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Influence of angle κ on visual and refractive outcomes after implantation of a diffractive trifocal intraocular lens

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Purpose: To evaluate changes in angle κ after the implantation of a trifocal intraocular lens (IOL) and to assess the postoperative outcomes of patients with different angle κ values.

Setting: IOA Madrid Innova Ocular, Madrid, Spain.

Design: Prospective trial.

Methods: Sixty-three patients who had bilateral implantation of the diffractive trifocal IOL (POD F, PhysIOL) were included. Pupil offset was used as the best estimate of angle κ and was measured using Pentacam (Oculus) preoperatively and at 3 months postoperatively. Postoperative refractive outcomes (sphere, cylinder, and manifest refraction spherical equivalent) and visual outcomes at far, intermediate, and near distance were assessed and compared between eyes with small pupil offset and eyes with large pupil offset. Quality of vision was assessed using a subjective questionnaire.

Results: There was a significant decrease in pupil offset values postoperatively (mean: 0.197 ± 0.12 mm) compared with those preoperatively (mean: 0.239 ± 0.12 mm), with a mean decrease of -0.042 mm ($P = .0002$). The same significant decrease was found for both right and left eyes, when analyzed separately. No statistically significant difference was found in any of the refractive and visual acuity outcomes between eyes with small pupil offset and eyes with large pupil offset. The majority of patients (14 of 16) complaining of significant halos had eyes with small pupil offset.

Conclusion: Large pupil offset did not negatively affect visual and refractive outcomes. The tolerance to larger pupil offset might be due to the IOL optical design, with the first diffractive ring being larger than other commonly used multifocal IOLs. More studies comparing various diffractive IOL models would be useful to confirm such hypothesis.

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With advances in both cataract surgery techniques and the technology of intraocular lenses (IOLs), achieving full refractive correction and optimal vision quality at all distances has become the goal for both surgeons and patients. Multifocal IOLs (MIOLs) are designed to reduce spectacle dependence at all distances after cataract surgery, thus improving the quality of life.¹ Unlike monofocal IOLs, MIOLs split the light distribution to the retina between different foci corresponding to different viewing distances.^{2–4} Bifocal IOLs have 2 focal points: one for near and one for far distance; trifocal IOLs have a third focal point with the aim of improving intermediate vision.^{5–7} Multifocal IOLs can be based on refractive, diffractive, or a combined design.⁸ Refractive IOLs use concentric or annular ring-shaped zones of varying dioptric powers to achieve their multifocality, and diffractive IOLs, based on the Huygens-Fresnel principle, are

engineered with microscopic steps of a specific phase delay.⁸ Diffractive IOLs have shown to provide a better optical quality, better contrast sensitivity, and less photic phenomena than refractive IOLs; however, the theoretical drop in contrast sensitivity function and perceived blurriness and photic phenomena—including halos and glare—might still represent an issue and negatively influence the patient's level of satisfaction.^{9–13} Several factors such as lens decentration, posterior capsule opacification, dry-eye syndrome, postoperative uncorrected distance visual acuity (UDVA), and spherical equivalent might be involved in the occurrence of these undesired outcomes.^{12–14}

Another factor affecting the patient's satisfaction is angle κ , and it has been suggested that large angle κ may contribute to MIOL decentration and that patients with a large angle κ tend to suffer from decreased quality of vision and increased visual symptoms, such as glare and halos.^{15–19}



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Although the clinical significance of the association between angle κ and postoperative outcomes is not fully understood, these findings prompted some authors to suggest that patients with a high angle κ should be carefully evaluated before trifocal IOL implantation because of their higher risk of postoperative photic phenomena.^{16–19}

The aim of this study was to evaluate how angle κ changes after the implantation of a trifocal IOL and to assess and compare the postoperative visual and refractive outcomes of eyes with low angle κ and eyes with large angle κ . Angle κ was assessed using the pupil offset, as this is commonly used in refractive surgery by clinicians to estimate angle κ and decide whether patients are suitable for surgery.

METHODS

Patients and Study Design

This study was performed in accordance with the tenets of the Declaration of Helsinki, and approval by the local ethics committee was obtained before initiation of any clinical procedures. All patients provided written consent.

