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Predictive value of pre-operative ocular biometric parameters for visual outcomes following Evolux extended depth-of-focus intraocular lens implantation

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ABSTRACT

Introduction: Extended depth-of-focus (EDOF) intraocular lens (IOLs) are designed to provide a continuous range of functional vision, particularly at distance and intermediate ranges, while reducing spectacle dependence and photic phenomena associated with multifocal designs. However, post-operative visual performance may be influenced by individual ocular biometric characteristics, and evidence regarding their predictive value remains limited. This study aimed to evaluate whether pre-operative ocular biometric parameters can predict visual outcomes following implantation of the Evolux™ EDOF IOL.

Methods: In this prospective, observational study, 50 eyes from patients with age-related cataract underwent phacoemulsification and Evolux EDOF IOL implantation. Pre-operative assessments included keratometry, axial length, anterior chamber depth, white-to-white corneal diameter, pupil diameter (PD), higher-order aberrations, and angles alpha and kappa. Visual acuity outcomes were measured 3 months postoperatively. Receiver operating characteristic curve analysis and multivariable models determined biometric predictors of favorable visual function.

Results: Evolux EDOF IOL implantation resulted in excellent mean uncorrected and corrected distance visual acuity (UDVA: 0.027 logarithm of the minimum angle of resolution [logMAR]; CDVA: 0.0056 logMAR) as well as intermediate visual acuity (uncorrected intermediate visual acuity: 0.104 logMAR; corrected intermediate visual acuity: 0.008 logMAR) at 3 months. Among pre-operative parameters, PD, mean keratometry, and angle alpha (AA) demonstrated the highest discriminative ability for predicting favorable uncorrected visual outcomes. Multivariable analysis showed that the combination of PD and AA improved predictive accuracy (area under the curve = 0.902, sensitivity 95.6%, specificity 80.0%).

Conclusion: Pre-operative assessment of PD and AA improves prediction of post-operative visual outcomes following Evolux EDOF IOL implantation. Incorporating these biometric parameters into patient selection and counseling may optimize refractive cataract surgery outcomes. Further research is required to validate these findings and establish clinical thresholds.

Keywords: Cataract surgery; biometric eye parameters; extended depth-of-focus intraocular lens; Evolux intraocular lens

INTRODUCTION

Cataract is one of the leading causes of visual impairment and blindness worldwide, despite being highly treatable. It substantially affects quality of life and remains an important public health concern. Approximately 36 million people are blind worldwide, with more than 12 million cases attributable to cataract. In developing countries, cataract

accounts for more than 90% of blindness-related disability-adjusted life years and is predominantly associated with aging (1).

Cataract surgery is the most frequently performed ophthalmic procedure worldwide, with more than 26 million procedures annually. Its evolution from intracapsular and extracapsular cataract extraction to modern phacoemulsification has substantially improved surgical safety and visual outcomes. Modern phacoemulsification uses small incisions (1.9-3.2 mm), provides intraoperative stability, reduces complications, and enables implantation of foldable intraocular lens (IOLs) (2,3).

Cataract surgery has progressively transitioned from a procedure focused solely on restoring lens transparency to one

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that also serves as refractive surgery. Contemporary IOLs correct refractive errors, minimize spherical aberrations, and, through advanced optical designs, enhance vision at various distances and address presbyopia (4).

Monofocal IOLs offer optimal vision at a single focal distance but typically necessitate spectacles for near activities. In contrast, multifocal IOLs provide multiple focal points and decrease dependence on spectacles, although they may induce photic phenomena such as glare and halos. Therefore, visual quality, functional performance, and patient satisfaction are critical outcomes alongside visual acuity, and IOL selection should be tailored to individual visual requirements and lifestyle (5).

Extended depth of focus (EDOF) IOLs represent an alternative to monofocal and multifocal technologies, providing an expanded range of vision, particularly at intermediate distances, with reduced visual disturbances. In contrast to monofocal IOLs, which offer a single focal point, and multifocal IOLs, which produce multiple discrete focal points, EDOF IOLs create an elongated focal region to enhance depth of focus. Optical studies indicate that EDOF IOLs deliver superior optical quality compared to multifocal IOLs (6).

