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Preliminary Visual Outcomes of a Novel Non-Diffractive Extended Monofocal Intraocular Lens (Evolux) 3 Months After Cataract Surgery

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Abstract: Background: This study aims to evaluate the visual performance, both quantitative and qualitative, of the novel non-diffractive extended monofocal intraocular lens (Evolux, Sifi) following cataract surgery. This serves as a preliminary study to assess its feasibility and improve the research methodology. Methods: We conducted a single-arm, non-randomized, retrospective study at Onioptic Hospital, Craiova, Romania, involving patients who underwent cataract surgery from November 2022 to August 2023. The following visual parameters were evaluated 3 months postoperatively: monocular uncorrected (UDVA) and corrected (CDVA) distance visual acuity at 4 m; uncorrected (UIVA) and distance-corrected (DCIVA) intermediate visual acuity at 60 cm; uncorrected (UNVA) and distance-corrected (DCNVA) near visual acuity at 40cm; postoperative refraction expressed as spheric equivalent (SE) and Quality of Vision (QoV) questionnaire scores. The contrast sensitivity and defocus curve were evaluated 1 month postoperation in 22 patients who underwent surgery in both eyes. SPSS Statistics 26.0 was used for statistical analysis, employing percentages, standard deviations (SDs), and a 95% confidence interval (95% CI). Results: Among the 103 eyes from 81 patients (mean age of 68.7 ± 1.845), 64% achieved an UDVA of logMAR 0.1 or better, and 91.26% achieved a CDVA of logMAR 0.1 or better at 3 months. Additionally, 83.24% of the eyes exhibited a UIVA of logMAR 0.3 or better, and 60.19% attained an UNVA of logMAR 0.3 or better. The SE was within ±0.50 D in 77.76% of the eyes. The QoV mean scores were as follows: frequency = 30.20 ± 16; severity = 17.19 ± 12.45; bothersome = 15.45 ± 12.94. Conclusions: The Evolux IOL demonstrated very good biometric predictability and excellent distance visual performance and very good intermediate vision, with no photopic side effects or glare in our sample population. This study provides a strong foundation for a larger comparative study with an extended depth-of-focus (EDOF) IOL, incorporating contrast sensitivity and defocus curve assessments to enhance the research quality.

Keywords: intraocular lens; Evolux; cataract surgery; postoperative visual acuity; extended depth of focus

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1. Introduction

Cataract surgery is a common procedure aimed at restoring vision impaired by lens opacification. With advancements in intraocular lens (IOL) technology, the quest for optimal visual outcomes post-surgery continues to evolve.

Presbyopia correction involves balancing three interrelated factors: visual quality, depth of field, and dysphotopsia. Presbyopia-correcting IOLs can be categorized into three main types: multifocal (MF) IOLs (including diffractive or refractive designs), extended depth-of-focus (EDOF) IOLs, and accommodative IOLs (either intracapsular or sulcus-placed) [1]. In recent years, a wide range of MF IOLs has been developed, surpassing traditional monofocal IOLs in popularity. With increasing life expectancy and lifestyle

changes, there is a growing demand to improve the quality of spectacle-independent intermediate vision, as many daily and meaningful activities—such as grocery shopping, meal preparation, and computer work—engage the intermediate vision (50–100 cm) [2]. Patients have reported that being free from spectacles while performing these tasks can significantly enhance their quality of life [3].

The basic optical principle of EDOF IOL is to create a single elongated focal point, rather than the several foci used in MF IOLs. EDOF lenses aim to eliminate the overlapping of near and far images caused by traditional MF IOLs, thereby reducing halo effects [4]. Reports indicate that EDOF lenses generally offer better optical quality than MF and monofocal lenses [4]. In practice, though, EDOF lenses excel in providing excellent intermediate vision but may fall short in near vision quality [5].