Criteria for inclusion into the study were the need for bilateral cataract surgery and the absence of ocular comorbidities. Patients were excluded from the study if they had ocular diseases such as pseudoexfoliation syndrome or floppy-iris syndrome, corneal or retinal pathologies, and a history of ocular surgery or trauma.

IOL Description

The FineVision POD F is manufactured by PhysiOL. It is a foldable trifocal IOL made of 26% hydrophilic material. The single-piece IOL has an optical body diameter of 6.00 mm, with the 26 diffractive trifocal steps covering the full optical surface. The diameter of the first diffractive ring (after hydration) is 1.125 mm. The haptic consists of a double C loop with an angulation of 5 degrees, which is supposed to increase the contact surface of the optic with the capsule. Other features of the technical design of this IOL are described in detail elsewhere.^{20,21}

Surgical Procedure

All surgical procedures were performed by the same experienced surgeon (F.P.) under topical anesthesia using the computer-assisted cataract surgery system CALLISTO eye from Zeiss' Cataract Suite markerless (Carl Zeiss) to guide capsulotomy and to center the IOL in the right position. For phacoemulsification, a 2.2 mm clear temporal corneal incision was made. Next, a continuous curvilinear capsulorhexis measuring approximately 5.5 mm in diameter was created. Two ophthalmic viscosurgical devices were used during surgery: the cohesive Healon and the dispersive Amvisc. The chosen IOL was then implanted in the capsular bag aided by a single-use injection system (Medical Accusject, PhysiOL). In all cases, a capsular tension ring was inserted. After IOL implantation, all traces of ophthalmic viscosurgical device were removed. All implanted IOLs were aligned to the center of the dilated pupil. All surgeries were successful; no intraoperative or postoperative complications occurred.

Angle κ Measurements

Although angle κ is defined as the angle difference between the visual axis and pupillary axis, in this study, the distance in the corneal plane between the corneal vertex and pupil center, the pupil offset, was used as an estimate of angle κ and was reported in polar coordinates (distance in millimeters and angle in degrees).²² Pupil offset was measured under photopic conditions preoperatively and at 3 months postoperatively with the Pentacam HR topographer (Oculus). In case of error indicating insufficient

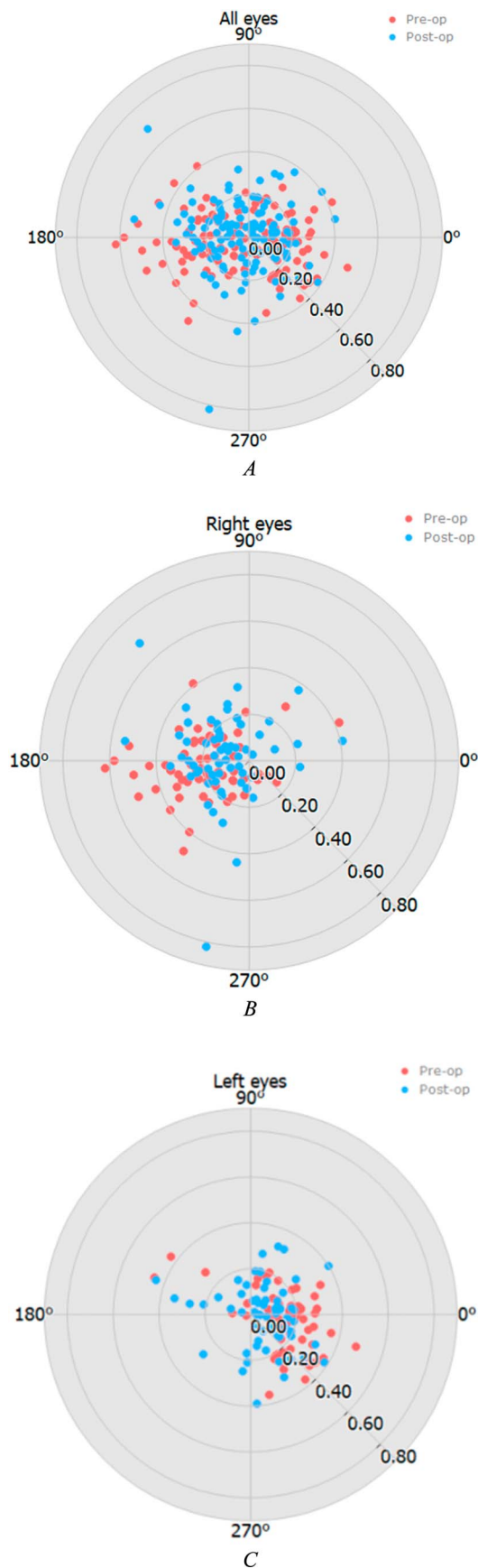


Figure 1. Polar plot graphs showing the preoperative and postoperative pupil offset obtained in all eyes (A), right eyes (B), and left eyes (C).

