Clinical outcomes after implantation of a posterior chamber collagen copolymer phakic intraocular lens with a central hole for myopic correction

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PURPOSE: To evaluate the efficacy, predictability, safety, and stability of a new-model posterior chamber Implantable Collamer Lens phakic intraocular lens (pIOL) (V4c Visian) to correct myopia.

SETTING: Private practice, Oviedo, Spain.

DESIGN: Case series.

METHODS: This study enrolled patients who had implantation of a new pIOL design with a central hole for more natural aqueous flow, eliminating the need for neodymium:YAG iridotomy or peripheral iridectomy. The uncorrected (UDVA) and corrected (CDVA) distance visual acuities, refractive error, intraocular pressure (IOP), endothelial cell count, central vault, and adverse events were evaluated 6 months postoperatively.

RESULTS: The study enrolled 138 eyes (70 patients). The mean spherical equivalent decreased from −8.73 diopters (D) ± 2.54 (SD) preoperatively to −0.03 ± 0.19 D 6 months postoperatively; 98.5% of eyes were within ±0.50 D and 100% of eyes were within ±1.00 D. The mean UDVA and CDVA were 20/20 or better in 92.1% and 95.0% of eyes, respectively, at 6 months. The safety and efficacy indices were 1.01 and 1.00, respectively. Postoperatively, the IOP remained stable over time. No significant rises in IOP (including pupillary block) and no secondary cataract were found. After 6 months, the mean vault was 482.7 ± 210.5 μm (range 90 to 970 μm) and the mean endothelial cell loss was 8.5%.

CONCLUSIONS: Implantation of the pIOL was effective, predictable, safe, and stable for the correction of moderate to high myopic errors. This design, which avoids iridotomy or iridectomy, provided good IOP outcomes.

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Phakic intraocular lens (pIOL) implantation has become an important refractive surgery option to correct moderate to high levels of ametropia. The predictability, stability of visual quality, reversibility, and preservation of accommodation are several advantages that have been attributed to this surgical procedure.[1,2]

The Visian Implantable Collamer Lens (Staar Surgical Co.) is a pIOL designed to be placed in the posterior chamber, just behind the iris with the haptic zone resting on the ciliary sulcus.[1] Previous studies have reported that implantation of this pIOL is a safe and effective treatment option in the refractive correction of myopia,[2–4] hyperopia,[5,6] and astigmatism[7,8] and in patients who may not be suitable candidates for corneal reshaping procedures.[9,10] However, due to its location, short-term and long-term postoperative complications have been described.[11] Complications include anterior subcapsular cataract,[12–17] increased intraocular pressure (IOP),[18] endothelial cell loss,[19] pigment dispersion,[20] pupillary block,[21,22] and glaucoma.[18,20,21] Anterior subcapsular opacities are also common in the early days of pIOL implantation. They result from surgical trauma or continuous pIOL–crystalline lens contact because of insufficient vaulting.[12–17] On the other hand, the increase in IOP, mostly associated with acute pupillary block or with chronic pigment dispersion, is related to inadequate preoperative or intraoperative iridectomies[2,11,21,22] and

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the mechanical contact between the pIOL and the iris in eyes with excessive pIOL vault.[11,15]

The Staar pIOL models have undergone successive improvements to overcome these disadvantages. Recently, the model V4c Visian Implantable Collamer Lens pIOL was designed with a central hole of 0.36 mm. Shimizu et al.[23] performed a preliminary study in a small series of 20 eyes in which an Implantable Collamer Lens pIOL with a hole was implanted. The purpose of the present study was to assess the clinical and refractive outcomes in a large sample of patients who had implantation of the model V4c pIOL to correct myopia over a 6-month follow-up.

PATIENTS AND METHODS

Enrollment and Baseline

This prospective study comprised patients who had implantation of a myopic V4c Visian Implantable Collamer Lens pIOL for the correction of moderate to high myopia. All patients provided written informed consent after the nature and possible consequences of the study were explained fully in accordance with the Declaration of Helsinki. Institutional review board approval was obtained.