EVOLUX^{TM} is a novel extended monofocal IOL designed to enhance intermediate vision and functional near vision between 60 and 44 cm, while maintaining good distance vision [6]. It is associated with minimal photic phenomena compared to a standard aspheric monofocal IOL. The patented technology platform pioneers the extension of depth of focus through wavefront engineering [7]. The innovative optical design optimizes spherical aberration (SA) technology [7], already proven effective in Mini Well and Mini Well Proxa IOLs. It provides partial compensation for corneal aberrations [8,9], ensuring a smooth visual experience without the interference of diffractive rings. The non-diffractive profile reduces optical disturbances, such as glare and halos, while offering depth-of-focus gains similar to those of diffractive EDOF and some multifocal IOLs [10]. Additionally, the Evolux IOL is made from hydrophobic material, which allows for minimal glistening and clarity of optics [11,12]. According to SIFI internal data, it maintains optical performance and image contrast at both far and intermediate distances, regardless of pupil size [6]. A key factor in achieving emmetropia is an IOL that resides at the targeted position in the visual axis. Evolux's safety is comparable to that of a standard aspheric monofocal IOL, with good tolerance to tilt and decentration [13] and no reduction in image contrast [6].

This study aims to assess visual performance, both quantitative and qualitative, of the novel non-diffractive extended monofocal intraocular lens (Evolux^{TM}, Sifi, Catania, Italy) following cataract surgery. The following research represents a preliminary study to evaluate its feasibility and improve the research methodology. This is the first study to report Evolux postoperative visual outcomes at 3 months on a sample population comprising more than 100 eyes.

2. Materials and Methods

We conducted a single-arm, non-randomized, retrospective study at Onioptic Hospital, Craiova, Romania, involving patients who underwent cataract surgery from November 2022 to August 2023. The participants were aged 45–84, provided informed consent, and were diagnosed with uncomplicated age-related cataract. The exclusion criteria included significant ocular pathologies (advanced glaucoma, advanced age-related macular degeneration, optic neuropathies, retinal dystrophies, Fuchs endothelial dystrophy, pseudoexfoliation syndrome, zonular abnormalities, diabetic retinopathy, and amblyopia), preexisting total corneal astigmatism > 0.75D, prior intraocular or refractive surgery, recurrent anterior or posterior segment inflammation, and subjects with any systemic disease that could increase operative risk. If one or more of the following events occurred during surgery, the patient (the operated eye) could not be included: irregularity and decentration of capsulorhexis, significant vitreous loss, significant anterior chamber hyphema, uncontrollable intraocular pressure (IOP), zonular or capsular rupture, ciliary sulcus, bag–sulcus, sulcus–sulcus, or unknown placement of the haptics.

The principles of the Declaration of Helsinki were followed in this study. Ethical approval was received from the Ethics Committee of Onioptic Ophthalmology Hospital (810/16 July 2024)—Supplementary Material S1.

Optical biometry was performed using the IOL Master 700 (Zeiss, Jena, Germany), targeting postoperative refraction at emmetropia using the Barrett formula with an A

constant of 1.52 (Hoffer protocol [14]). All surgeries were performed under topical anesthesia by the same experienced surgeon (D.P.). Each procedure involved corneal incisions, manual capsulorhexis, ultrasound lens fragmentation, and in-the-bag lens implantation. Phacoemulsification was conducted using the standard ultrasound technique (Centurion, Alcon Laboratories, Fort Worth, TX, USA). All patients received sutureless 2.2 mm corneal incisions located temporally.

The following visual parameters were evaluated 3 months postoperatively: monocular uncorrected (UDVA) and corrected (CDVA) distance visual acuity at 4 m (photopic); uncorrected (UIVA) and distance-corrected (DCIVA) intermediate visual acuity at 66 cm under photopic conditions (85 cd/m^2); uncorrected (UNVA) and distance-corrected (DCNVA) near visual acuity at 40 cm (photopic); postoperative refraction expressed as spheric equivalent (SE); adverse events during surgery; postoperative complications. The binocular contrast sensitivity and defocus curve were evaluated 1 month postoperatively in 22 patients who underwent surgery in both eyes. Contrast sensitivity was performed using the spatial frequency contrast sensitivity test on Topcon optotype CC100 under mesopic conditions from a 4 m distance. The defocus curve was plotted by adding + and − lenses to the best corrected distance VA.