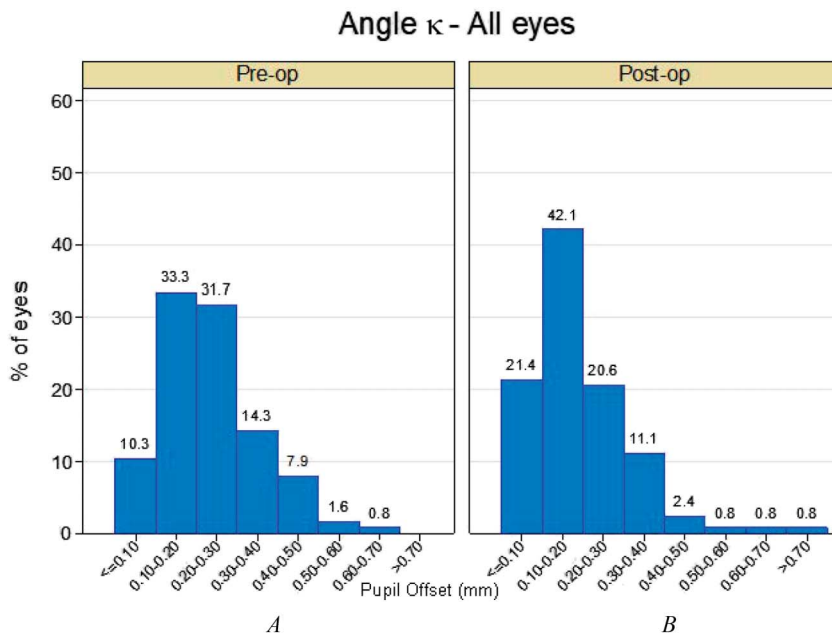


Figure 2. Distribution of pupil offset in the population for all eyes preoperatively (A) and postoperatively (B).

image quality, data collection was repeated after 5 minutes. The mesopic pupil diameter was measured with the OPD Scan III (Nidek Co. Ltd.).

A cutoff value of 0.3 mm was selected. Thus, eyes with a pupil offset value of 0.30 mm or less were defined as low pupil offset eyes, and those with a pupil offset value of greater than 0.30 mm were defined as high pupil offset eyes. It is accepted that eyes with a pupil offset value lesser than 0.3 mm are at a very low risk of suffering from decentration issues and dissatisfaction. However, there is no clear cutoff for a pupil offset value that will result in some unwanted side effects. Therefore, in this study, a cutoff of 0.3 mm was chosen with the objective that the group with the low pupil offset value represents a control group in which no unwanted side effects or decrease in vision is expected.

Preoperative and Postoperative Assessments

Preoperatively, all patients underwent a full ophthalmologic examination, including routine biometry, corneal topography, and optical coherence tomography imaging. Monocular corrected distance visual acuity (CDVA) was assessed using logarithm of the minimum angle of resolution (logMAR) acuity charts under photopic conditions.

All patients were seen for follow-up at the first postoperative day, as well as at 1 week, 1 month, and 3 months postoperatively. The results obtained at the 3-month postoperative follow-up are presented in this study, as it is the time after which the adaptation to the tested IOL was observed.²³

At the 3-month follow-up, all patients underwent a slitlamp examination and measurement of subjective refraction [sphere, cylinder, and manifest refraction spherical equivalent (MRSE)]. UDVA, CDVA, distance-corrected intermediate visual acuity (DCIVA) at 80 cm, and distance-corrected near visual acuity (DCNVA) at 40 cm and 25 cm were evaluated using logMAR acuity charts under photopic conditions. Patients were asked to complete a satisfaction questionnaire about their surgical outcome in terms of vision quality at distance and overall satisfaction; scores based on a 6-point scale were used, with 0 being complete dissatisfaction and 5 being extreme satisfaction. Patients were also asked to score for the perception of photic phenomena (glare and halo); a 6-point scale was used, with 0 being a lot of halos and 5 being no perception of halos.