The Evolux™ IOL incorporates a non-diffractive optical profile designed to extend depth of focus and facilitate seamless intermediate-to-distance vision, while minimizing photic phenomena including halos and glare. The lens design also reduces spherical aberrations, potentially enhancing contrast sensitivity and overall visual clarity. These characteristics position the Evolux™ IOL as a promising option for patients seeking improved functional vision after cataract surgery (7).

Accurate measurements of keratometry, axial length (AL), lens thickness, and anterior chamber depth (ACD), combined with advanced IOL power calculation formulas, are critical for achieving optimal outcomes after cataract surgery. While surgical competence ensures safety, an experienced surgeon strives for superior post-operative visual quality. As a result, modern ophthalmologists are increasingly regarded as both cataract and refractive surgeons. Enhanced understanding and management of ocular surface disease, along with advancements in diagnosing ocular surface abnormalities, have further increased the precision of pre-operative assessments and enabled consistently high-quality refractive cataract surgery (8).

Studies have reported near-spectacle independence rates ranging from approximately 30% to 70% following EDOF IOL implantation. Growing evidence indicates that ocular biometric and optical parameters may affect both the post-operative range and quality of vision. Notably, a larger pupil diameter (PD) and a greater κ angle have been associated with a reduced range of clear vision, while increased PD has also been linked to more frequent post-operative photic phenomena such as halos and glare. Despite these observations, data on the impact of ocular parameters on the visual performance of EDOF IOLs remain limited. Further research into these factors may help identify patients who are most likely to achieve an extended range of vision and greater spectacle independence after EDOF IOL implantation (9).

The aim of this study is to determine whether pre-operative biometric eye parameters can predict uncorrected and corrected distance and intermediate visual acuity 3 months after implantation of the Evolux extended depth-of-focus (EDOF) IOL. The findings may inform patient selection and counseling for EDOF IOLs.

METHODS

A prospective, observational study was conducted at the Eye Clinic Svjetlost Sarajevo, Bosnia and Herzegovina, in compliance with the ethical principles of the Declaration of Helsinki and with approval from the institutional Ethics Committee (number: 51-049-22388, date September 06, 2023). Fifty eyes from patients scheduled for phacoemulsification cataract surgery with implantation of an EDOF IOL (Evolux IOL, SIFI Medtech, Italy) were enrolled in the study. Post-operative examinations were performed 3 months after IOL implantation. Measurements included uncorrected and corrected distance visual acuity as well as intermediate visual acuity.

Patients were eligible if they were diagnosed with age-related cataract and scheduled for Evolux EDOF IOL implantation. Exclusion criteria included ocular comorbidities, a history of previous ocular surgery, intra- or post-operative complications, amblyopia, or refusal to provide informed consent.

All cataract procedures utilized the Evolux EDOF IOL (SIFI, Aci Sant'Antonio, Catania, Italy) to achieve emmetropia. The Evolux is a non-diffractive, hydrophobic acrylic IOL created to improve biocompatibility. It has an optical zone diameter of 6.0 mm, a total diameter of 13.0 mm, and is available in diopter powers from +6.00 D to +30.00 D in 0.5 D increments. The lens incorporates a proprietary wavefront-shaping technology that extends the depth of focus without relying on diffractive elements. It possesses a negative spherical aberration of $-0.27 \mu\text{m}$, increasing both intermediate and distance vision (10).

All surgeries were performed by a single experienced surgeon using the standard phacoemulsification technique. This procedure consists of fragmenting and aspirating the opacified crystalline lens with ultrasonic energy, followed by IOL implantation. Local anesthesia and pharmacologic mydriasis were administered in every case. The surgical protocol included a 2.75 mm corneal incision at the 90° meridian, continuous curvilinear capsulorhexis, phacoemulsification, aspiration of lens fragments, and in-the-bag IOL implantation. The self-sealing corneal incision obviated the need for sutures. All patients were discharged on the day of surgery and received instructions regarding post-operative topical therapy.

All subjects underwent a comprehensive pre-operative ophthalmologic evaluation, including uncorrected and corrected visual acuity measurement, intraocular pressure assessment, and slit-lamp biomicroscopy of the anterior and posterior segments. Distance visual acuity testing employed early treatment diabetic retinopathy study charts at 6 m, recorded in logarithm of the minimum angle of resolution (logMAR) units, with controlled illumination (85 cd/m²). Intermediate visual acuity was assessed at 66 cm and recorded in logMAR units.