At the 3-month follow-up, the patients were asked to complete a Romanian translation of the Quality of Vision (QoV) questionnaire regarding vision quality [15] (Supplementary Material S2). The QoV questionnaire is a 30-item instrument that measures symptom frequency, severity, and discomfort. The score ranges from 0 to 100; the higher the number, the worse the vision quality. The first 7 questions were accompanied by pictures to better explain the phenomenon. The QoV questionnaire has proven its excellent specificity and sensibility in assessing patients with various refractive corrections, eye surgeries, and eye diseases [15]. The authors obtained copywrite permission for the QoV questionnaire [15] (Supplementary Material S3).

Statistical analysis was carried out using SPSS Statistics 26.0. Percentages, standard deviations (SDs) and a 95% confidence interval (95% CI) were employed for the descriptive part of this study. The following formula was applied to determine the appropriate sample size: $n = [(Z)2p(1 - p)]/\delta 2$, where Z is the value based on a confidence level = 1.96, using a 95% CI; p is the sample proportion = 50%; and δ is the margin of error = 5%. An anticipated population percentage (P) of 50% was used, obtaining an ideal sample size equal to 385.

3. Results

This study included 103 eyes from 81 patients with a mean age of 68.7 ± 1.85 years and an age range of 46 to 84 years old. The cohort consisted of 51.25% males and 48.75% females.

The mean axial length was 23.42 mm ± 0.79 (95% CI: [23.27–23.57]), and the mean anterior chamber depth was 3.20 mm ± 0.45 (95% CI: [3.11–3.20]). The implanted IOL powers ranged from 16 to 25 diopters. The biometric results are illustrated in Table 1.

The mean values of the monocular uncorrected and distance-corrected distance, intermediate, and near visual acuity at 3 months after surgery can be seen in Table 2.

At 3 months after surgery, the majority of eyes achieved an UDVA of logMAR 0 (32.04%) and a CDVA of logMAR 0 (69.90%). For intermediate visual acuity, most eyes reported an UIVA of logMAR 0.2 (41.75%) and a DCIVA of logMAR 0.2 (46.60%). Regarding near visual acuity, the highest percentage of eyes recorded an UNVA of logMAR 0.3 (41.75%) and a DCNVA of logMAR 0.3 (56.31%). Only a small proportion of eyes exhibited UDVA/CDVA, UIVA/DCIVA, and UNVA/DCNVA of logMAR 0.4 or worse (Tables 2 and 3).

An excellent functional UDVA of logMAR 0.05 or better was observed in 55.34% of the eyes (Figure 1). An UDVA of logMAR 0.15 or better was reported in 89.32% of the eyes, and 99.03% of the eyes had a CDVA of logMAR 0.15 or better (Figure 2). Additionally, 83.24% of the eyes exhibited a UIVA of logMAR 0.3 or better, while 60.19% of the eyes attained an UNVA of logMAR 0.3 or better (Figure 1).

Table 1. Pre-operative biometry data of study population.

Biometry Data	Mean	SD	95% CI
K1 (D)	43.03	±1.47	42.76–43.32
K2 (D)	43.57	±1.48	43.28–43.85
Axial length (mm)	23.42	±0.79	23.27–23.57
ACD (mm)	3.20	±0.45	3.11–3.29
LT (mm)	4.38	±0.54	4.27–4.48
WTW (mm)	11.71	±0.42	11.63–11.80
CCT (um)	543.15	±30.4	537.25–549.05
IOL power (D)	21	±1.73	20.67–21.33

K = keratometry; ACD = anterior chamber depth; LT = lens thickness; WTW = white-to-white diameter; CCT = central corneal thickness; IOL = intraocular lens; D = diopter; SD = standard deviation; CI = confidence interval.

Table 2. Mean values of monocular uncorrected and distance-corrected distance, intermediate, and near visual acuity at 3 months after surgery.