Inclusion criteria were myopia in the range correctable with the V4c pIOL (from −0.50 diopter [D] to −18.00 D), age older than 20 years, corrected distance visual acuity (CDVA) of 20/40 or better, stable refraction, and a clear central cornea. Exclusion criteria included previous corneal refractive surgery, anterior chamber depth (ACD) from the endothelium of less than 2.8 mm, corneal endothelial cell density less than 2000 cell/mm^2, mesopic pupil larger than 7.0 mm, cataract, history of glaucoma, amblyopia, retinal detachment, diabetic retinopathy, macular degeneration, neuro-ophthalmic disease, and a history of ocular inflammation.

Preoperative Evaluation

Before surgery, patients had a full ophthalmologic examination including uncorrected distance visual acuity (UDVA), CDVA, manifest and cycloplegic refractions, slitlamp evaluation, tonometry, gonioscopy, keratometry, corneal pachymetry and topography (Orbscan II, Bausch & Lomb), central endothelial cell count (ECC) (SP 3000P, Topcon Europe Medical), and binocular indirect ophthalmoscopy through dilated pupils.

Intraocular Lens

The V4c Visian Implantable Collamer Lens posterior chamber pIOL is made from Collamer, a biocompatible hydrophilic copolymer of collagen and hydroxyethyl methacrylate with an ultraviolet light–filtering chromophore. This model is designed to correct myopia. It has a plate-haptic design with a central convex–concave optical zone and incorporates forward vault to minimize contact of the pIOL with the central anterior capsule of crystalline lens. A central hole of 0.36 mm, the KS-Aquaport, defines the new design of the V4c pIOL (Figure 1). This hole allows more natural flow of the aqueous humor (Centraflow technology), eliminating the need to perform preoperative or intraoperative Nd:YAG peripheral iridectomies. The pIOL is available in 4 overall lengths (12.1 mm, 12.6 mm, 13.2 mm, and 13.7 mm) and a myopic dioptric power range of −0.50 to −18.00 D.

The power of the pIOL was calculated using the pIOL power table software provided by the manufacturer; the table uses a modified vertex formula. The targeted refraction was emmetropia in all cases. The size of the pIOL was also chosen by the manufacturer based on the horizontal white-to-white distance and ACD measured with the Orbscan II device.

Surgical Technique

All surgeries were performed by the same experienced surgeon (J.F.A) at the Department of Refractive Surgery, the Ophthalmologic Institute Fernández-Vega, Spain. Thirty minutes before surgery, tropicamide and phenylephrine eyedrops were instilled. Five minutes before surgery, povidone–iodine 5% (Betadine) was applied. The surgical procedure was performed through a single-plane 3.0 to 3.2 mm corneal incision centered at the steepest meridian under peribulbar anesthesia. The anterior chamber was filled with sodium hyaluronate 1% (Provisc), which was completely removed at the end of the surgery. The pIOL was inserted with the use of an injector cartridge (Staar Surgical Co.). No preoperative or intraoperative peripheral iridectomies were performed in any case.

Postoperative topical therapy included tobramycin and dexamethasone 0.1% (Tobradex) eyedrops 4 times for 7 days, after which diclofenac sodium eyedrops (Voltaren) were prescribed 4 times daily for 2 weeks. Lubricant eyedrops were also prescribed 3 to 4 times daily when needed. In cases of bilateral implantation, the second eye was operated on within 1 week after the first surgery.

Postoperative Assessment

Postoperative follow-up visits were scheduled at 3, 6, and 24 hours (early postoperative); 1 week; and 1, 3, and 6 months. The examinations included UDVA, CDVA, refractive status, slitlamp examination, tonometry, gonioscopy, ECC, subjective (slitlamp) and objective (Visante optical coherence tomography [OCT], Carl Zeiss Meditec AG) vault assessment, and fundoscopy. The vault between the crystalline lens and the pIOL was measured perpendicular to the lens apex or at the narrowest space between both.