AL, ACD, and white-to-white corneal diameter (WTW) were measured with the IOL Master 700 to provide precise biometric data for IOL selection.

Higher-order aberrations (HOA) and PD were measured using the Schwind Peramis topo aberrometer (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany).

Angle alpha (AA), angle kappa (AK), and mean keratometry (Km) were measured with the Pentacam HR (Oculus Optikgeräte GmbH, Wetzlar, Germany). IOL power was calculated using the IOL Master 700 (Carl Zeiss Meditec AG).

Statistical analysis

The discriminative ability of individual biometric parameters for predicting post-operative functional outcomes was assessed using receiver operating characteristic (ROC) curve analysis. The area under the ROC curve (AUC) was calculated for each parameter, with 95% confidence intervals (CIs). Discriminative performance was interpreted based on AUC values.

The regression models included horizontal corneal diameter (WTW), PD, and HOAs, based on their previously identified associations in correlation analyses. For each model, the correlation coefficient (R), coefficient of determination (R^2), adjusted R^2 , F-statistic, p -value, and regression coefficients with their standard errors and corresponding p -values were reported.

RESULTS

Descriptive statistics for pre-operative biometric and aberrometric parameters are presented in Table 1.

Table 1 summarizes the main biometric characteristics of the examined eyes. The median AL was 23.5 mm (interquartile range [IQR], 22.7-23.5), with values ranging from 21.4 to 29.1 mm. Mean ACD was 3.09 ± 0.47 mm, while mean keratometry (Km) was 42.9 ± 1.66 D. The median horizontal corneal diameter (WTW) was 11.9 mm (IQR, 11.6-12.1), and the median PD was 3.37 mm (IQR, 2.91-3.98). HOAs had a median value of $0.499 \mu\text{m}$ (IQR, 0.427-0.603), with a range of 0.115-1.18 μm .

Mean spherical aberration was $0.303 \pm 0.101 \mu\text{m}$, while the mean alpha and kappa angles were 0.467 ± 0.190 mm and 0.301 ± 0.164 mm, respectively. Overall, the biometric parameters demonstrated considerable variability within the study population, with the widest ranges observed for AL and PD.

TABLE 1. Biometric characteristics

Variable	Mean $\pm$ SD/median (IQR)	Min-max
Axial length	23.5 (22.7-23.5)	21.4-29.1
Anterior chamber depth	3.09 ± 0.47	2.15-4.15
Mean keratometry	42.9 ± 1.66	38.5-46.0
Horizontal corneal diameter	11.9 (11.6-12.1)	10.5-12.8
Pupil diameter	3.37 (2.91-3.98)	2.05-7.70
Higher-order aberrations	0.499 (0.427-0.603)	0.115-1.18
Spherical aberration	0.303 ± 0.101	0.043-0.498
Alpha angle	0.467 ± 0.190	0.060-0.950
Kappa angle	0.301 ± 0.164	0.010-0.740

SD: Standard deviation, IQR: Interquartile range

Table 2 presents the results of the assessment of post-operative visual function 3 months after surgery. The mean best uncorrected distance visual acuity (UDVA) was 0.027 logMAR, with a median of 0.00 (IQR: 0.00-0.05) and a range of 0.00-0.15 logMAR. Best corrected distance visual acuity (CDVA) was nearly optimal, with a mean value of 0.0056 logMAR, a median of 0.00 (IQR: 0.00-0.00), and a maximum value of 0.05 logMAR.

Uncorrected intermediate visual acuity (UIVA) had a mean value of 0.104 logMAR and a median of 0.10 (IQR: 0.05-0.15), whereas corrected intermediate visual acuity (CIVA) showed nearly optimal results, with a mean of 0.008 logMAR and a median of 0.00 (IQR: 0.00-0.01).

Table 3 compares pre-operative ocular biometric parameters between patients with good and poor uncorrected post-operative vision 3 months after implantation of an EDOF IOLs. A statistically significant difference between the groups was observed only for mean corneal keratometry (Km), which was significantly higher in patients with poorer post-operative outcomes than in those who achieved good uncorrected vision (44.14 ± 0.64 D vs. 42.78 ± 1.68 D; $p = 0.004$).

