviation, and range. The information recorded from all the subjects was registered into an Excel spreadsheet (Microsoft Corporation, Redmond, USA) to provide mean, standard deviation and ranges for all the variables studied.

Results

In the present study, a total of 40 eyes from 28 consecutive patients who were implanted with the isofocal IOL were included. The demographic characteristics of the patients recruited are presented in Table 1. The mean age of the patients was 68.70±8.04 years, with a range from 50 to 89 years. The mean spherical IOL power of the isofocal IOL implanted

Table 1 Demographic Characteristics of Participants Shown as Means, Standard Deviations (SD) and Ranges

	Isopure 1.2.3 IOL
Patients (n)	28
Eyes (n)	40
Age (y)	68.70±8.04 (50 to 89)
K1 (D)	43.39±1.41 (41.17 to 48.13)
K2 (D)	44.27±1.59 (42.25 to 49.25)
Axial length (mm)	23.78±1.08 (22.22 to 27.17)
IOL power (D)	20.77±3.06 (12.50 to 25.50)

Abbreviations: K, keratometry; IOL, intraocular lens.

was 22.77±3.06 D, with a range from 12.50 to 25.50 D. All the surgeries were successfully performed with no adverse events recorded during the procedure or up the 3 months follow-up period after the surgery.

Figure 1 illustrates an example of the report provided by the ray tracing device for the depth-of-focus considering the VSOTF metric for an eye of the cohort of patients implanted with the isofocal IOL. It shows the percentage of degradation on the VSOTF versus the through-focus. For a specific percentage value, a depth-of-focus is obtained, with lower percentages being a more permissive criterion of image degradation that provides higher depth-of-focus values (ie it is expected that 60% will provide a higher depth-of-focus value than a 90%). Mean values for the VSOTF at 90%, 80% and 60% are shown in Table 2. Note that, as indicated previously, higher (better) depth-of-focus values are found for lower percentages. In our case, it was 2.12 D, 3.16 D and 4.94 D at 90%, 80% and 60%, respectively. As mentioned earlier in the methods section, wavefront aberrations were also measured in our patients' post-isofocal IOL