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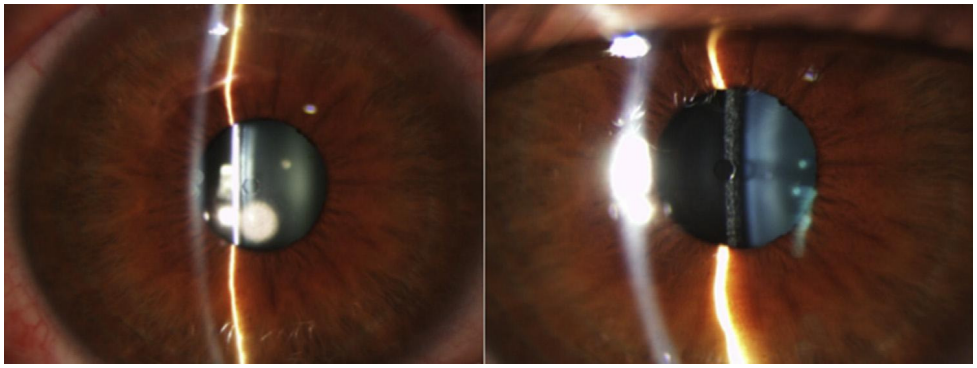

Figure 1. The pIOL implanted in 2 eyes.

Outcomes

Assessment of outcomes was based on preoperative versus postoperative UDVA and CDVA values (efficacy and safety, respectively), the expected versus the achieved refractive outcomes postoperatively (predictability), and adverse complications. The efficacy index (ratio of postoperative UDVA to preoperative CDVA) and the safety index (ratio of postoperative to preoperative CDVA) were also calculated.

Statistical Analysis

Data analysis was performed using SPSS statistical software (version 18.0, SPSS, Inc.). Normality of data was checked by the Kolmogorov-Smirnov test. Statistical differences between preoperative and postoperative refractive and visual outcomes were analyzed with Wilcoxon signed-rank test. All recorded visual acuity data were converted to logMAR values. Differences with a *P* value less than 0.05 were considered statistically significant.

RESULTS

This study evaluated 138 eyes of 70 patients. Of the 70 patients enrolled, 19 (27.1%) were men and 51 (72.9%) were women. The mean age at the time of surgery was 30.5 years ± 4.8 (SD) (range 20 to 41 years). Table 1 shows the preoperative patient demographics and pIOL parameters.

Table 1. Patient demographic data and pIOL characteristics.

Parameter	Mean ± SD	Range [Min, Max]
Age (y)	30.5 ± 4.8	20, 41
Refractive sphere (D)	−8.16 ± 2.54	−3.00, −17.50
Refractive cylinder (D)	−1.16 ± 0.64	−0.25, −3.00
CDVA (Snellen lines)	0.9 ± 0.1	0.5, 1.0
Pachymetry (μm)	539 ± 35	448 to 625
ECD (cells/mm^2)	2770 ± 390	2000, 3839
ACD (mm)	3.31 ± 0.25	2.80, 3.40
White to white (mm)	11.99 ± 0.44	11.25, 13.45
IOP (mm Hg)	13.2 ± 1.9	10, 17
pIOL size (mm)	13.16 ± 0.34	12.6, 13.7
pIOL power (D)	−9.52 ± 2.60	−3.50, −18.00

ACD = anterior chamber depth; CDVA = corrected distance visual acuity; ECD = endothelial cell density; IOP = intraocular pressure; pIOL = phakic intraocular lens

Efficacy

The mean postoperative UDVA was 0.055 ± 0.111 logMAR, 0.019 ± 0.040 logMAR, 0.020 ± 0.041 logMAR, and 0.009 ± 0.062 logMAR at 1 week, 1 month, 3 months, and 6 months. There was a statistically significant difference between the preoperative and 6-month postoperative logMAR UDVA ($P < .0001$). The decimal UDVA was 0.5 (20/40) or better in all eyes at all times after surgery. It was 1.0 (20/20) or better in 86 eyes (62.3%) at 1 week, in 104 eye (75.4%) at 1 month, in 114 eyes (82.6%) at 3 months, and in 127 eyes (92.0%) at 6 months. The efficacy index at 6 months was 1.00.

