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RayOne EMV and TECNIS PureSee in postoperative correction of aphakia. Why do some patients see near without additional correction?



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HIGHLIGHTS

Factors allowing near vision without the need for additional correction indicates small pupil diameter values (Tecnis PureSee) and large alpha angles together with low spherical aberration values (RayOne EMV). The type of implanted lens influenced the achievement of good near vision.

ABSTRACT

Two groups of patients (85 eyes) differing by the implanted intraocular lens model were analyzed to answer the question of why some of them see well at near without additional correction, even though the design of these lenses theoretically should not allow it. Given the eligibility criteria, most of the group consisted of patients with preoperative hyperopia. Statistical analysis showed that large alpha angles as well as low spherical aberration values after implantation of the RayOne EMV model, and a small pupil diameter in the case of the Tecnis PureSee lens, have a statistically significant effect on achieving near vision without the need for additional correction. This result was achieved in 43.8% of the RayOne EMV group and in 82% of eyes with the Tecnis PureSee lens. In the study addressing the probable causes of the above effect, the structure of the eye, the type and magnitude of the preoperative refractive error, and the structure of the intraocular lenses were taken into account.

Key words: aphakia, near vision, RayOne EMV, PureSee

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INTRODUCTION

Correction of postoperative aphakia has become an art form due to the wide range of intraocular lens models available. Proper preoperative qualification is the result of several factors, including the structure of the eye, the structure of the intraocular lens, and the patient's expectations. Although the patient's expectations seem to be the most important, the first two factors play the main role in the qualification process. Analysis of ocular structure includes the assessment of higher-order aberrations (HOA) generated by the cornea, pupil diameter, kappa angles, alpha angles, and the size and type of preoperative refractive error. Only after knowing these parameters can a lens be selected for implantation, and even then the human factor will influence the final, albeit subjective, assessment of vision after the procedure.

Tecnis PureSee is a relatively new model using EDOF technology with an addition of +2.0 Dsph. Introduced in February 2024, it should provide excellent distance and intermediate vision, and in some cases also near vision. According to Reuters, data presented at the ESCRS 2025 congress showed that 3 months after implantation, 96% of patients did not require additional correction for distance and 93% for intermediate vision. Such good results stem, among other things, from a fully refractive optical design that increases depth of focus while maintaining excellent distance image quality. In contrast to conventional diffractive lenses, PureSee does not use concentric diffractive rings, thereby minimizing halo and glare while improving contrast sensitivity and visual comfort in low-light conditions [1–4].

RayOne EMV is another new intraocular lens model, classified as a so-called monofocal plus. Its design uses positive spherical aberration, which makes it significantly different from the Tecnis PureSee model. Despite the generated addition of +1.5 Dsph, this lens provides the ability to see near without additional correction in more than 50% of patients in the study group (50 eyes), in which patients with hyperopia predominated. Good postoperative visual quality and visual acuity allow the RayOne EMV model to be used as a lens of choice in the correction of postoperative aphakia, replacing monofocal lenses, with the difference that thanks to this lens the patient achieves good vision at least at 2 distances, namely distance and intermediate vision [5–7].

What makes both models allow good near vision without the need for additional correction? Which parameters of ocular structure or the intraocular lens influence this?

AIM OF THE STUDY

Analysis of ocular structure parameters, including spherical aberrations, HOA generated by the cornea, kappa angles, alpha angles, pupil diameter, and the type and magnitude of refractive error, in order to identify the cause that affects the achievement of near vision without the need for additional correction.

The study group included 33 patients qualified for implantation of the RayOne EMV model and 52 patients qualified for implantation of the Tecnis PureSee model. The above groups included patients with normal visual acuity qualified for refractive lens exchange (RLE) and cataract extraction.