	Mean VA (logMAR)	SD
UDVA	0.08	±0.08
CDVA	0.02	±0.04
UIVA	0.2	±0.09
DCIVA	0.2	±0.07
UNVA	0.3	±0.09
DCNVA	0.3	±0.07

VA = visual acuity; SD = standard deviation; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; DCIVA = distance-corrected intermediate visual acuity; UNVA = uncorrected near visual acuity; DCNVA = distance-corrected near visual acuity.

Table 3. Uncorrected and distance-corrected distance, intermediate, and near monocular visual acuity at 3 months after surgery.

	No. of Eyes					
	UDVA	CDVA	UIVA	DCIVA	UNVA	DCNVA
logMAR 0	33	72	4	3	1	1
logMAR 0.05	24	22	0	0	0	0
logMAR 0.1	9	0	5	8	1	1
logMAR 0.15	26	8	10	9	1	1
logMAR 0.2	7	0	43	48	16	14
logMAR 0.3	2	1	23	22	43	58
logMAR 0.4	1	0	7	2	34	24
logMAR 0.5	1	0	1	0	4	1

UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; DCIVA = distance-corrected intermediate visual acuity; UNVA = uncorrected near visual acuity; DCNVA = distance-corrected near visual acuity.

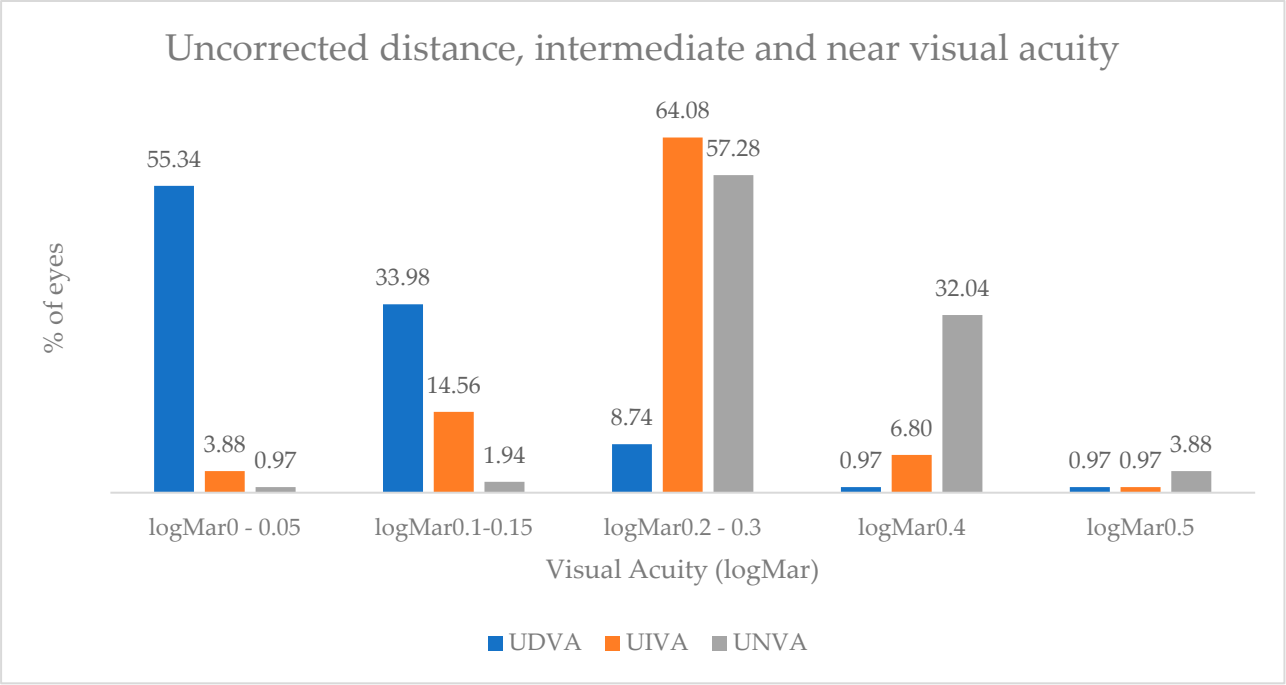

Figure 1. Functional uncorrected distance, intermediate, and near monocular visual acuity at 3 months after surgery.