Predictability

Figure 2 shows the deviation of the achieved spherical equivalent (SE) from the attempted refraction

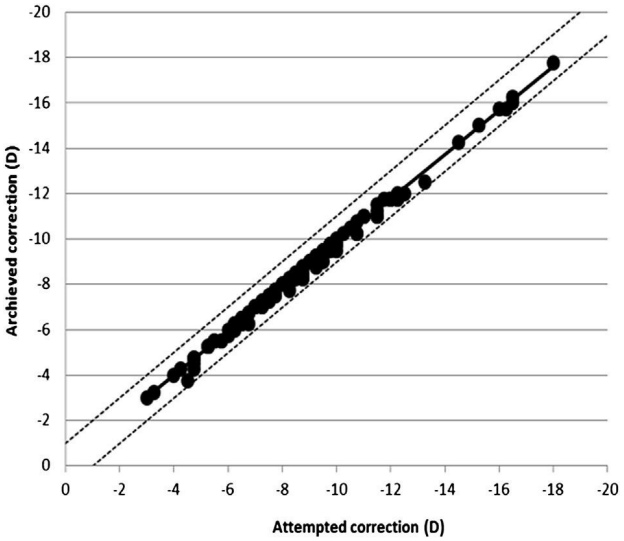

Figure 2. Spherical equivalent predictability (attempted versus achieved correction) 6 months postoperatively. The continuous line represents the best linear fit to the data (0.973x–0.101; $r^2 = 0.99$). *Dotted lines* correspond to ±1.00 D of intended correction.

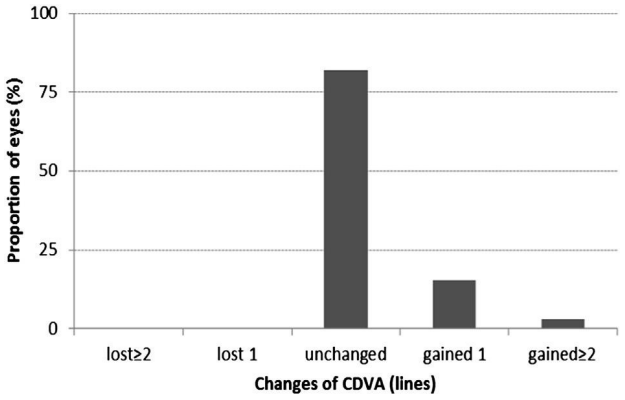

Figure 3. Changes in CDVA from preoperatively to 6 months postoperatively (safety) (CDVA = corrected distance visual acuity).

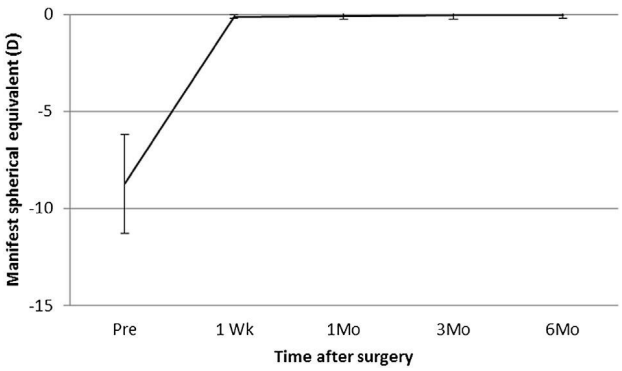

Figure 4. Time course of manifest SE.

(r^2 = .995). Six months postoperatively, the SE was close to emmetropia (mean −0.03 ± 0.19 D), with 136 eyes (98.55%) within ±0.50 D and all eyes (100%) within ±1.00 D.