Qualification criteria

Loss of accommodation in the case of qualification for RLE. Due to the addition (RayOne EMV +1.5 Dsph, Tecnis PureSee +2.0 Dsph) used in both lens models, patients with preoperative emmetropia and hyperopia, as well as myopia not greater than -2.0 D, were qualified for the procedure. Large kappa and alpha angles were not a contraindication, although they indicated implantation of the RayOne EMV model.

Exclusion criteria

Exclusion criteria were preserved accommodation, moderate and high myopia, corneal, retinal, and optic nerve pathologies that could affect postoperative visual acuity.

A pupil narrower than 2.8 mm was a contraindication to implantation of the Tecnis PureSee lens due to its EDOF design.

Statistical analysis

A significance level of $p = 0.05$ was adopted. The significance level is the maximum allowable probability of an error consisting in rejecting the true null hypothesis H0, which assumes that the compared groups do not differ with respect to the feature of interest. It is therefore the level of stringency at which the decision to reject or retain the hypothesis is made. In accordance with the above, $p < 0.05$ indicates significant relationships between variables.

Variables expressed on an ordinal or nominal level were analyzed using tests based on the chi-square distribution. For 2×2 tables, a continuity correction was used, while when the conditions for applying the chi-square test were not met, Fisher's exact test was used, with the extension for tables larger than 2×2. The test assumes the following hypotheses:

H0: The variables are not dependent.

H1 (alternative): There are significant relationships between the variables.

Verification of the existence of a relationship between the variables was carried out using linear regression analysis, for which the following hypotheses are assumed:

H0: The independent variable does not have a significant effect on the dependent variable.

H1 (alternative): The independent variable has a significant effect on the dependent variable.

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The calculations were performed in the statistical environment R ver. 3.6.0, PSPP, and MS Office 2019.

RESULTS

Information about the implanted lens model, the type of procedure performed, the eye that underwent the procedure, and the preoperative refractive error is presented in table 1.

TABLE 1

Demographic and clinical characteristics of the study group, including the type of lens implanted and the procedure performed, as well as the preoperative visual defect.

Lens type	Frequency	Percentage
RayOne EMV	33	38.80%
Tecnis PureSee	52	61.20%
Eye		
Right	37	43.50%
Left	48	56.50%
Type of procedure		
RLE	44	51.80%
Cataract	41	48.20%
Type of refractive error		
Myopia	7	8.20%
Hyperopia	70	82.40%
Astigmatism	8	9.40%

RLE – refractive lens exchange.

The RayOne EMV lens was implanted in 38.8% of eyes, and the Tecnis PureSee model in 61.2% of the group. The right eye was operated on in 43.5% of cases and the left eye in 56.5%. Refractive lens exchange was performed in 51.8% of eyes, and cataract extraction in 48.2% of patients. Patients with preoperative hyperopia predominated (82.4%); myopia was found in 8.2% of cases and astigmatism in 9.4%. Astigmatism coexisted in 51.5% of eyes.

Table 2 presents information on patients' age, preoperative and postoperative distance and near visual acuity, pupil diameter, kappa and alpha angles, spherical aberrations generated by the cornea and the entire optical system, axial length, and addition for near correction.

The patients' mean age was 61.5 years. The mean preoperative refractive error was +1.94 D.

The hypotheses analyzed were as follows:

Hypothesis 1: There is a significant relationship between the type of implanted lens and postoperative uncorrected near visual acuity.

With the RayOne EMV lens, postoperative uncorrected near visual acuity values greater than 0.5 Sn were obtained (56.3%). With the Tecnis PureSee lens, near uncorrected visual acuity of 0.5 Sn was obtained most often (82.0%). The study showed that, in the case of the Tecnis PureSee lens, the best postoperative uncorrected near visual acuity (0.5 Sn) was obtained significantly more often ($p < 0.05$) than in the case of RayOne EMV. Distance visual acuity with correction, however, did not depend significantly on the type of lens used. It should be noted that the addition generated by the Tecnis PureSee lens is +2.0 D and, in the case of the RayOne EMV lens, +1.5 Dsph. The variables are illustrated below in the chart (fig. 1).