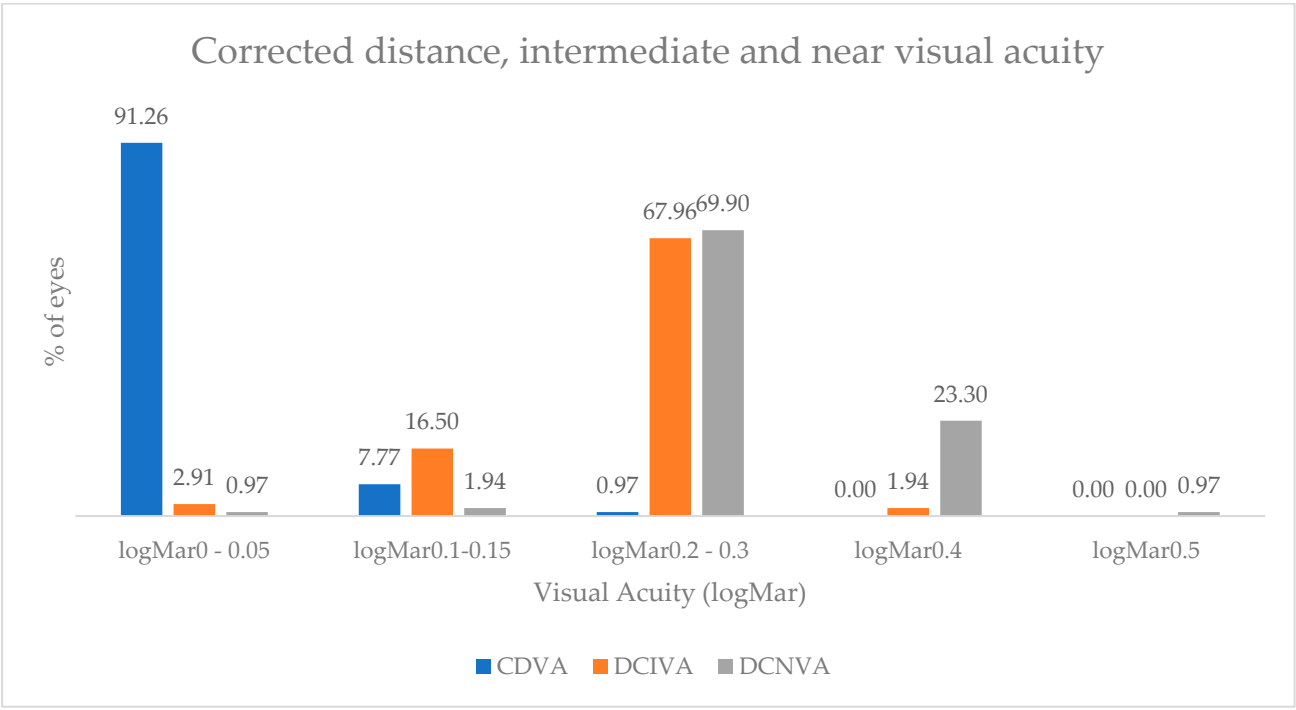

Figure 2. Functional corrected distance, intermediate, and near monocular visual acuity at 3 months after surgery.

The mean postoperative SE was ±0.38 with SD = ±0.27. The SE predictability was high, with 77.67% of the eyes within ±0.50 D, and only three eyes (2.9%) exceeding ±1.00 D.

The lens function was tested by obtaining the defocus curve. The defocus curve was plotted by adding + and − lenses to the best corrected distance VA. A typical range of defocus from +1.5 D to −2.5 D was applied. The results were averaged and plotted. At 1 month after surgery, Evolux provided continuous extended performance from distance to

intermediate and functional near vision, with good tolerance of small refractive errors. The defocus curve confirmed functional vision of at least 0.2 logMAR throughout a continuous defocus range of 2 D (Figure 3).

