



Posterior chamber collagen copolymer phakic intraocular lens with a central hole to correct myopia: One-year follow-up

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PURPOSE: To assess the predictability, stability, efficacy, and safety of a newly developed posterior chamber phakic intraocular lens (pIOL) (model V4c Visian Implantable Collamer Lens) to correct moderate to high myopia.

SETTING: Fernández-Vega Ophthalmological Institute, Oviedo, Spain.

DESIGN: Prospective case series.

METHODS: This study evaluated eyes that had implantation of the new pIOL model with a central hole for myopia correction. Uncorrected (UDVA) and corrected (CDVA) distance visual acuities, refraction, intraocular pressure (IOP), endothelial cell density, pIOL vault, and adverse events were evaluated over 12 months.

RESULTS: The study comprised 147 eyes of 80 patients. Preoperatively, the mean spherical equivalent (SE) was -8.80 diopters (D) \pm 2.60 (SD). At 12 months, the mean SE was -0.14 ± 0.26 D, with 93.9% of eyes within ± 0.50 D of the target and 100% of eyes within ± 1.00 D. The mean UDVA and CDVA were 0.028 ± 0.055 logMAR and 0.003 ± 0.013 logMAR, respectively. The efficacy and safety indices were 1.00 and 1.04, respectively. All eyes had unchanged CDVA or gained 1 or more lines during the follow-up. The IOP remained stable over time; no eye developed anterior subcapsular cataract. Twelve months postoperatively, the mean vault was 405.5 ± 184.7 μ m (range 100 to 980 μ m), and the mean endothelial cell loss was 1.7%.

CONCLUSION: The good refractive and visual acuity outcomes and the highly stable IOP values obtained over 12 months support the use of the new pIOL model with a central hole for the correction of moderate to high myopia.

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Phakic intraocular lens (pIOL) implantation is widely accepted as an effective refractive option for surgical correction of moderate to high ametropia. It is a reversible procedure that provides highly predictable and stable results while preserving accommodation.^{1,2}

Today, the Visian Implantable Collamer Lens (Staar Surgical Co.) is the only posterior chamber (PC) pIOL approved by the U.S. Food and Drug Administration for myopia correction. This pIOL is specifically designed to be implanted in the PC behind the iris and in front of the anterior capsule of the crystalline

lens, with the haptic zone resting on the ciliary sulcus.¹ Although previous studies have reported good refractive outcomes achieved with these IOLs in terms of predictability, safety, efficacy, and stability over time,^{2–7} several short-term and long-term postoperative complications have been described.⁸ Cataract formation is the major concern after pIOL implantation. This complication can result from direct physical contact between the pIOL and the crystalline lens because of insufficient vaulting once the IOL is implanted or from localized malnutrition caused by poor circulation

of the aqueous humor.⁸⁻¹⁵ On the other hand, the increase in intraocular pressure (IOP) frequently reported after pIOL implantation inevitably requires the surgeon to perform preoperative laser iridotomy or intraoperative peripheral iridectomy.^{2,8,16-18} These complementary procedures might be accompanied by some pain, especially in young patients, or with intraoperative iris hemorrhage, respectively, which adds surgical difficulties.¹⁸⁻²¹

Recently, a new pIOL model was developed to overcome such disadvantages. The V4c Visian Implantable Collamer Lens pIOL incorporates an artificial hole of 0.36 mm located in the center of the optic, the KS-Aquaport. Preliminary studies by Shimizu et al.^{22,23} and Alfonso et al.²⁴ have shown that implantation of this pIOL model for the treatment of myopia is safe and effective, with no vision-threatening complications and predictable and stable refractive results through the first months after surgery. The aim of the present study was to evaluate the clinical and refractive outcomes at 12 months in patients who had implantation of the new pIOL model to correct moderate to high myopia.

PATIENTS AND METHODS

This prospective study included patients who had Visian Implantable Collamer Lens (model V4c) pIOL implantation to correct myopia at Fernández-Vega Ophthalmological Institute, Oviedo, Spain. The study followed the tenets of the Declaration of Helsinki and was approved by an institutional review board. Written informed consent was obtained from all patients after they received a full explanation of the nature and possible consequences of the study.

The inclusion criteria were a corrected distance visual acuity (CDVA) of 20/40 or better, stable refraction with a myopic refractive error in the range correctable with the new pIOL (from -0.50 to -18.00 diopters [D]), and a clear central cornea. The exclusion criteria included age younger than 20 years, anterior chamber depth (ACD) from the corneal endothelium of less than 2.8 mm, endothelial cell density (ECD) less than 2000 cell/mm², mesopic pupil larger than 7.0 mm, cataract, history of glaucoma or retinal detachment, amblyopia, macular degeneration or retinopathy,

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neuro-ophthalmic disease, and a history of ocular inflammation.