TABLE 2

Summary of clinical parameters, and biometric data.

Variable	N	M	SD	Min	Max	Me
Age	85	61.55	11.91	42.00	85.00	61.00
Preoperative spherical equivalent (D)	82	1.94	2.14	-6.00	7.25	2.00
Preoperative distance UBVA (logMAR)	47	0.77	0.68	0.10	3.00	0.60
Preoperative distance BCVA (logMAR)	77	0.32	0.51	0.00	3.00	0.20
Preoperative near UBVA (Snellen)	17	1.87	0.85	0.50	3.00	2.25
Preoperative near BCVA (Snellen)	81	0.57	0.26	0.50	2.00	0.50
Postoperative spherical equivalent (D)	85	-0.47	0.43	-1.50	0.50	-0.50
Postoperative distance UBVA (logMAR)	85	0.14	0.15	0.00	1.00	0.10
Postoperative distance BCVA (logMAR)	34	0.16	0.13	0.00	0.50	0.10
Postoperative near UBVA (Snellen)	82	0.70	0.42	0.50	3.00	0.50
Postoperative near BCVA (Snellen)	48	0.51	0.05	0.50	0.75	0.50
Pupil diameter (mm)	85	4.31	0.81	2.90	5.90	4.30
Kappa angle (mm)	74	0.41	0.13	0.15	0.68	0.41
Alpha angle (mm)	74	0.47	0.16	0.04	0.85	0.49
Corneal HOA	23	0.12	0.09	0.02	0.46	0.10
Corneal spherical aberrations	23	0.03	0.03	0.00	0.09	0.03
Spherical aberrations – entire optical system	22	0.06	0.09	0.00	0.42	0.03
Axial length (mm)	52	22.71	0.98	20.54	24.55	22.66
Addition for near vision (diopters)	19	0.92	0.28	0.50	1.50	1.00
Last visit (weeks)	52	6.25	5.86	1.00	26.00	5.00

BCVA – best corrected visual acuity; HOA – higher-order aberrations; M – mean; Max – maximum; Me – median; Min – minimum; N – number; SD – standard deviation; UBVA – uncorrected best visual acuity.

Hypothesis 2: There is a significant relationship between postoperative uncorrected near visual acuity and postoperative uncorrected distance visual acuity for the Tecnis PureSee lens.

The hypothesis was rejected – no significant relationship was observed ($p > 0.05$) between postoperative uncorrected near visual acuity and uncorrected distance visual acuity for the Tecnis PureSee lens.

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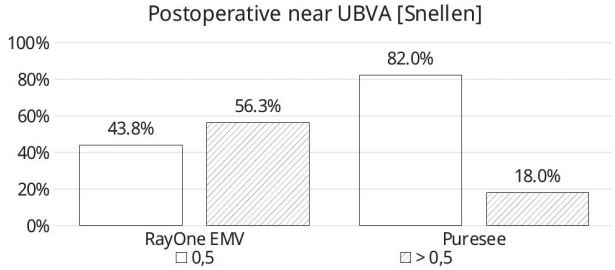
FIGURE 1

Comparison of uncorrected near visual acuity values obtained with both lens models.



UBVA – best uncorrected visual acuity

Hypothesis 3: There is a significant relationship between postoperative uncorrected near visual acuity and postoperative uncorrected distance visual acuity for the RayOne EMV lens.

The hypothesis was rejected – no significant relationship was observed ($p > 0.05$) between postoperative uncorrected near visual acuity and uncorrected distance visual acuity for the RayOne EMV lens.

Hypothesis 4: Age, type of procedure, refractive error, preoperative spherical equivalent, preoperative distance uncorrected and corrected visual acuity and near corrected visual acuity, pupil diameter, kappa and alpha angle, and axial length are significant predictors of postoperative uncorrected near visual acuity for the PureSee lens.