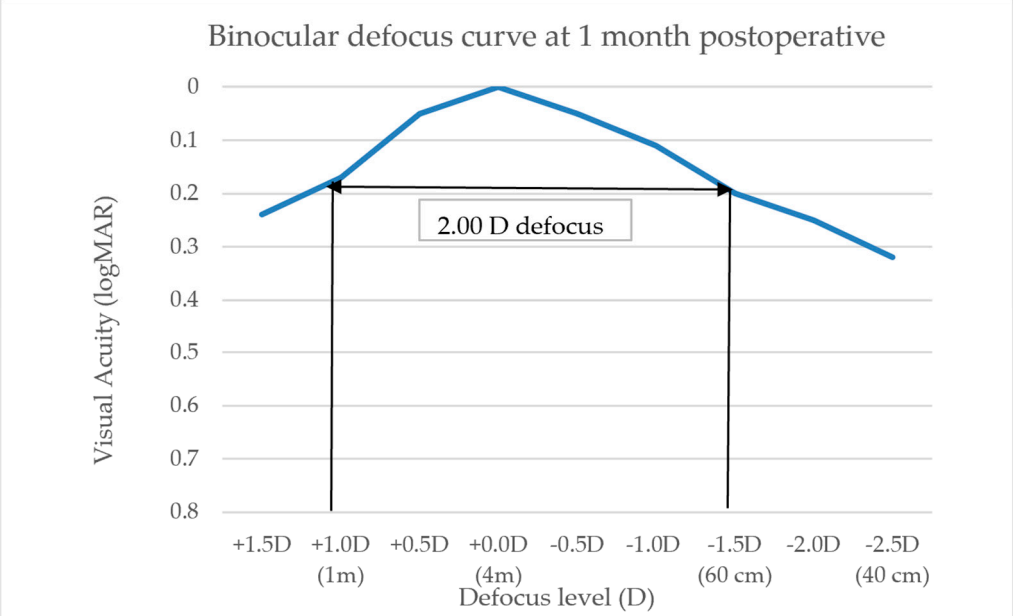

Figure 3. Binocular defocus curve of patients with Evolux at 1 month after surgery.

The binocular contrast sensitivity was tested using the spatial frequency contrast sensitivity test with a Topcon CC100 optotype under mesopic conditions from a 4 m distance. The results are shown in Figure 4.

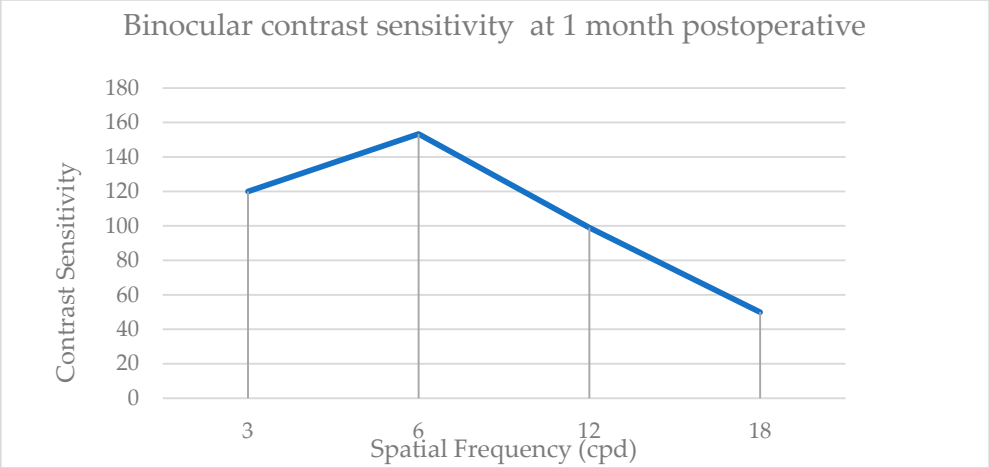

Figure 4. Binocular contrast sensitivity curve under mesopic conditions of patients implanted with Evolux IOL at 1 month after surgery.