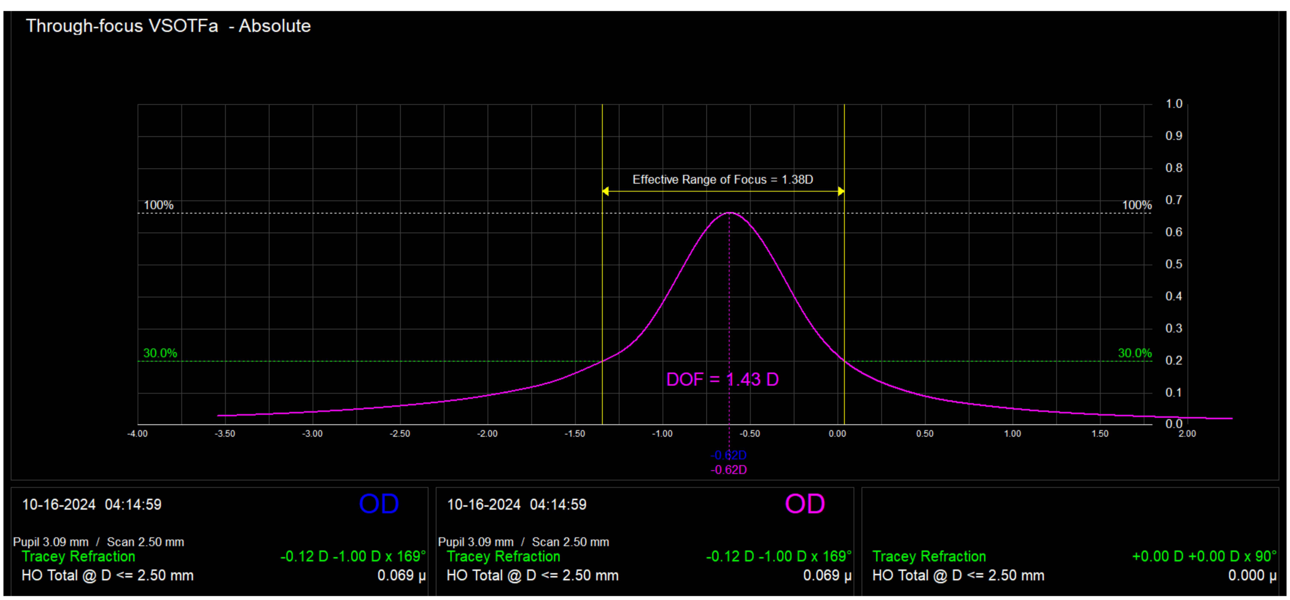

Figure 1 Report provided by the ray tracing device for the depth-of-focus (DOF) measurement in a pseudophakic eyes implanted with the isofocal intraocular lens, taking into account the degradation on the Visual Strehl ratio based on the optical transfer function (VSOTF) metric.

 https://doi.org/10.2147/OPTH.S536795

Table 2 Postoperative Wavefront Aberration and Depth-of-Focus (DOF) from the Visual Strehl Ratio of Optical Transfer Function (VSOTF) Shown as Means, Standard Deviations and Ranges

	Isopure 1.2.3 IOL
Higher order aberrations (microns)	0.10±0.09 (0.04 to 0.54)
Spherical aberration (microns)	0.02±0.02 (0.00 to 0.09)
DOF from VSOFT 90% (diopters)	2.12±0.39 (1.50 to 3.00)
DOF from VSOFT 80% (diopters)	3.16±0.68 (1.87 to 5.20)
DOF from VSOFT 60% (diopters)	4.94±1.26 (1.87 to 8.00)

implantation. Table 2 provides the postoperative mean, standard deviation, and range of the higher-order aberrations and the spherical aberration.

Refractive outcomes and visual acuity results were also recorded in our cohort at the 3-months postoperative visit. Specifically, the mean postoperative spherical equivalent was –0.50±0.52 D and the mean postoperative refractive cylinder was –0.50±0.30 D. The mean monocular Snellen decimal UDVA and CDVA values after surgery were 0.78 ±0.14 (ranging from 0.60 to 1.0) and 0.95±0.10 (ranging from 0.80 to 1.20), respectively. At intermediate vision, the mean UIVA at 80 and 60 cm was 0.85±0.13 (ranging from 0.50 to 1.0) and 0.69±0.13 (ranging from 0.50 to 1.0), respectively. At near vision, the mean UNVA and DCNVA was 0.56±0.14 (ranging from 0.20 to 0.80) and 0.83±0.11 (ranging from 0.50 to 1.0), respectively.

Discussion

The use of wavefront aberrometry allows us to know the optical quality in vivo of a pseudophakic eye, and, in addition, to estimate the objective depth-of-focus. This value is based on the VSOTF that depends on the optical quality image analysed and the percentage or level of degradation accepted in the measurement process. The main purpose of our study was to obtain objective depth-of-focus values based on the VSOTF from eyes implanted with the isofocal IOL using the ray tracing device. This is, to our knowledge, the first study analysing this metric on this IOL model. Our values were about 2 D, 3 D and 5 D at 90%, 80% and 60%, respectively (see Table 2 for detailed values). Different clinical studies have used objective depth-of-focus values using this instrument. It implemented the assessment of the VSOTF using its software and provided the through-focus VSOTF curve for different levels of degradation. In our study, as indicated, we have used three levels of degradation. Unfortunately, there are no studies measuring objective depth-of-focus in the isofocal IOL for a direct comparison. However, recent studies have used this instrument and different levels of degradation to measure objective depth-of-focus in other IOLs available in the market.