Statistical Analysis

Statistical analysis was performed with the IBM SPSS Statistics for Windows software (version 21.0, IBM Corp.). Values are reported as mean ± SD.

The paired *t*-test was used to compare the preoperative and postoperative pupil offset values. Analysis of variance was used to compare the postoperative visual outcomes between low and high pupil offset groups. The Fisher exact test and the Wilcoxon test were used to compare the differences in the change of pupil offset values between the right and left eyes. The statistical significance threshold was defined as *P* < .05.

RESULTS

A total of 63 right eyes from 63 patients (21 men and 42 women) were included in the study. The mean age of the patients at the time of surgery was 62.3 years ± 11.8 (range 44 to 86 years). The mean photopic pupil size was 4.79 ± 0.85 mm, and the mean mesopic pupil size was 5.48 ± 0.91 mm.

Angle κ

Figure 1 shows the plots of preoperative and postoperative pupil offset in all eyes, right eyes, and left eyes (Figure 1, A to C).

Table 1. Distribution of the change in pupil offset (defined as the difference between the postoperative value and the preoperative value) for all tested eyes.

Pupil offset change (mm)	All eyes	
	n	%
≤-0.3	1	0.8
-0.29 to -0.20	5	4.0
-0.19 to -0.10	39	31.0
-0.09 to 0.10	69	54.8
0.11 to 0.20	8	6.3
0.21 to 0.30	1	0.8
>0.30	3	2.4
Subtotal	126	100

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The mean preoperative pupil offset value was 0.24 ± 0.12 mm (range: 0.02 to 0.62). The mean postoperative pupil offset value was 0.20 ± 0.12 mm (range: 0.02 to 0.82). There was a statistically significant reduction in pupil offset values postoperatively ($P < .001$).

F2 **Figure 2** shows the distribution of pupil offset in the population. Preoperatively, 75% of eyes had a pupil offset value of 0.30 mm or less, whereas postoperatively 84% of eyes had a pupil offset value of 0.30 mm or less.

T1 **Table 1** provides the distribution of the change in pupil offset (defined as the difference between the postoperative value and the preoperative value). Of the 126 eyes, 116 eyes (92.1%) showed a change in pupil offset of less than 0.2 mm, 6 eyes (4.8%) showed a reduction in pupil offset greater than 0.2 mm, and 4 eyes (3.2%) showed an increase in pupil offset greater than 0.2 mm. The statistical analysis revealed that there was no significant difference in pupil offset change between right and left eyes ($P = .315$, Fisher exact test).

Visual Acuity Outcomes

T2 **Table 2** provides the mean postoperative visual acuity at the 3-month follow-up for both the small pupil offset group (≤ 0.30 mm) and the large pupil offset group (> 0.30 mm) measured at the preoperative visits. There were no statistically significant differences in UDVA, CDVA, DCIVA at 80 cm, and DCNVA at 40 cm and 25 cm between the 2 groups (all P values $> .05$). The large pupil offset group demonstrated as good visual performance as the small pupil offset group. **F3** **Figure 3** shows the distribution of postoperative visual outcomes for the 2 groups.

Refractive Outcomes

T3 **Table 3** provides the postoperative refractive outcomes at the 3-month follow-up for both the small pupil offset group (≤ 0.30 mm) and the large pupil offset group (> 0.30 mm). There were no statistically significant differences in any of the tested variables (sphere, cylinder, and MRSE) between the 2 groups ($P > .05$). The large pupil offset group demonstrated as good refractive outcomes as the small pupil offset group. **F4** **Figure 4** shows the distribution of postoperative refractive outcomes for the 2 groups.

Refractive accuracy was good for both groups: The MRSE was within ± 0.50 diopters (D) of the attempted correction for 94% of eyes in the small pupil offset group and for 97%

of eyes in the large pupil offset group. The MRSE was within ± 1.00 D of the attempted correction for all eyes in the small pupil offset group and for 97% of eyes in the large pupil offset group.