By courtesy of Colm et al. [15], we were able to analyze the QoV results, which can be seen in Table 4. Night driving performance was also very good, with 89% patients reporting no haloes. Patient satisfaction was high regarding intermediate vision as well, demonstrating excellent vision for activities such as cooking and viewing the dashboard, and very good vision for computer work. The UNVA results were very good, with a 69% satisfaction rate and favorable outcomes for reading, sewing, and shaving.

Table 4. Descriptive statistics of Quality of Vision questionnaire.

	Mean ± SD	Median	Mode	Range
Frequency	30.20 ± 16	32	37	0–67
Severity	17.19 ± 12.45	22	0	0–44
Bothersome	15.45 ± 12.94	14	0	0–53

4. Discussion

While most studies evaluating the performance of monofocal enhanced IOLs are based on Technis Eyhance [16,17], we wanted to evaluate both the quantitative and qualitative aspects of visual quality of a novel mono-enhanced lens. EVOLUX is a non-diffractive extended monofocal IOL that was first launched in Europe in 2022. Ever since, ophthalmologists have started to collect postoperative results to assess its biometric predictability, visual performance, and patient satisfaction. As far as we know, this is the first study comprising over 100 eyes that analyzes the postoperative results after implanting the Evolux IOL.

Our study population comprised 103 eyes from 81 patients, with a mean age of 68.7 ± 1.85 years. The cohort included 51.25% males and 48.75% females. The biometric data in Table 1 indicate a homogenous sample population.

Impressive results were obtained for distance visual acuity, with an UDVA of logMAR 0.1 or better obtained in 64% of the eyes, and a CDVA of logMAR 0.1 or better in 91.26% of the eyes. The results are similar with those of another preliminary study by Nicula et al. on 30 eyes implanted with Evolux IOL [18]. The results of the QoV questionnaire indicate a high rate of satisfaction, especially for daytime activities such as watching TV, doing housework, and driving. A total of 89% of the subjects reported no haloes during night driving.

Although the Evolux IOL provided excellent results for distance vision, its performance for intermediate and near vision was also promising, with 83.24% and 60.19% of eyes achieving a logMAR of 0.3 or better for intermediate and near vision, respectively. This suggests that while distance vision was prioritized, the IOL offered a balanced approach to improving visual acuity at different focal points. Our population gained an UIVA of logMAR 0.1 or better in 8.7% of the eyes, logMAR 0.15 or better in 18.44%, and logMAR 0.2 or better in 60.19%. The DCIVA was slightly better, with a logMAR of 0.15 or better in 19.42% of the eyes. Interestingly, even though Nicula et al. analyzed fewer eyes, their postoperative results were very similar, with a UIVA of logMAR 0.1 or better in 6.7%, logMAR 0.15 or better in 30%, and logMAR 0.2 or better in 80% of the eyes [18]. These similar data suggest high predictability for Evolux, and including a larger number of eyes refines the results without substantial changes. Patient satisfaction was high regarding intermediate vision as well, demonstrating excellent vision for activities such as cooking and viewing the dashboard, and very good vision for computer work.

Near vision was satisfactory for most of our patients, with an UNVA of logMAR 3 or better reported in 60.19% of the eyes and a DCNVA of logMAR 3 or better in 72.81% of the eyes. The results of the QoV questionnaire concluded a 69% satisfaction rate and favorable outcomes for reading, sewing, and shaving.

The mean postoperative SE was ±0.38 with SD = ±0.27, which is the main parameter to assess the accuracy of cataract surgery. The SE predictability was high, with 77.67% of the eyes within ±0.50D and only three eyes (2.9%) exceeding ±1.00 D. Similar results were obtained for the enhanced monofocal TECNIS Eyhance IOL (ICB00), with a postoperative SE of 0.46 ± 0.25 D (n = 58 eyes) [19]. We followed the Hoffer protocol to assess the intraocular lens accuracy. For visual acuity data and postoperative SE, the eyes were tested monocularly.