For example, Palomino-Bautista et al[15] measured the depth-of-focus with VSOTF at 90% in 100 eyes after cataract surgery with six groups of IOLs: Tecnis ZMB and ZLB bifocal designs (Abbott Laboratories, Illinois, USA), FineVision (Beaver-Visitec International, Inc. [BVI], Waltham, USA), AT LISA Tri (Carl Zeiss Meditec., Jena, Germany) trifocal designs, Symfony (Abbott Laboratories, Illinois, USA) and MiniWell (SIFI MedTech, Catania, Italy) EDOF designs. They used the ray tracing device under scotopic conditions with all participants having a pupil size of more than 3 mm. These authors found that in depth-of-focus measures for 90% threshold level, no statistically significant differences were found for the following comparisons: ZMB vs ZLB (p=0.045), ZMB vs FineVision (p=0.210), ZMB vs AT LISA TRI (p=0.999), ZMB vs MiniWell (p=0.780), ZLB vs AT LISA TRI (p=0.825), ZLB vs MiniWell (p=0.675) and AT LISA TRI vs MiniWell (p=0.999). In contrast, statistically significant differences were found for ZLB vs FineVision (p<0.001), FineVision vs AT LISA TRI (p=0.030) and FineVision vs MiniWell (p=0.030). They found that the Symfony IOL showed better depth-of-focus than the other lenses, with statistically significant differences (p<0.001). Specifically, the mean values were: 0.33, 0.40, 0.28, 0.35, 0.49, 0.35 for ZMB, ZLB, FineVision, AT LISA TRI, Symfony and MiniWell, respectively. In this study, the authors also compared the subjective depth-of-focus measured with defocus curves and concluded that objective and subjective measures of depth-of-focus were not comparable due to differences in methodologies and criterions to define the level of degradation acceptance. The same authors, in another study,[16] measured 150 eyes, classified in a further six groups depending on the IOL implanted: AT LISA TRI, FineVision, PanOptix (Alcon Laboratories, Fort Wort, TX, USA), Symfony, MiniWell and Synergy (Johnson & Johnson Vision). They measured the VSOTF with a percentage of degradation of 90%, 80% and 60% to quantify the depth-of-focus objectively. In this cohort, aberrometry was performed under scotopic conditions with a scan size of 3.5 mm in all patients, and none of the subjects had a pupil size under this value. They found, for the 90% level, no statistically significant differences for the following comparisons: AT LISA tri vs FineVision (p=0.999), AT LISA tri vs MiniWell (p=0.075), FineVision vs MiniWell (p=0.075), PanOptix vs Synergy (p=0.999), and Symfony vs Synergy (p=0.150). For the 80% level, no statistically significant differences were found for: AT LISA tri vs FineVision (p=0.090), PanOptix vs Symfony (p=0.060), PanOptix vs Synergy (p=0.999), and Symfony vs Synergy (p=0.075). And, finally, for the 60% level, statistically significant differences were found for all comparisons except for PanOptix vs Synergy (p=0.999). The values obtained in this study were for the AT LISA TRI 0.31, 0.51 and 0.72 for 90%, 80% and 60%, respectively. These values changed to 0.30, 0.54 and 0.76 respectively for the FineVision IOL, to 0.43, 0.83 and 1.56 respectively for the PanOptix IOL, to 0.50, 0.80 and 1.17 respectively for the Symfony IOL, to 0.45, 0.83 and 1.53 respectively for the Synergy IOL, and to 0.34, 0.71 and 1.01 respectively for the MiniWell IOL. Comparing lenses, this study indicated that the depth-of-focus achievable with the IOL designs studied did not totally depend on the IOL type (ie, trifocal, EDOF or Synergy), since individual differences were also found between the different IOLs assessed. They indicated that similar depth-of-focus values were found in both studies, for example for the FineVision IOL (0.29 vs 0.30 D), for the AT LISA TRI IOL (0.36 vs 0.31 D), for the Symfony IOL (0.50 vs 0.50 D) and for the MiniWell IOL (0.36 vs 0.34 D). As expected according to a previous study,[17] a more permissive criterion (different percentage value) provides a higher tolerance and, therefore, a higher depth-of-focus for all IOLs. These authors also compared the subjective depth-of-focus obtained from the defocus curves and found that subjective measures were significantly higher in all IOL groups (p<0.001). They considered that both measures of depth-of-focus (subjective vs objective) were not comparable due to differences in methodologies and criteria to define the level of degradation tolerance. Authors finally concluded that both objective and subjective measures showed a trend to a higher depth-of-focus for Symfony and Synergy IOLs compared to most trifocal diffractive designs, with the exception of the PanOptix IOL. The values obtained in our cohort were higher than those reported by these authors, and this may be related to the different design of the IOLs, different corneal aberrations and the different pupil size of the patients recruited in each study.