Preoperative Assessment

Before pIOL implantation, patients had a complete ophthalmologic examination. The examination included uncorrected distance visual acuity (UDVA), CDVA, manifest and cycloplegic refractions, slitlamp examination, keratometry, corneal topography, and pachymetry (Orbscan II, Bausch & Lomb), ECD measurement (SP 3000P, Topcon Europe Medical B.V.), Goldmann applanation tonometry, anterior segment optical coherence tomography (AS-OCT) (Visante, Carl Zeiss Meditec AG), and binocular indirect ophthalmoscopy through dilated pupils.

Phakic Intraocular Lens

The V4c Visian Implantable Collamer Lens model is made of Collamer, a flexible, hydrophilic, and biocompatible material composed of collagen and hydroxyethyl methacrylate with an ultraviolet-absorbing chromophore. It has a plate-haptic design with a central convex-concave optical zone and incorporates forward vault to minimize contact with the crystalline lens. The new model used in this study has an artificial hole of 0.36 mm diameter in the center of the optic that is designed to improve aqueous humor circulation and obviates the need for laser or surgical peripheral iridotomy or iridectomy. This pIOL is available in 4 overall lengths as follows: 12.1 mm, 12.6 mm, 13.2 mm, and 13.7 mm. It is designed to correct myopia in a power range from -0.50 to -18.00 D. In all eyes, emmetropia was selected as the postoperative target refraction. The pIOL size was individually determined based on the horizontal white-to-white distance and ACD measured with pachymetry and following the pIOL manufacturer's recommendations. Power calculation of the pIOL was performed using the modified vertex formula of the pIOL power table software also provided by the manufacturer. The pIOL implantation technique has been described.²⁴

Postoperative Assessment

Postoperative follow-up visits were scheduled at 3, 6, and 24 hours; 1 week; and 1, 3, 6, and 12 months. The examinations included measurement of UDVA and CDVA, refraction, slitlamp evaluation, tonometry, ECD, and funduscopy. The central distance between the pIOL and the crystalline lens (vault) was also assessed subjectively (slitlamp) and objectively (AS-OCT); subjective assessment was always performed first. The vault was measured perpendicular to the lens apex or at the narrowest space between both surfaces.

Outcome Measures

Assessment of outcomes was based on a comparison of preoperative and postoperative visual acuity values, UDVA (efficacy) and CDVA (safety), and the achieved versus the expected refractive outcomes postoperatively (predictability). A complete analysis of adverse complications was performed. The efficacy index (ratio of postoperative UDVA to preoperative CDVA) and the safety index (ratio of postoperative to preoperative CDVA) were also calculated. The percentage of ECD loss was determined as follows: endothelial cell loss (%) = (preoperative ECD - postoperative ECD)/preoperative ECD.

Statistical Analysis

Statistical analysis was performed using SPSS for Windows software (version 18.0, SPSS, Inc.). The Kolmogorov-Smirnov test was used to evaluate the normality of the data distribution. The nonparametric Wilcoxon signed-rank test was used to determine statistical significant differences between preoperative and postoperative refractive and visual outcomes. Visual acuity data were converted to logMAR values. Differences were considered statistically significant when the *P* value was less than 0.05.

RESULTS

This study enrolled 147 eyes of 80 patients, of which 61 (76.2%) were women and 19 (23.8%) were men. **Table 1** shows the preoperative demographic data of the patients and the pIOL characteristics. All patients completed the follow-up period.

Predictability

Figure 1 shows a scatterplot of the attempted versus the achieved spherical equivalent (SE) correction. Twelve months after surgery, 138 eyes (93.9%) were within ± 0.50 D of the desired SE refraction and all eyes (100%) were within ± 1.00 D ($r^2 = .991$).

Stability

Figure 2 shows the change in the mean SE and the stability of refraction over time. The mean SE was -8.80 ± 2.60 D preoperatively and -0.14 ± 0.26 D 12 months postoperatively; the decrease was statistically significant ($P < .0001$). The mean change in SE throughout the follow-up was -0.02 ± 0.18 D.