Safety

The mean postoperative CDVA was 0.018 ± 0.092 logMAR, 0.006 ± 0.021 logMAR, 0.008 ± 0.040 logMAR, and −0.015 ± 0.032 logMAR at 1 week, 1 month, 3 months, and 6 months, respectively. All eyes achieved a decimal CDVA of 0.8 (20/25) or better after pIOL implantation, with 131 eyes (94.9%) having a CDVA of 1.0 (20/20) or better after 6 months of follow-up. There was a significant improvement in logMAR CDVA after surgery ($P < .05$). No eye lost 1 or more lines, 113 eyes (81.9%) did not change from preoperatively, 21 eyes (15.2%) gained 1 line, and 4 eyes (2.9%) gained 2 lines (Figure 3). The safety index was 1.01 at 6-month follow-up.

Stability

Figure 4 shows the improvement and stability of the mean SE over time. The mean preoperative SE was −8.73 ± 2.54 D. The mean postoperative SE was −0.11 ± 0.10 D at 1 week, −0.09 ± 0.15 D at 1 month, −0.04 ± 0.20 D at 3 months, and −0.03 ± 0.19 D at 6 months. The decrease in the mean SE from preoperatively to 6 months postoperatively was statistically significant ($P < .0001$).

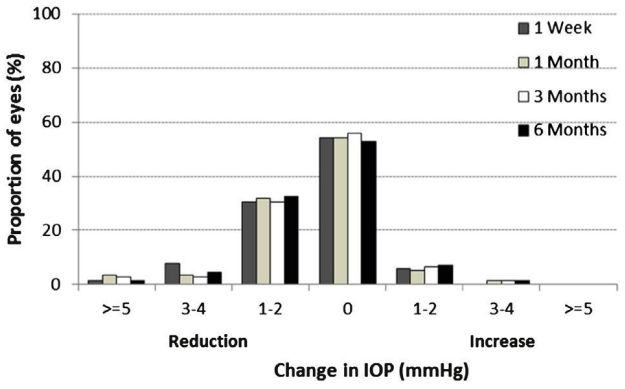

Figure 5. Postoperative changes in IOP (IOP = intraocular pressure).

Intraocular Pressure, Vault, and Endothelial Cell Count

Figure 5 shows the change in IOP over time. The figure reflects the percentage of eyes over the whole sample that had an increase or reduction of 1 to 2 mm Hg, 3 to 4 mm Hg, or more than 5 mm Hg or no variations from preoperatively to postoperatively. The mean IOP was 13.2 ± 1.9 mm Hg preoperatively. Postoperatively, the mean IOP was 11.9 ± 1.1 mm Hg in the early postoperative period, 12.2 ± 1.6 mm Hg at 1 week, 12.3 ± 1.3 mm Hg at 1 month, 12.4 ± 1.3 mm Hg at 3 months, and 12.4 ± 1.5 mm Hg at 6 months. No significant rise in IOP (>20 mm Hg) occurred in any case during the 6-month follow-up.

The mean postoperative vault measured with OCT was 571.5 ± 188.8 µm (range 210 to 990 µm), 565.1 ± 188.6 µm (range 210 to 990 µm), 534.5 ± 202.9 µm (range 120 to 980 µm), and 482.7 ± 210.5 µm (range 90 to 970 µm) at 1 week, 1 month, 3 months, and 6 months, respectively. There was a trend toward a decrease in the mean objective vault over time. There were statistically significant differences in the mean vault between follow-up visits ($P < .0001$). Figure 6 shows the distribution of vault postoperatively over time.

The mean ECC varied significantly from 2770 cells/mm^2 preoperatively to 2533 cells/mm^2 6 months after surgery ($P < .0001$). This represents a mean endothelial cell loss of 8.5%.