Questionnaire Response

The patients were asked to record their satisfaction in regard to the presence of halos (0 = a lot of halos to 5 = no halos). Sixteen patients (25%) reported significant halos (grade 1 or 2 of the questionnaire), although all patients gave a score of 3 or more (satisfied to extremely satisfied) on satisfaction in terms of far distance. Of the 16 patients, 14 patients were in the small pupil offset group, 1 patient was in the large pupil offset group (with angle κ values of 0.41 and 0.44 mm), and 1 patient had 1 eye in the small pupil offset group (0.19 mm) and 1 eye in the large pupil offset group (0.31 mm).

When asked to score overall visual satisfaction, only 2 patients gave a score of 2 (quite dissatisfied): both patients were in the small pupil offset group. This demonstrated that large pupil offset does not appear to increase the risk of halos or dissatisfaction.

Lens Decentration After Implantation

With the exception of only 1 IOL, all IOLs were perfectly centered after implantation. In the eye with the decentered IOL, pupil offset increased from 0.11 mm preoperatively to 0.44 mm postoperatively. In the fellow eye, in which the IOL was well centered, pupil offset increased from 0.25 to 0.39 mm; however, the patient did not complain of significant halos (score = 3) and reported a complete overall satisfaction (score = 5). Refractive results and visual acuity were excellent. Moreover, at the 3-month follow-up visit, all IOLs were found to be perfectly centered in the bag.

DISCUSSION

New trifocal diffractive IOLs aim to achieve optimal vision at far, intermediate, and near distance; however, some patients may still experience some photic phenomena and complain about suboptimal quality of vision. Perception of photic phenomena is multifactorial; however, in the past few years, increasing attention has focused on the possible role of angle κ .^{12,14,15} In regular practice, examination of angle κ before implantation of MIOLs is not yet a standard component of preoperative examination.¹⁸

Table 2. Comparison of postoperative visual outcomes (expressed as logarithm of the minimum angle of resolution, mean \pm SD) between the small pupil offset group and the large pupil offset group measured at the preoperative visits.

Parameter	All (n = 126)	Comparison		
		Small pupil offset (n = 95)	Large pupil offset (n = 31)	P value
UDVA	0.04 ± 0.08	0.04 ± 0.09	0.04 ± 0.07	.855
CDVA	0.02 ± 0.13	0.03 ± 0.15	0.01 ± 0.0	.569
DCIVA at 80 cm	0.22 ± 0.07	0.22 ± 0.07	0.23 ± 0.08	.189
DCNVA at 40 cm	0.15 ± 0.10	0.14 ± 0.08	0.17 ± 0.13	.289
DCNVA at 25 cm	0.41 ± 0.11	0.42 ± 0.10	0.41 ± 0.12	.729