Efficacy

The mean postoperative UDVA was 0.026 ± 0.052 logMAR, 0.028 ± 0.059 logMAR, 0.030 ± 0.054 logMAR, and 0.028 ± 0.055 logMAR at 1, 3, 6, and 12 months, respectively. Twelve months after pIOL implantation, the logMAR UDVA was statistically significantly better than the preoperative logMAR CDVA ($P < .05$). All eyes had a decimal UDVA of 0.5 (20/40) or better at every follow-up visit. The decimal UDVA was 1.0 (20/20) or better in 108 eyes (73.5%), 109 eyes (74.2%), 101 eyes (68.7%), and 100 eyes (68.0%) at 1, 3, 6, and 12 months, respectively. The efficacy index was 1.00 at 12 months.

Safety

Preoperatively, the mean CDVA was 0.020 ± 0.059 logMAR. After pIOL implantation, the mean CDVA was 0.010 ± 0.033 logMAR, 0.007 ± 0.030 logMAR, 0.010 ± 0.034 logMAR, and 0.003 ± 0.013 logMAR at 1, 3, 6, and 12 months, respectively. There was a statistically significant improvement in logMAR CDVA

Table 1. Preoperative patient demographics and pIOL characteristics.

Parameter	Mean \pm SD	Range
Patients		
Age (y)	30.4 \pm 4.8	20, 40
Manifest refraction (D)		
Sphere	-8.38 \pm 2.51	-17.50, -2.75
Cylinder	-0.84 \pm 0.77	-3.00, 0.00
Keratometry (D)		
Steep	44.44 \pm 1.84	40.00, 48.00
Flat	43.39 \pm 1.61	39.50, 46.50
Pachymetry (μ m)	534 \pm 36	441, 630
ECD (cells/mm ²)	2697 \pm 371	2000, 3839
ACD (mm)	3.18 \pm 0.24	2.80, 3.83
WTW distance (mm)	11.73 \pm 0.37	11.00, 13.45
ATA distance (mm)	11.97 \pm 0.45	11.09, 13.45
IOP (mm Hg)	13.1 \pm 1.9	10, 18
Pupil size (mm)		
Photopic	4.7 \pm 0.9	2.5, 6.0
Scotopic	6.4 \pm 0.6	5.0, 7.0
Phakic IOL		
Size (mm)	13.1 \pm 0.3	12.6, 13.7
Power (D)	-9.65 \pm 2.47	-3.50, -18.00

ACD = anterior chamber depth; ATA = angle to angle; ECD = endothelial cell density; IOL = intraocular lens; IOP = intraocular pressure; WTW = white-to-white

after surgery ($P < .05$). All eyes achieved a decimal CDVA of 0.8 (20/25) or better at every follow-up visit; 137 eyes (93.2%) had a CDVA of 1.0 (20/20) or better 12 months after pIOL implantation. **Figure 3** shows the changes in CDVA outcomes. By 12 months, no eye lost 1 or more lines, 116 eyes (78.9%) did not change from preoperatively, 21 eyes (14.3%) gained 1 line, 5 eyes (3.4%) gained 2 lines, and 5 eyes (3.4%)

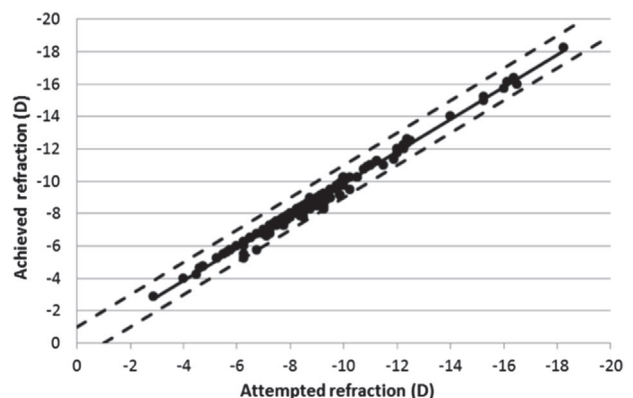


Figure 1. Predictability of mean SE (attempted versus achieved correction) 12 months after pIOL implantation. The continuous line represents the best linear fit to the data ($0.997 \times +0.112$, $r^2 = 0.991$). Dotted lines correspond to ± 1.00 D of intended correction.