Although they did not reach statistical significance, several biometric parameters demonstrated a notable trend toward association with post-operative outcomes. Patients with good uncorrected vision had PD (3.44 mm [3.01-4.10] vs. 3.05 mm [2.40-3.30]; $p = 0.058$) and greater AA values (0.48 ± 0.19 vs. 0.34 ± 0.13 ; $p = 0.064$). These findings suggest a potential relationship between these parameters and early functional visual recovery, although the differences did not reach the conventional threshold for statistical significance in this univariate analysis.

TABLE 2. Analysis of post-operative visual function at 3 months after surgery

Variable	Mean	Median (IQR)	Min-max
Uncorrected distance visual acuity	0.027	0.00 (0.00-0.050)	0.00-0.15
Corrected distance visual acuity	0.0056	0.00 (0.00-0.00)	0.00-0.050
Uncorrected intermediate visual acuity	0.104	0.100 (0.05-0.150)	0.00-0.400
Corrected intermediate visual acuity	0.008	0.00 (0.00-0.010)	0.00-0.100

IQR: Interquartile range

TABLE 3. Association between pre-operative ocular biometric parameters and visual outcomes after 3 months

Characteristic	Poor uncorrected vision	Good uncorrected vision	p-value ²
AL (mm)	23.93 (23.22, 28.16)	23.47 (22.72, 24.33)	0.244
ACD (mm)	3.44 ± 0.67	3.05 ± 0.44	0.259
Km (D)	44.14 ± 0.64	42.78 ± 1.68	0.004
WTW (mm)	11.60 (11.60, 11.70)	11.90 (11.60, 12.10)	0.194
Pupil (mm)	3.05 (2.40, 3.30)	3.44 (3.01, 4.10)	0.058
HOA (μm)	0.46 (0.42, 0.78)	0.50 (0.43, 0.60)	0.796
SA (μm)	0.30 ± 0.05	0.30 ± 0.11	0.892
Alpha (mm)	0.34 ± 0.13	0.48 ± 0.19	0.064
Kappa (mm)	0.25 ± 0.06	0.31 ± 0.17	0.127

AL: Axial length, ACD: Anterior chamber depth, HOA: Higher-order aberrations, WTW: White-to-white

Figure 1 presents the results of the ROC analysis assessing the ability of pre-operative ocular biometric parameters to distinguish patients with good versus poor uncorrected post-operative visual acuity 3 months after implantation of EDOF IOLs. Among the parameters evaluated, PD demonstrated the highest discriminative ability (AUC = 0.762; 95% CI: 0.565-0.959; $p = 0.009$), followed closely by mean keratometry (Km; AUC = 0.758; 95% CI: 0.609-0.906; $p < 0.001$) and AA (AUC = 0.747; 95% CI: 0.577-0.917; $p = 0.004$).

These parameters demonstrated acceptable discriminative ability for predicting the achievement of good uncorrected visual acuity 3 months after surgery. The optimal cut-off for PD was ≥ 3.37 mm (sensitivity 55.56%, specificity 100%), and for AA, it was ≥ 0.47 (sensitivity 55.56% and specificity 100%). For Km, the optimal cut-off value was ≤ 43.85 D, with a sensitivity of 75.56% and specificity of 60.46%.

Moderate discriminative ability was observed for AL (AL; AUC = 0.662), ACD (ACD; AUC = 0.664), and WTW corneal diameter (WTW; AUC = 0.680); however, their AUC values did not reach statistical significance ($p > 0.05$). The weakest discriminative performance was observed for HOA (HOA; AUC = 0.462), spherical aberration (AUC = 0.547), and AK (AUC = 0.607), none of which demonstrated statistically significant discriminatory ability for post-operative visual outcomes.

Overall, the ROC analysis indicates that PD, Km, and AA were the most promising pre-operative biometric parameters for predicting a favorable functional outcome 3 months after surgery. These parameters were therefore included in the subsequent multivariable analysis.

Individual ROC analysis (Figure 2 and Table 4) demonstrated that PD (AUC = 0.762; 95% CI: 0.565-0.959; $p = 0.009$) and AA (AUC = 0.747; 95% CI: 0.577-0.917; $p = 0.004$) had acceptable discriminative ability for distinguishing between patients with good and poor uncorrected visual outcomes 3 months after surgery. Both parameters demonstrated maximum specificity (100%), with moderate sensitivity of 55.6%.