A linear regression model was used to analyse the hypothesis. Analysis of the regression model showed that pupil diameter explained the variability of postoperative uncorrected near visual acuity well – the fit coefficient was $R2 = 0.09$; $F(1, 33) = 4.29$; $p < 0.05$ – so the assumed model explains 9% of the variance in visual acuity. Detailed analysis confirmed a significant effect of pupil diameter, $\beta = 0.34$; $t = 2.07$; $p < 0.05$. We are therefore dealing with a moderately strong positive relationship between visual acuity and pupil diameter. Table 3 shows the marginal means of visual acuity depending on pupil diameter.

It was shown that the best visual acuity was observed for a diameter of 3.44 mm and averaged $M = 0.52$; $SE = 0.03$, while the worst was observed for a diameter of 5.13 mm and averaged $M = 0.61$; $SE = 0.03$. It was therefore shown that pupil diameter was a statistically significant predictor of postoperative uncorrected near visual acuity for the Tecnis PureSee lens – the larger the pupil diameter, the significantly worse the visual acuity (higher Snellen values). The hypothesis in this respect was accepted. The result obtained is illustrated in figure 2.

TABLE 3

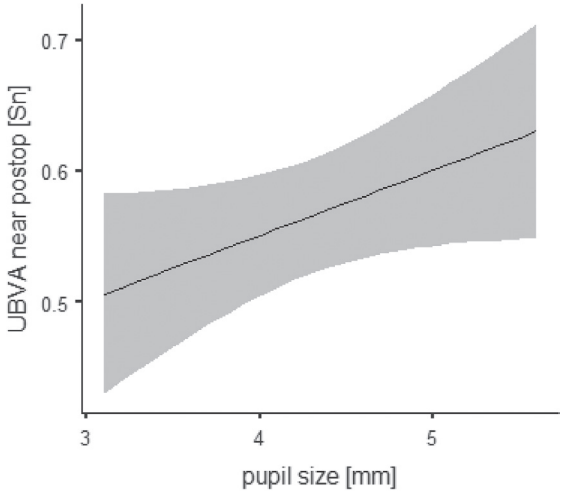
Marginal means of visual acuity depending on pupil diameter.

Postoperative near UBVA (Sn)				95% confidence interval	
Pupil diameter (mm)		M	SE	Lower bound	Upper bound
3.44	$^{-}$	0.52	0.03	0.46	0.59
4.28	μ	0.56	0.02	0.52	0.61
5.13	$^{+}$	0.61	0.03	0.54	0.67

M – mean; SE – standard error; $^{-}$ – mean -1 SD; μ – mean; $^{+}$ – mean +1 SD.

FIGURE 2

Relationship between near visual acuity and pupil diameter in eyes with the Tecnis PureSee lens.



Hypothesis 5: Age, preoperative spherical equivalent, pupil diameter, kappa and alpha angle, HOA generated by the cornea, and corneal and total ocular spherical aberration are significant predictors of postoperative uncorrected near visual acuity for the RayOne EMV lens.

A linear regression model was used to analyse the hypothesis. Analysis of the regression model in the first step showed that ocular spherical aberration explained the variability of visual acuity well – the fit coefficient was $R2 = 0.54$; $F(1, 20) = 25.34$; $p < 0.001$ – so the assumed model explains 54% of the variance in visual acuity. In the second step, spherical aberration together with alpha angle explained the variability of visual acuity even better, $R2 = 0.76$; $F(2, 19) = 34.10$; $p < 0.001$. The change in the R2 coefficient was statistically significant.

Detailed analysis confirmed a significant effect of ocular spherical aberration, $\beta = 0.59$; $t = 5.21$; $p < 0.001$, and alpha angle, $\beta = 0.50$; $t = 4.41$; $p < 0.001$. There is therefore a strong positive relationship between visual acuity and ocular spherical aberration, and a strong negative relationship with alpha angle. The marginal means of visual acuity depending on ocular spherical aberration and alpha angle are presented in table 4.