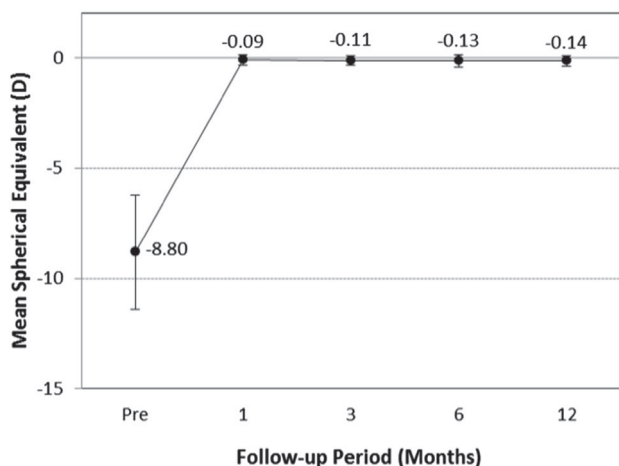


Figure 2. Time course of SE (stability) after pIOL implantation.

gained more than 2 lines of CDVA. The safety index was 1.04 at 12 months after surgery.

Intraocular Pressure, Endothelial Cell Density, and Vault

Figure 4 shows the IOP variation over time. The mean IOP was 13.1 ± 1.9 mm Hg (range 10 to 18 mm Hg) before surgery. Postoperatively, the mean IOP was 12.3 ± 1.2 mm Hg, 12.4 ± 1.1 mm Hg, 12.4 ± 1.3 mm Hg, and 12.4 ± 1.4 mm Hg at 1, 3, 6, and 12 months, respectively. No statistically significant differences in mean IOP between visits were detected ($P > .05$). Twelve months after pIOL implantation, 109 eyes (74.1%) had no variation or a reduction from the preoperative IOP, 32 eyes (21.8%) increased 1 to 2 mm Hg from the preoperative IOP, 6 eyes (4.1%) increased 3 mm Hg from the preoperative IOP, and no

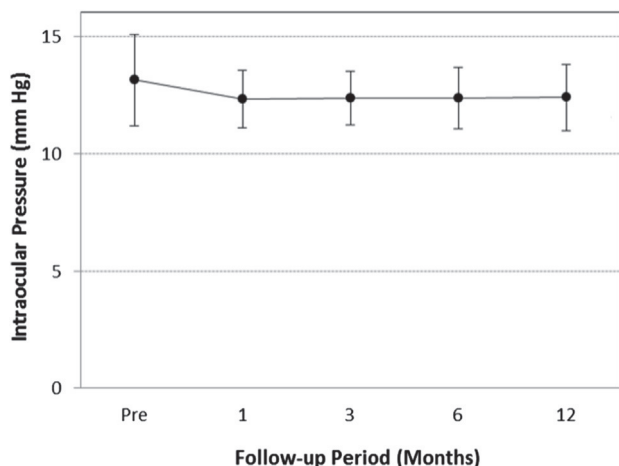


Figure 4. Time course of IOP after pIOL implantation.

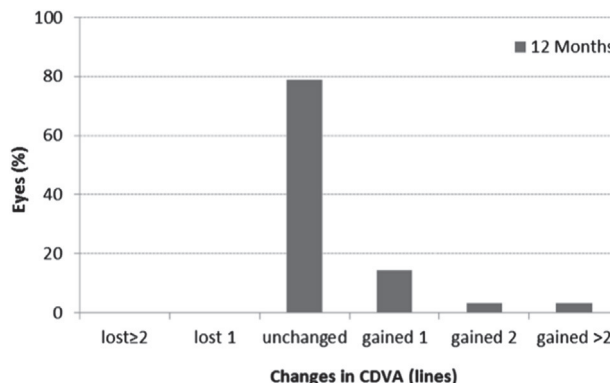


Figure 3. Changes in CDVA from preoperatively to 12 months postoperatively (safety) (CDVA = corrected distance visual acuity).

eyes had an increase of 4 mm Hg or more. No significant rise in IOP (> 20 mm Hg) occurred in any case.

The mean ECD decreased from 2696.58 ± 370.94 cells/ mm^2 preoperatively to 2650 ± 348 cells/ mm^2 12 months postoperatively, representing a mean endothelial cell loss of 1.7%. The mean postoperative vault assessed at the slitlamp was 2.2 ± 0.6 at 1 month, 2.1 ± 0.6 at 3 months, 2.0 ± 0.6 at 6 months, and 2.1 ± 0.6 at 12 months. The mean vault measured with AS-OCT was 495.97 ± 185.5 μm (range 150 to 990 μm), 446.9 ± 189.2 μm (range 100 to 980 μm), 422.5 ± 185.2 μm (range 120 to 970 μm), and 405.5 ± 184.7 μm (range 100 to 980 μm) at 1, 3, 6, and 12 months, respectively. Statistically significant differences in the mean vault between follow-up visits were found ($P < .0001$).