The defocus curve facilitates the assessment of visual acuity and the depth of field at various degrees of defocus, providing insight into an IOL's ability to maintain visual clarity across a spectrum of focal distances. By plotting the visual acuity against incremental levels of defocus—ranging from hyperopia to myopia—the curve offers a quantitative measure

of the IOL's performance under different visual conditions. At 1 month after surgery, the binocular defocus curves of 22 patients implanted with Evolux confirmed a functional vision of at least logMAR 0.2 throughout a continuous defocus range of 2D (+1.0 D to −1.5 D). Similar results were reported by Nicula et al. [18]. Spagnuolo et al. obtained a functional VA of at least logMAR 0.2 from −1.50 D to + 1.50 D in 25 eyes [20].

The binocular contrast sensitivity curve under mesopic conditions in 22 eyes was the highest at 6 cpd. Similar results were reported by Pagnacco et al. [21].

The QoV questionnaire results reported better outcomes in bothersomeness (mean = 15.45 ± 12.94) than Symfony (47.2 ± 16.0), Fine Vision (32.8 ± 16.0), and PanOptix (37.9 ± 12.0) [22]. The findings of another study align with ours, showing PanOptix scores as follows: frequency = 25; severity = 13; bothersomeness = 0 [23]. Meanwhile, the FineVision scores were as follows: frequency = 38; severity = 28; bothersomeness = 14 [23]. The QoV scores reflect that the Evolux IOL resulted in minimal photic phenomena, with low levels of glare and halo complaints in the sample population. This indicates the potential for improved patient quality of life after surgery, enhancing both functional vision and patient comfort in various lighting conditions.

The limitations of this study include the absence of a control group and a short follow-up duration of only 3 months. This study may also be susceptible to selection bias, as patients were included only after completing surgery. Patients who developed intraoperative complications were excluded. A final limitation is the closed-ended questionnaire, which was useful for gathering data and standardizing responses, but the respondents had a limited number of choices and the information collected may be incomplete or inaccurate. Some photopic events, such as negative dysphotopsia, were not included [24].

An important parameter to be considered in future studies could be the contrast sensitivity, which has been recently analyzed in multiple IOL types [17,18]. Moreover, future directions include comparing the Evolux outcomes with an extended depth-of-focus IOL, especially regarding the intermediate visual performance and glare and halo perception.

In this preliminary study, we specifically chose patients without any significant ocular pathologies. Further research should consider including patients with ocular comorbidities to evaluate whether the performance of the Evolux IOL is comparable to that of a monofocal IOL, particularly regarding visual quality.

5. Conclusions

The Evolux IOL provided very good biometric predictability with the best performance for distance vision and very good performance for intermediate vision. The postoperative refraction was highly stable, with 77.76% of the eyes achieving a spherical equivalent within ±0.50 D, indicating reliable refractive outcomes and contributing to better patient satisfaction in terms of vision clarity. The spherical aberration optimization resulted in no photopic side effects or glare in our sample population. The QoV scores suggest minimal photic phenomena, contributing to patient satisfaction, with low levels of glare and halos. These findings suggest that the Evolux IOL offers a balanced approach to improving visual acuity across various distances, making it well-suited for patients seeking strong distance vision with good intermediate and near vision performance. Its lack of significant photopic side effects makes it a viable option for individuals who prioritize clarity and the predictability of visual outcomes. This study provides a strong foundation for a larger comparative study with an extended depth-of-focus (EDOF) IOL, incorporating contrast sensitivity and defocus curve assessments to enhance the research quality.

Supplementary Materials: The following supporting information can be downloaded at https://www.mdpi.com/article/10.3390/jcto2040014/s1: Supplementary Material S1—Ethics Committee approval, Supplementary Material S2—Romanian translation of QoV questionnaire, Supplementary Material S3—Copyright permission for QoV questionnaire.

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Institutional Review Board Statement: This study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Onioptic Hospital of Ophthalmology (810/16 July 2024).

Informed Consent Statement: Informed consent was obtained from all subjects involved in this study. Written informed consent was obtained from the patient(s) to publish this paper.

Data Availability Statement: The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Conflicts of Interest: The authors declare no conflicts of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript; or in the decision to publish the results.

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