Adverse Events and Secondary Surgeries

There were no complications during the surgical procedure. Postoperatively, no eye required pIOL

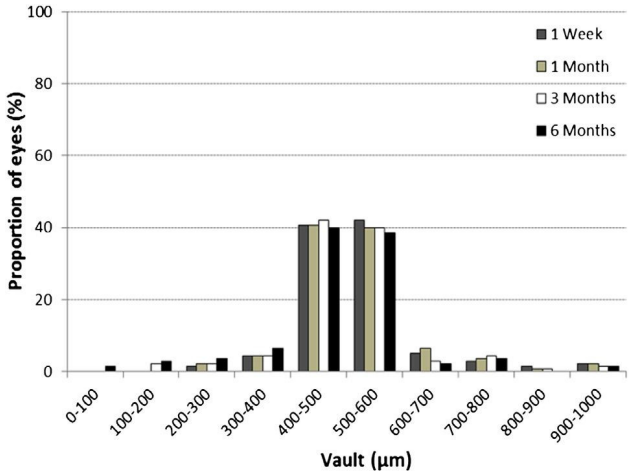

Figure 6. Distribution of eyes according to the vault over time.

explantation or repositioning, and there were no cases of decentration of the pIOL optic. No cataract formation, pigmentary glaucoma, pupillary block, or other vision-threatening complications occurred at any time during the 6-month follow-up.

DISCUSSION

The aim of the current study was to determine whether implantation of the V4c Visian Implantable Collamer Lens pIOL is safe, predictable, and effective for myopia correction and to analyze the benefits or disadvantages related to the new design. A preliminary study of a pIOL with a central hole was performed by Shimizu et al.[23] in 2011. They evaluated 20 myopic eyes (SE −7.36 ± 2.13 D) of 20 patients and found high safety (1.13) and efficacy (1.03) indices, with 95% and 100% of eyes within ±0.50 D and ±1.00 D, respectively, of the targeted correction at the 6-month follow-up. The current study followed similar methodology but in a larger sample of patients (138 eyes of 70 patients) who had V4c Visian Implantable Collamer Lens pIOL implantation. We obtained similar refractive outcomes; results were stable and near to emmetropia (mean SE −0.03 ± 0.19 D). In our study, 136 eyes (98.55%) were within ±0.50 D of the targeted correction and all eyes (100%) were within ±1.00 D.

With regard to visual acuity, Shimizu et al.[23] obtained UDVA and CDVA values better than 20/20 during all follow-up periods. Our study also had good visual acuity outcomes. The postoperative UDVA and CDVA were 0.009 ± 0.062 logMAR and −0.015 ± 0.032 logMAR, respectively, with 92.1% of patients achieving a UDVA of 20/20 or better 6 months after pIOL implantation. We found a slightly lower safety index (1.01) and similar efficacy index (1.00). No serious complications, such as a significant rise in IOP or secondary cataract, were documented in either study.

It is reasonable to believe that a central artificial hole in the optic of the V4c Visian Implantable Collamer Lens pIOL may deteriorate the optical quality of the pIOL by, for example, introducing halos or glare and consequently decreasing the visual quality of patients. However, a previous study by Shiratani et al.[24] that evaluated the modulation transfer function (MTF) of an Implantable Collamer Lens pIOL with and without a central hole reported similar MTFs for both pIOL designs. Their results agreed with those reported in the in vitro study of Uozato et al.,[25] in which small differences in the optical performance with negligible clinical effect were found with a pIOL with a 0.36 mm central hole and a conventional pIOL. These outcomes suggest that the central hole in the V4c Visian Implantable Collamer Lens pIOL does not affect the optical quality and therefore the patient's visual quality. Our results agree with this considering our good visual acuity outcomes, which are similar to those reported in previous studies that evaluated the earlier version of this pIOL.[2,13,16,26]