Adverse Events and Secondary Surgeries

There were no intraoperative complications, and no eye required pIOL explantation or repositioning. Over the 12-month follow-up, no cases of cataract, pigment dispersion glaucoma, pupillary block, or other vision-threatening complications were found.

DISCUSSION

Previous studies²²⁻²⁴ have reported the clinical and refractive results of patients who had implantation of the V4c Visian Implantable Collamer Lens pIOL for the correction of moderate to high myopia. However, these studies focused on outcomes after only 3 to 6 months. Considering that the number of complications associated with pIOL implantation, such as cataract formation, endothelial cell loss, pigmentary glaucoma, and pupillary block, is expected to increase with time,^{8-20,25} a long-term assessment is required.

The aim of the present study was to confirm good results in terms of predictability, stability, efficacy, and safety of the new pIOL model with a central hole to correct myopia and to analyze the possible occurrence of adverse events throughout a 12-month follow-up. We evaluated 147 myopic eyes (mean SE -8.80 ± 2.60 D) of 80 patients who had V4c Visian Implantable Collamer Lens pIOL implantation. We obtained stable (mean SE change -0.02 ± 0.18 D) and predictable refractive outcomes, with 138 eyes (93.9%) being within ± 0.50 D of the attempted correction and all eyes (100%) within ± 1.00 D at 12 months. The visual outcomes in relation to the safety index (1.04 at 12 months) and efficacy index (1.00 at 12 months) were also satisfactory, with most eyes maintaining or improving CDVA and no eye losing 1 or more lines. In addition, there was an improvement in UDVA (0.028 ± 0.055 logMAR), with 68.0% of eyes achieving a UDVA of 20/20 or better 12 months after pIOL implantation. These results were in line with those of previous studies.^{22,24}

The first study of a pIOL with a central hole performed by Shimizu et al.²² in 20 myopic eyes (mean SE -7.36 ± 2.13 D) reported 95% and 100% of eyes being within ± 0.50 D and ± 1.00 D, respectively, of the target correction. With regard to visual acuity, they found postoperative UDVA and CDVA values better than 20/20 (mean -0.25 ± 0.06 logMAR) during all follow-up visits and high safety (1.13) and efficacy (1.03) indices. Alfonso et al.²⁴ also reported highly predictable results in a previous study of 138 eyes (70 patients), with 98.6% and 100% of eyes within ± 0.50 D and ± 1.00 D, respectively, 6 months after surgery. In that study, the mean postoperative UDVA and CDVA were 0.009 ± 0.062 logMAR and -0.015 ± 0.032 logMAR, respectively, with almost all eyes maintaining CDVA or gaining 1 or more lines, resulting in a safety index of 1.01 at 6 months. Although all these studies evaluated the same pIOL model, a different amount of myopia might cause slight variations in the outcomes between studies.

Despite these good results, there are still concerns about whether the presence of an artificial hole in the center of the optic will deteriorate the optical quality of the V4c Visian and therefore the patient's visual performance (eg, as a result of the halos or glare introduced by the IOL). An animal model²⁶ and in vitro optical studies²⁷⁻²⁹ have reported good and comparable optical quality outcomes of a pIOL with and without a central hole, even when different degrees of decentration are induced.²⁹ Therefore, no significant differences in visual performance are expected between the IOL types. A recent study by Shimizu et al.²³ evaluated 58 eyes of 29 patients who had a conventional

pIOL in 1 eye and hole pIOL in the other eye to correct moderate to high myopia. Higher-order ocular aberrations, contrast sensitivity function, and subjective symptoms were assessed 3 months after surgery. This study concluded that implantation of the pIOL with the hole appears to be equivalent to the standard nonhole pIOL model in terms of visual performance. Similarly, Ferrer-Blasco et al.³⁰ and Pérez-Vives et al.³¹ performed a comparative study of the visual quality provided by the 2 pIOL designs, the first one using a contact lens-based system and the other using an adaptive optic system to simulate vision from the pIOL's aberration pattern. Both studies agreed that there were no statistically differences in visual performance (ie, visual acuity and contrast sensitivity) between conventional and hole pIOLs. These outcomes suggest that the impact of the central artificial hole in the optic of the V4c Visian pIOL is clinically negligible. Our results agree with this finding considering that our good visual outcomes are similar to those reported in previous studies evaluating the earlier version of this pIOL.^{2,4,11,13}