Combining these two biometric parameters into a multivariable predictive model resulted in a substantial improvement in discriminative performance, with the area under the ROC curve increasing to 0.902 (95% CI: 0.756-1.000;

$p < 0.001$), indicating excellent discriminatory ability of the model for distinguishing patients with good and poor post-operative outcomes. At the same time, sensitivity increased to 95.6%, while specificity remained at 80.0%. These findings confirm that the combination of AA and PD provides a considerably more reliable predictive model than either individual biometric parameter alone.

DISCUSSION

Our study found that AL and PD showed the greatest variability among the measured ocular biometric parameters. This variability aligns with the descriptive statistics in Table 1, where AL ranged from 21.4 to 29.1 mm and PD from 2.40 to 4.10 mm. These findings underscore the need to consider these parameters in patient selection, as Kanellopoulos et al. highlight the clinical relevance of pre-operative assessment of AL and PD in optimizing cataract surgery outcomes.

The observed wide range in AL and PD supports a personalized approach to cataract surgery, as reflected in our study population. Incorporating these individual biometric differences into pre-operative assessment and surgical planning may improve visual outcomes, consistent with the personalized concept advocated by Kanellopoulos et al. (11).

At 3 months postoperatively, mean uncorrected distance visual acuity (UDVA) was 0.027 logMAR and mean UIVA was 0.104 logMAR, while corrected visual acuities were nearly optimal (CDVA: 0.0056 logMAR; CIVA: 0.008 logMAR), as summarized in Table 2. These results confirm that Evolux IOL implantation provides excellent post-operative visual function at both distance and intermediate ranges. Amir-Asgari et al. reported similar findings, describing outstanding visual outcomes with EDOF IOLs, especially at intermediate distances and in low light, supporting the outcomes observed in our cohort (12).

Our results show that 90% of patients (45 out of 50) achieved good post-operative visual acuity (0.0-0.1 logMAR) 3 months after surgery, while only 10% (5 patients) had poorer outcomes (>0.1 logMAR). This high success rate emphasizes the clinical value of EDOF IOLs for consistent visual rehabilitation. Kim et al. also reported sustained improvements in visual function with EDOF IOLs in their 2-year follow-up study, echoing the favorable outcomes seen

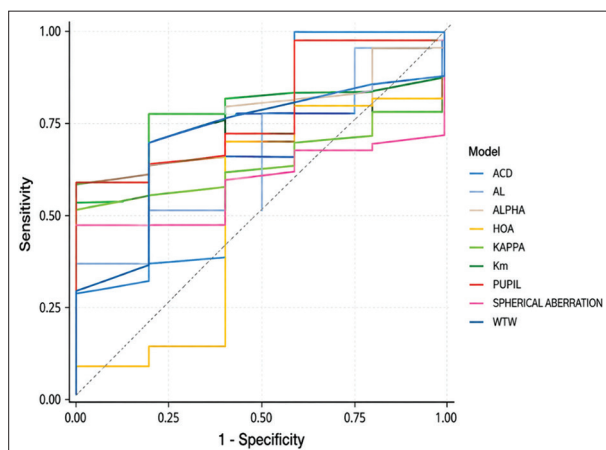


FIGURE 1. Receiver operating characteristic Analysis at 3 months after surgery.

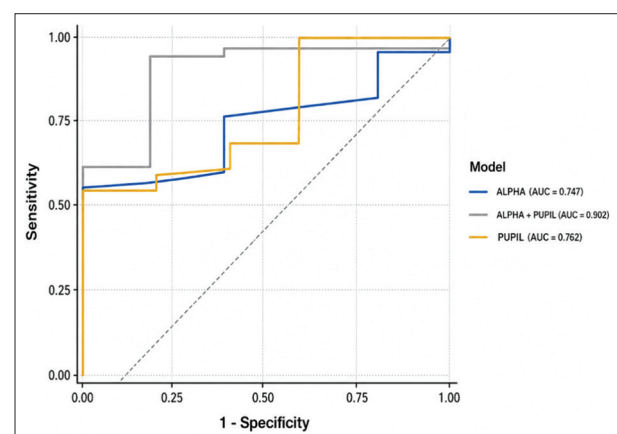


FIGURE 2. Receiver operating characteristic model of variables showing significant discriminatory ability for visual outcomes at 3 months.