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

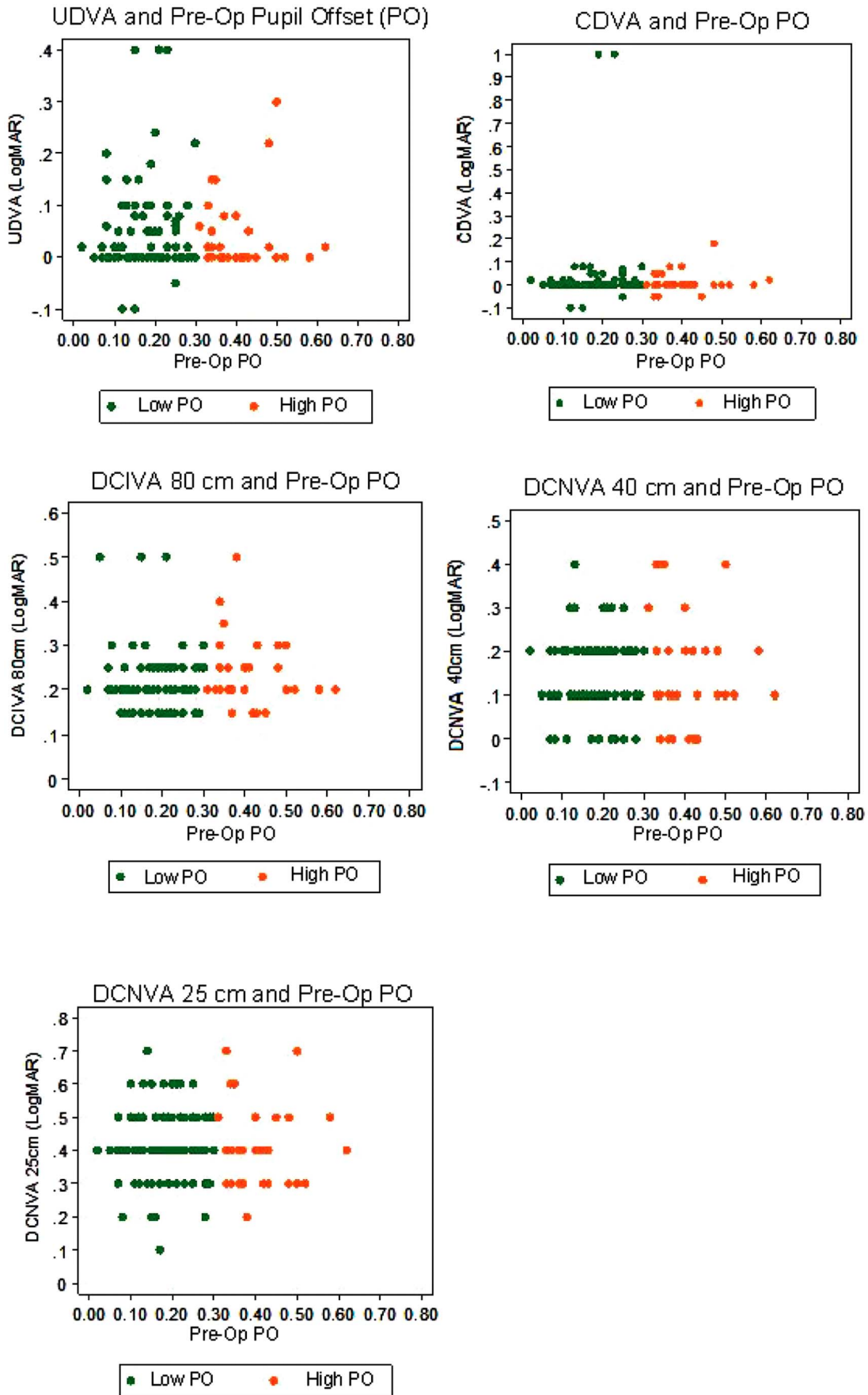


Figure 3. Distribution of visual outcomes for both the small pupil offset group (≤ 0.30 mm) and the large pupil offset group (>0.30 mm). The x-axis represents the PO in millimeters and the y-axis represents postoperative visual acuity measured in logMAR (CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; logMAR = logarithm of the minimum angle of resolution; PO = pupil offset; UDVA = uncorrected distance visual acuity).

Table 3. Comparison of postoperative refractive outcomes (sphere, cylinder, and MRSE in diopters) between the small pupil offset group and the large pupil offset group measured at the preoperative visits.

	All (n = 126)	Comparison		
		Small pupil offset (n = 95)	Large pupil offset (n = 31)	P value
Sphere (D)	-0.004 ± 0.26	-0.016 ± 0.25	0.032 ± 0.31	.318
Cylinder (D)	-0.173 ± 0.34	-0.187 ± 0.36	-0.129 ± 0.28	.784
MRSE (D)	-0.90 ± 0.26	-0.109 ± 0.26	-0.032 ± 0.27	.235

MRSE = manifest refraction spherical equivalent

In this study, we evaluated whether the pupil offset changes after trifocal IOL implantation and whether larger pupil offset was associated with a deterioration of postoperative visual acuity, as well as refractive and visual quality outcomes. A cutoff value of 0.3 mm was chosen to separate eyes into 2 groups: small and large pupil offset groups, based on the knowledge that eyes with a pupil offset lesser than 0.3 mm are at a very low risk to suffer from decentration issues and dissatisfaction. In our study, the mean postoperative pupil offset was significantly lower than the mean preoperative pupil offset, with a mean decrease of 0.042 mm. However, only 8% of all eyes had a change in pupil offset of 0.2 mm or more. This decrease in the mean postoperative pupil offset value compared with the preoperative value was observed in both right and left eyes.