Regarding adverse events, the major concerns of PC pIOL implantation are cataract formation^{8-15,31,32} and increased IOP.^{8,16} Cataract formation has been attributed mainly to the lack of or lower vault and the tendency of the vault to decrease slightly over time, causing continuous or intermittent pIOL-crystalline lens contact (late cataract formation).^{14,31} Specifically, insufficient vault can provoke the formation of cataract by mechanical irritation of the anterior capsule or by obstruction of the aqueous humor circulation toward the anterior surface of the crystalline lens.^{8,15} Several studies suggest the possibility of preventing cataracts by placing a hole in the center of the pIOL optic to improve the circulation of the aqueous humor.^{15,26} Fujisawa et al.¹⁵ found in a porcine model that implantation of a pIOL with a 3.0 mm central hole was highly effective for reducing the incidence of cataract formation. Then, Shiratani et al.²⁶ reported that a pIOL with a central hole of 1.0 mm diameter had no optical effect on vision and was sufficient to increase the aqueous humor-perfusion volume on the anterior surface of the crystalline lens, preventing cataract formation. According to these studies, the central hole in the V4c Visian pIOL used in the present study contributes to improved aqueous humor circulation and, therefore, less cataract formation is expected. We found no cataract formation in any case throughout the follow-up, which agrees with findings reported in previous studies.²²⁻²⁴ However, considering the tendency of vault to decrease over time, a detailed control of the amount of central vault after pIOL implantation has to be performed. In a 3-year follow-up study,

Alfonso et al.¹⁴ reported a significantly higher reduction of vault in the first 6 months after surgery, with slight vault variations beyond this period. Similarly, our study showed a trend toward a decrease in vault over time, with the mean vault being $405.5 \pm 184.7 \mu\text{m}$ (range 100 to 980 μm) at 12 months. However, when we evaluated the distribution of eyes taking into account the vault obtained, we found that in most of the eyes, the vault was between 400 μm and 600 μm . Despite this finding, eyes with vault values from 100 to 200 μm (approximately 8%) and from 900 to 1000 μm (approximately 1.5%) were followed closely.

On the other hand, the introduction of an artificial central hole in the pIOL offers surgical advantages over the earlier models. Conventional pIOL implantation inevitably requires a preoperative neodymium:YAG iridotomy or intraoperative peripheral iridectomy to prevent an increase in IOP¹⁶ that is frequently associated with pupillary block^{18,19} or with chronic pigment dispersion.²⁰ In some cases, these complementary procedures can cause discomfort for the patient or intraoperative surgical difficulties.^{18–21} However, the central hole in the optic of the V4c Visian pIOL allows better flow of aqueous humor, which eliminates the need for laser iridotomy or iridectomy and, therefore, the potential complications of these additional procedures. Despite this advantage, it is important to control the changes in IOP after pIOL implantation. Previous studies^{22,24,33,34} found no statistically significant variations in IOP over time after V4c pIOL implantation. In addition, Higuera-Esteban et al.³⁴ found comparable IOP values 3 months after model V4b and V4c pIOL implantation, even without performing preoperative or intraoperative peripheral iridotomies or iridectomies. In the present study, we found no significant rise in IOP (>20 mm Hg) in any case, with stable IOP values during the 12-month follow-up. However, our postoperative IOP outcomes were lower than those reported in previous studies.^{22,24,33,34} Thus, when we evaluated variations in IOP over time and calculated the change between preoperative and postoperative values, we found that most eyes (74.1%) had no IOP variations or showed a reduction of 1 to 2 mm Hg from the preoperative IOP.

In summary, the outcomes in the present study indicate that V4c pIOL implantation is an effective, safe, and predictable alternative for the correction of moderate to high myopia. The central port simplifies surgery and appears to reduce postoperative complications. Future studies should include the toric V4c pIOL model and long-term evaluation to assess the safety and stability of that surgical procedure.

WHAT WAS KNOWN

- Implantation of a pIOL is a safe and effective procedure that provides predictable and stable results in the correction of moderate to high ametropia. Conventional pIOL implantation inevitably requires the surgeon to perform a preoperative laser iridotomy or intraoperative peripheral iridectomy, which adds surgical difficulties.
- The newly developed pIOL with an artificial central hole of 0.36 mm diameter improves aqueous humor circulation and removes the need for additional procedures.

WHAT THIS PAPER ADDS

- Implantation of the pIOL with a central hole for the treatment of myopia was safe and effective, with no vision-threatening complications and with predictable and stable refractive results throughout a 12-month follow-up.

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