Nanavaty et al[18] in a cross-sectional study with 42 eyes implanted with the Eyhance (Johnson & Johnson Vision) and Rayone (Rayner) obtained the VSOTF for 20%, 25%, 30%, 50% and 60%. The mean values obtained were 3.29, 2.91, 2.50, 1.64 and 1.29 for the Eyhance IOL, and 2.09, 2.42, 2.24, 2.04, 1.39 and 1.23 for the Rayner IOL, for 20%, 25%, 30%, 50% and 60%, respectively. This study also examined the correlation between clinical (subjective) and objective depth-of-focus at various VSOTF degradation percentages, allocating the 25% to 30% threshold as the most accurate measurement (they named it the "Nanavaty Threshold"). These authors suggest that this threshold should be used in studies to interpret VSOTF degradation values obtained by the ray tracing aberrometer, being equivalent to subjective depth-of-focus values derived from defocus curves (irrespective of the IOL's optical properties). In another study, Yi et al[12] analysed the relationship between subjective and objective measures through two threshold levels (50% and 80%) and concluded that depth-of-focus values associated to 60% of VSOTF were the most representative of subjective measures. Note that these results cannot be directly compared to the results of our study and the others discussed,[15,16,18] since depth-of-focus was measured based on just noticeable blur and Badal stage movement. In our case, and for Palomino-Bautista et al,[15,16] no more degradation levels below 60% were studied, but Nanavaty et al[18] analysed up to 20%. Based on all the outcomes, it seems that higher levels are not appropriate for comparison with patients' subjective values obtained from defocus curves. In this sense, future studies with percentages lower than 60% should be carried out in eyes implanted with isofocal IOLs in order to determine if lower percentages correlate better with subjective outcomes. Note that in our case, higher values were found for lower degradation percentages (up to 4.94 D for 60%). We have to note that Lago et al[7] using adaptive optics, assessed the effect of ocular aberrations on the simulated performance of the isofocal IOL. These authors reported that the depth-of-focus of this lens increased to 1.53±0.21 D, while maintaining good visual acuity, –0.07±0.05 logMAR. This study was carried out on 10 young subjects with a mean age of 29.8±3.4 years, and all conditions analysed returned higher averages for the depth-of-focus focus compared to conditions without the IOL. As previously indicated, several factors (ie IOL design, corneal aberrations and pupil size) may play a role in the possible differences obtained between clinical studies and between objective versus subjective depth-of-focus values.

In relation to wavefront aberrations, our results are shown in Table 2. Previous studies obtained the following values. Bova and Vita[9] used the Osiris wavefront sensor-based aberrometer (Osiris, CSO, Florence, Italy) to examine 42 eyes implanted with isofocal IOLs. Their results at 3-mm pupil diameter were about 0.28 μm for higher order aberrations and about −0.05 μm for spherical aberration. Mencucci et al[10] measured aberrations in 24 eyes implanted with the isofocal IOL using the Osiris-T pyramidal aberrometer at 4.0-mm pupil, obtaining mean values of 0.16±0.04 and 0.06±0.03 μm for higher order aberrations and spherical aberration, respectively. And Assaf et al[11] using the ray tracing device at 3-mm pupil, obtained mean values of 0.23 and 0.05 for higher order aberrations and spherical aberration, respectively. In relation to refractive and visual acuity outcomes our values were good, about half a dioptre for the mean spherical equivalent and about 20/20 for CDVA, about 20/25 for UIVA at 80 cm, about 20/30 for UIVA at 60 cm, and about 20/25 for DCNVA.

We have to point out some limitations of our study. First, despite we have compared with previous clinical studies published, we have not included other type of IOLs in order to be able to compare directly. Second, a large sample of eyes would be also desirable. And finally, other variables such as spectacle independence or defocus curves were not included. Then, more measurements in eyes implanted with different types of IOLs should be included in future studies.

Conclusion

In conclusion, we analysed the in vivo objective depth-of-focus of isofocal IOLs based on the VSOTF using ray tracing optical technology and found that the lens provides high values of depth-of-focus when implanted after cataract surgery.

Data Sharing Statement

Data are not available for sharing.

Funding

There is no funding to report.

Disclosure

Authors have no financial interests or relationships to disclose.

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