In our study, as reported previously, good vision was obtained at all distances, with mean logMAR values for CDVA (0.02 ± 0.13 logMAR), DCIVA at 80 cm (0.22 ± 0.07 logMAR), and DCNVA at 40 cm (0.15 ± 0.10 logMAR) that varied between 0.02 and 0.22. Most importantly, there was no difference in any of the tested visual acuity (UDVA, CDVA, DCIVA at 80 cm, and DCNVA at 40 cm and 25 cm) between small and large pupil offset groups. Thus, large pupil offset did not negatively impact visual outcomes after IOL implantation of the FineVision IOL. In other words, the FineVision IOL used in this study demonstrated good tolerance, in terms of visual acuity outcomes, to larger pupil offset values; of course, more clinical studies comparing various diffractive IOL models will be useful to confirm these findings.

Similarly, the lack of statistically significant differences in the mean postoperative refractive outcomes (sphere, cylinder, and MRSE) between eyes with small and large pupil offset confirmed that the pupil offset did not play a role in refractive outcomes.

These findings are in agreement with those obtained in a recent study in which a different type of diffractive trifocal IOLs was implanted after cataract surgery; however, Qi et al. also found that, when angle κ was greater than 0.4 mm, the incidence of glare and halo increased and when it was greater than 0.5 mm, visual quality of the patients decreased.¹⁹ These findings are in contrast with those of our study. In our study, pupil offset did not appear to be a risk factor for halos. Our results are also in contrast with the findings of the study by Prakash et al., who found a correlation between the incidence of glare and halo and the size

of angle κ .¹⁵ However, 2 aspects should be considered in this regard: first, in that study, a refractive IOL was used, which is known to be associated with a higher incidence of glare and halos compared with a diffractive IOL, and second, many patients with high angle κ were also asymptomatic: as a matter of fact, the same authors concluded that the association between photic phenomena and angle κ needed to be evaluated in detail.^{15,24} It has been suggested that a large angle κ may contribute to functional decentration of MIOs, but the effect of this decentration is not clear.¹⁶

In our study, the good tolerance to larger pupil offset might be related to technical design of the tested IOL and, in particular, to the size of the first diffraction ring. In our opinion, it is likely that different optical designs of IOLs are likely to have different tolerance/threshold for pupil offset values. There are a number of arguments pointing to our conclusion. First, it was suggested that a probable reason for the potential incidence of photic phenomena in the case of a high angle κ after implantation of a diffractive MIOs may be the fact that the ray directed into the fovea does not pass directly through the center of the MIOs in the case of a high angle κ but approaches the edge of the first concentric ring.¹⁷ Second, it was demonstrated that the critical κ value depends mainly on the central part (diameter) of the IOL and that angle κ can be defined as critical if the incident ray passes through the first ring's edge area.¹⁸ In addition, it was suggested that a MIOs is unacceptable for use if the κ value is greater than half of the diameter of the central optical zone.¹⁶ Based on that hypothesis, the ReSTOR IOL (Alcon Laboratories, Inc.) would have a tolerance for a pupil offset value no greater than 0.4 mm, and the Tecnis IOL (Abbott Medical Optics, Inc.) would have a tolerance for a pupil offset value no greater than 0.5 mm.¹⁶ For the FineVision POD F IOL tested in this study, the diameter of the first diffraction ring (after hydration) is 1.125 mm—which is larger than usual—meaning that the critical value for pupil offset would be 0.6 mm. Thus, this might be one of the reasons for the low incidence of complaints for halos found in our study, even in those patients with pupil offset values exceeding the threshold values reported in other studies found in the literature.^{16,19}

This study has some limitations, mainly due to the small population size and the questionnaire not being validated. However, our study indicated that after implantation of the PhysIOL POD F IOL, there was a small but significant decrease in pupil offset values. Moreover, the size of the