TABLE 4. ROC model of variables showing significant discriminatory ability for visual outcomes at 3 months

Parameter	AUC	95% CI	p	Cut-off	Sensitivity (%)	Specificity (%)
Pupil	0.762	0.565-0.959	0.009	≥3.37	55.56	100.00
Alpha	0.747	0.577-0.917	0.004	≥0.47	55.56	100.00
Alpha×Pupil	0.902	0.756-1.000	<0.001	≥0.773	95.56	80.00

ROC: Receiver operating characteristic, CI: Confidence interval, AUC: Area under the curve, Bold values indicate the highest discriminative performance among the evaluated parameters

in our cohort (13). Spagnuolo et al. demonstrated favorable visual acuity outcomes following Evolux IOL implantation, with improvements observed across distance, intermediate, and near vision compared with other EDOF IOLs. Visual acuity was evaluated 3 months postoperatively. Their findings are consistent with those of our study, particularly with regard to the high visual acuity achieved at different viewing distances (14).

Our analysis (Table 3) indicates that mean keratometry (Km) was significantly higher in patients with poorer visual outcomes (44.14 ± 0.64 D) compared to those with good uncorrected vision (42.78 ± 1.68 D; $p = 0.004$). Although not statistically significant, larger PD (3.44 mm vs. 3.05 mm; $p = 0.058$) and greater AA (0.48 ± 0.19 vs. 0.34 ± 0.13 ; $p = 0.064$) were more common in patients with good visual acuity. These trends suggest a possible association of these parameters with better outcomes, paralleling findings by Giménez-Calvo et al., who also reported negative correlations between PD, AL, and visual performance with EDOF IOLs (15).

Similarly, Lee et al. reported a mild negative correlation between WTW and visual acuity, while they observed a stronger negative correlation with AL. Other ocular biometric parameters showed no significant associations with visual acuity. These findings are comparable to those observed in our study 3 months after surgery, with significant correlations identified particularly for WTW and AL (16).

Our findings confirm that higher mean keratometry is significantly associated with poorer post-operative visual outcomes, while trends toward better outcomes were observed with larger PD and greater AA in patients with good uncorrected acuity. This is consistent with Cywiński who found that increased AA and PD were linked to improved visual quality after EDOF IOL implantation, further supporting our results (17).

ROC analysis (Figure 1) at 3-month post-surgery showed that PD (AUC = 0.762), mean keratometry (AUC = 0.758), and AA (AUC = 0.747) were the best discriminators of good uncorrected visual acuity. The optimal thresholds identified – PD ≥3.37 mm, AA ≥0.47 mm, and mean keratometry ≤43.85 D – correlate well with previously published ranges (Mao et al.), further validating our findings (9).

Combining PD and AA in a multivariable model resulted in an AUC of 0.902 (95% CI: 0.756–1.000; sensitivity 95.6%, specificity 80.0%), as shown in Figure 2 and Table 4. This combination significantly improves predictive accuracy over either parameter alone, reinforcing their utility in pre-operative assessment for EDOF IOL implantation.

Qin et al., in their study “Influence of AA on visual quality after implantation of extended depth of focus intraocular

lenses,” also investigated the individual and combined effects of pre-operative biometric parameters on visual quality following EDOF IOL implantation. The authors concluded that the combination of AA and PD may significantly influence post-operative visual quality. They reported an AA threshold of approximately 0.5 mm and identified PD as an important determinant of visual performance. In our study, the corresponding cut-off values were ≥0.47 mm for AA and ≥3.37 mm for PD. These findings further support the consistency between our results and those reported by Qin et al. (18).

CONCLUSION

Evolux EDOF IOL implantation provided very good post-operative distance and intermediate visual acuity 3 months after cataract surgery. Among the pre-operative ocular biometric parameters evaluated, PD, mean keratometry, and AA demonstrated the greatest ability to discriminate between good and poor uncorrected post-operative visual outcomes. Importantly, the combination of PD and AA showed excellent predictive performance, with an AUC of 0.902, 95.6% sensitivity, and 80.0% specificity. These findings suggest that pre-operative assessment of selected ocular biometric parameters, particularly PD and AA, may improve patient selection and enable more individualized counseling before EDOF IOL implantation. Further studies with larger cohorts and longer follow-up are warranted to validate these findings and establish clinically applicable biometric thresholds for predicting post-operative visual performance.

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DECLARATION OF INTEREST

The authors declare no conflict of interest.

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