With regard to safety of the surgical procedure, the central hole in the pIOL we used offers advantages over the earlier models. Conventional Implantable Collamer Lens pIOL implantation requires the surgeon to perform preoperative Nd:YAG iridectomies or an intraoperative peripheral iridectomy to prevent an increase in IOP,[18] mostly associated with pupillary block[21,22] or with chronic pigment dispersion.[20] These complementary procedures are frequently accompanied by pain, especially in young patients, or with intraoperative iris hemorrhage and IOP increase. However, the central hole in the optic of the V4c Visian Implantable Collamer Lens allows more natural aqueous humor circulation and Nd:YAG iridectomies or iridotomies are not necessary, eliminating the risks and complications of these procedures. In the present study, no significant rise in IOP (>20 mm Hg) was found in any case after the 6-month follow-up even without preoperative or intraoperative peripheral iridectomies. Our postoperative IOP outcomes were lower than those reported in the study by Shimizu et al.[23] Moreover, when we evaluated changes in IOP over time and calculated variations between preoperative and postoperative values, we found that in most eyes, the IOP remained unchanged or showed a reduction of 1 to 2 mm Hg from preoperatively at each follow-up.

Several authors describe other concerns associated with pIOL implantation, such as anterior subcapsular opacities[12–17,27] and endothelial cell loss.[19] Cataract formation has been related to surgical trauma (early

cataract) or to constant or intermittent pIOL–crystalline lens contact because of insufficient vaulting (late cataract formation).[15,28] Specifically, insufficient vault may 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. Because the central hole in the pIOL implanted in the current study improves the circulation of aqueous humor to the anterior crystalline lens surface, less cataract formation is expected. In fact, we found no anterior subcapsular opacities over the follow-up period.

However, it is important to control the amount of central vault after pIOL implantation. Gonvers et al.[27] suggest that a central vault of more than 0.09 mm protects the crystalline lens from cataract formation. In a 3-year follow-up study, Alfonso et al.[15] found a trend toward the vault to decrease over time, although no constant reduction was observed. They found a significantly higher reduction in the first 6 months after surgery; beyond this period, the variations in vault were likely to be smaller. Our results agree with those in previous studies. We found a trend toward a decrease in mean vault and no cataract formation throughout the 6-month follow-up. In most eyes, the vault was between 400 μm and 600 μm; eyes with lower values (approximately 6%) were followed closely.

Endothelial damage after this surgical procedure has also been evaluated,[5,10,15,28–30] although some data discrepancies exist. The rate of postoperative endothelial cell loss after pIOL implantation has been reported to be approximately 9.9% at 1 month[29] and 4.7% at 6 months,[5] remaining unchanged from the 2-year through the 10-year follow-up. Other authors report a mean endothelial cell loss of 6.5% at 2 years,[30] 6.1% after 3 years,[28] and 3.7% at 4 years.[16] Despite this, in all studies, the rate of endothelial cell loss slowed substantially from 1 to 2 years and tended to remain stable or progress less after that period. We found a mean endothelial cell loss of approximately 8.5% 6 months postoperatively, which it is in accordance with results in the previous studies. However, more prolonged assessment is necessary to determine the tendency of this cell loss over time.

In summary, based on the predictability, efficacy, and safety outcomes in our study, implantation of the V4c Visian Implantable Collamer Lens pIOL is a reliable alternative to correct moderate to high myopia. Long-term evaluation with a larger sample of patients is required to assess the safety and stability of this surgical procedure, particularly in terms of increased IOP. Future studies should include the toric model of the pIOL in eyes with high degrees of astigmatism.

WHAT WAS KNOWN

- Phakic IOL implantation is a safe and effective treatment option for the refractive error correction. Phakic IOL implantation requires one to perform preoperative Nd:YAG iridectomies or intraoperative peripheral iridectomies to prevent an increase in IOP that is mostly associated with pupillary block or with chronic pigment dispersion.
- The V4c Visian Implantable Collamer Lens pIOL with a 0.36 mm central hole allows more natural aqueous flow and eliminates the need to perform Nd:YAG iridotomies or peripheral iridectomies before implantation.

WHAT THIS PAPER ADDS

- Implantation of the V4c Visian Implantable Collamer Lens pIOL to correct moderate to high myopia was effective, predictable, safe, and stable, providing good IOP outcomes.

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