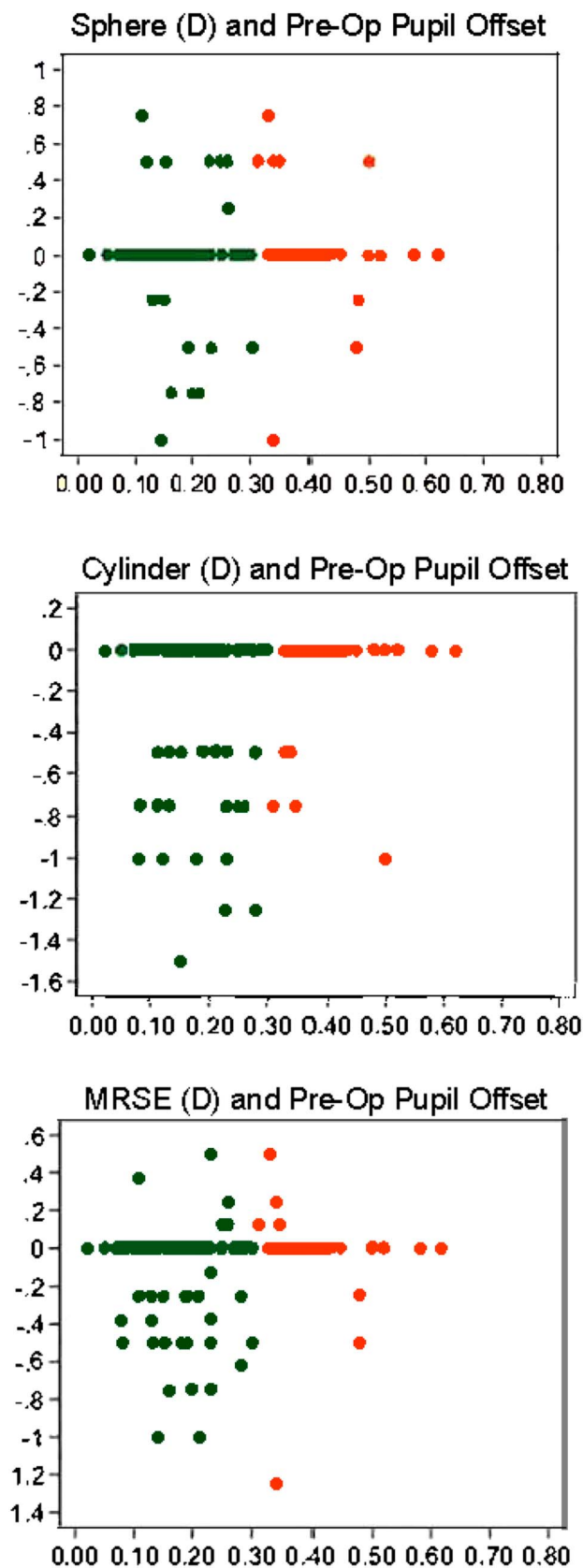


Figure 4. Distribution of refractive outcomes for both the small pupil offset group (≤ 0.30 mm) and the large pupil offset group (> 0.30 mm). The x-axis represents the pupil offset in millimeters and the y-axis represents the postoperative sphere, cylinder, and MRSE in diopters (MRSE = manifest refraction spherical equivalent).

pupil offset value did not affect the postoperative vision, as no significant impact was observed; refractive and visual acuity outcomes were good, including in those patients whose pupil offset values exceeded the threshold values reported in other studies. Finally, only few patients complained about postoperative photic phenomena, and, surprisingly, most of them presented with low postoperative pupil offset values.

Last but not least, although various diffractive IOL models should be assessed to get more evidence on the association between the size of the central diffractive ring and pupil offset in terms of patient satisfaction, such a tolerance for high values seems to be related to the peculiar design of the IOL, in particular, to the fact that its first diffractive ring is larger than most of the other commonly used MIOLs.

WHAT WAS KNOWN

- Large angle κ and pupil offset have been associated with higher risk of postoperative photic phenomena.
- Angle κ can be defined as critical if the incident ray passes through the first ring's edge area.

WHAT THIS PAPER ADDS

- With the use of the diffractive PhysIOL POD F intraocular lens (IOL), the size of the pupil offset exhibited no effect on postoperative refractive and visual acuity outcomes.
- The postoperative pupil offset values significantly decreased compared with the preoperative values, thus hypothetically reducing the risk of postoperative symptoms.
- The tolerance of the IOL for large pupil offset values may be related to the diameter of its first diffractive ring, which is larger than other commercially available multifocal IOLs.

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000 Influence of angle κ on visual and refractive outcomes after implantation of a diffractive trifocal intraocular lens

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Visual and refractive outcomes, as well as satisfaction, were not negatively affected by large pupil offset after implantation of the POD F trifocal IOL.