It was shown that the best visual acuity was observed for aberration of 0.03 and alpha angle of 0.68 mm, $M = 0.15$;

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TABLE 4

Average marginal values of near visual acuity depending on the value of the eye's spherical aberration and the alpha angle.

Postoperative near UBVA (Sn)						95% confidence interval	
Alpha angle (mm)		Spherical aberration total eye		M	SE	Lower bound	Upper bound
0.27	⁻	-0.03	⁻	0.75	0.13	0.48	1.02
0.27	⁻	0.06	μ	1.11	0.09	0.91	1.31
0.27	⁻	0.15	⁺	1.47	0.10	1.25	1.68
0.47	μ	-0.03	⁻	0.45	0.09	0.25	0.64
0.47	μ	0.06	μ	0.81	0.06	0.67	0.94
0.47	μ	0.15	⁺	1.16	0.09	0.97	1.36
0.68	⁺	-0.03	⁻	0.15	0.10	-0.07	0.36
0.68	⁺	0.06	μ	0.50	0.09	0.31	0.70
0.68	⁺	0.15	⁺	0.86	0.13	0.59	1.13

M – mean; SE – standard error; UBVA – uncorrected best visual acuity to the near; ⁻ – mean -1 SD, μ – mean, ⁺ – mean +1 SD.

SE = 0.10, while the worst was observed for aberration of 0.15 and angle of 0.27, M = 1.47; SE = 0.10. It was therefore shown that the larger the alpha angle and the smaller the total ocular spherical aberration, the better the postoperative uncorrected near visual acuity. These two factors were therefore significant predictors of visual acuity. The hypothesis in this respect was accepted.

DISCUSSION

The results obtained in the study group showed that useful near visual acuity can be achieved without the need for additional correction despite implantation of intraocular lenses with an addition of +1.5, +2.0 Dsph. 43.7% of patients with the RayOne EMV lens and 82% of patients with the Tecnis PureSee model achieved near visual acuity at the D -0.5 level.

Considering the selection criteria used for the procedure, most of the group, i.e. more than 82%, consisted of patients with preoperative hyperopia. Preoperative myopia was found mainly in individuals with diagnosed cataract and was of a refractive nature. The mean axial length in the group was 22.71 mm, and the maximum value did not exceed 24.55 mm. According to one of the rules, namely that eyes with a very narrow pupil are not eligible for implantation of EDOF lenses (Tecnis PureSee), the smallest pupil diameter in the group (scotopic conditions) was 2.9 mm and the mean value was 4.31 mm. Analysing the available literature, with the Tecnis PureSee lens near vision without additional correction was obtained in the range of 59–62%, which practically does not differ from the result obtained in the study group [1, 4]. In patients with the RayOne EMV lens, it was shown that 33% to more than 40% did not require near correction [7, 8]. Previous own studies showed that 50% achieved such a good result [5]. These rather large discrepancies in achieving "good" near vision with RayOne EMV may result from different qualification criteria for its implantation. Our own qualification criteria for implantation of this model excluded the correction method involving micromonovision and patients diagnosed with moderate and high myopia.

CONCLUSIONS

Analysis of the study group in terms of factors allowing near vision without the need for additional correction indicates small pupil diameter values in the group of patients implanted with the Tecnis PureSee model and large alpha angles together with low spherical aberration values in the group with RayOne EMV. The type of implanted lens influenced the achievement of good near vision. No relationship was observed between postoperative distance vision and achieved near vision, without correction. Taking the eligibility criteria into account, hyperopic eyes predominated in the study group.

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Authors' contributions:
Adam Cywiński: idea of the article, drafting, editing, proofreading.
Martyna Kubiak, Daria Bloch-Lubczyk, Aleksander Lubczyk, Filip Bukartyk: collection of data for the statistics.
Mikołaj Kurczyński: collection of material for the introduction and, partly, the references.

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The content presented in the article complies with the principles of the Helsinki Declaration, EU directives and harmonized requirements for biomedical journals.

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