

Refractive outcomes of posterior chamber phakic intraocular lens implantation with a central port design

Resultados refractivos de la implantación de lentes intraoculares fáquicas de cámara posterior con un diseño de puerto central

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Abstract

Objective: The objective of the study is to evaluate the visual and refractive outcomes of implantable Collamer lens (ICL) implantation with a new central port design. **Methods:** This is a retrospective observational study of patients with myopia and myopic astigmatism who underwent procedures for the ICL (STAAR Surgical) between 2013 and 2022. Measurements were taken for uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest and cycloplegic refraction, and intraocular pressure. **Results:** 254 eyes of 135 patients who underwent. Of the 254 ICLs implanted, 226 (88.97%) were toric. Mean follow-up was 15.05 ± 15.12 months. Mean pre-operative sphere was -9.65 ± 4.46 D (-0.00 – -25.00 D) and the post-operative sphere was 0.07 ± 1.12 D (-5.75 – 2.50 D). Pre-operative mean spherical equivalent was -11.24 ± 4.35 D (-25 – 6.25 D) and -0.38 ± 1.16 D (-6.75 – 2.12 D) postoperatively. Mean pre-operative UDVA was 1.58 ± 0.44 (0.4–2.5) and the mean post-operative UDVA was 0.17 ± 0.17 (0–1.18). Mean pre-operative CDVA was 0.15 ± 0.12 (0–0.6) and the post-operative CDVA was 0.08 ± 0.09 (0–0.54 D). **Conclusions:** This study showcases a noteworthy level of visual and refractive efficacy in individuals who underwent implantation of ICL V4c models. The surgical procedure proved highly effective and safe for correcting myopia and astigmatism.

Keywords: Implantable Collamer lens. Phakic intraocular lenses. Central port. Myopia.

Resumen

Objetivo: Evaluar los resultados visuales y refractivos de la implantación de lentes de colámero implantables (ICL) con un nuevo diseño de puerto central. **Métodos:** Estudio observacional retrospectivo de pacientes con miopía y astigmatismo miópico sometidos a procedimientos para ICL (STAAR Surgical) entre 2013 y 2022. Se tomaron medidas de agudeza visual a distancia no corregida (UDVA), agudeza visual a distancia corregida (CDVA), refracción manifiesta y ciclopléjica, y presión intraocular. **Resultados:** Se implantaron lentes en 254 ojos de 135 pacientes. De las 254 ICL implantadas, 226 (88,97%) eran tóricas. El seguimiento medio fue de 15.05 ± 15.12 meses. La esfera media preoperatoria era de -9.65 ± 4.46 D (-0.00 a -25.00 D) y la posoperatoria de 0.07 ± 1.12 D (-5.75 a 2.50 D). El equivalente esférico medio preoperatorio fue de -11.24 ± 4.35 D (-25 a 6.25 D) y el posoperatorio de -0.38 ± 1.16 D (-6.75 a 2.12 D). La UDVA preoperatoria media fue de 1.58 ± 0.44 (0.4 a 2.5) y la posoperatoria media fue de 0.17 ± 0.17 (0 a 1.18). La CDVA preoperatoria media fue de 0.15 ± 0.12 (0 a 0.6) y la posoperatoria de 0.08 ± 0.09 (0 a 0.54 D). **Conclusiones:** Este estudio muestra un notable nivel de eficacia

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Date of reception: 11-11-2024

Date of acceptance: 24-12-2024

DOI: 10.24875/CIRU.24000591

Cir Cir. (ahead of print)

Contents available at PubMed

www.cirugiaycirujanos.com

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cia visual y refractiva en los individuos que se sometieron a la implantación de los modelos ICL V4c. El procedimiento quirúrgico demostró ser altamente eficaz y seguro para corregir la miopía y el astigmatismo.

Palabras clave: Lentes de colámero implantables. Lentes intraoculares fáquicas. Puerto central. Miopía.

Introduction

To this day, laser *in situ* keratomileusis remains the most popular surgical method to correct refractive errors.^{1,2} However, its use is limited by many factors, such as thin corneas, dry eye syndrome, recurrent corneal erosions, and use of medications such as isotretinoin, among others.³⁻⁵ The use of phakic intraocular lenses (pIOLs) has increased in popularity as an alternative option for refractive surgery in patients who are not candidates for laser vision correction due to either high refractive error, corneal abnormalities, or both.

Implantable Collamer lenses (ICLs) are pIOLs designed to be implanted into the posterior chamber and have proven to effectively correct moderate to high myopia and astigmatism.^{6,7} The Visian ICL V4c model (STAAR Surgical, Monrovia, CA, USA) is the newer design of the original foldable Collamer lens that includes an innovative central port, the KS-Aqua-port. Its former model, the V4, was approved by the Food and Drug Administration (FDA) in 1998 to correct both myopia and astigmatism⁸ and has qualities that the V4c model shares, but it required previous iridotomies to avoid an anterior chamber (AC) block. On the other hand, the central port incorporated in the V4c's new design allows for free passing of the aqueous humor through the lens^{8,9} without the need to perform an iridectomy, as was in previous ICL models. This has been thought to significantly reduce common post-operative complications seen with other models, mainly cataract formation, by the maintenance of the physiological flow of aqueous humor in the AC and avoidance of pupillary block, which was proven to possibly occur even with prior iridotomies.¹⁰

The purpose of this study is to evaluate the visual and refractive outcomes of ICL implantation with a new central port design, for which we present a retrospective review of patients who underwent spherical or toric ICLs with a central port design (V4c) implantation.

Methods

A retrospective chart review was performed in the Department of Cornea, Ocular Surface, and

Refractive Surgery at the Instituto de Oftalmología "Fundación Conde de Valenciana," Mexico City, Mexico, including all patients with a diagnosis of myopia and myopic astigmatism treated with the ICL V4c model and the Toric ICL V4c model between 2013 and 2022. The protocol was approved by the Institution's Ethics Committee (CEI-2020/11/06). Patients over 21 years of age who fulfilled surgical criteria and underwent ICL implantation in the period before mentioned were included.

Before surgery, all patients went through a complete ophthalmological examination, including uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest and cycloplegic (Refractyl, 1% Cyclopentolate, Laboratorios Sophia) refraction, slit lamp examination, intraocular pressure (IOP) measurement by Goldmann applanation tonometry, gonioscopy, and funduscopy. Patients were instructed to discontinue contact lens wear for a minimum of 10 days for pre-operative corneal analysis with Orbscan® IIz (Bausch and Lomb, Laval, Quebec, Canadá) and OCULUS Pentacam® (OCULUS, Inc., Germany) to obtain keratometric, topographic, and pachymetric measurements, white-to-white (WTW) values, and AC depth (ACD) > 2.8 mm estimated from the corneal endothelium to the anterior lens capsule. Patients were examined at day 1, week 1, month 1, and every 3 months for a year, after which the follow-up was yearly with a complete ophthalmologic evaluation. At each visit, we evaluated pre-operative uncorrected visual acuity (UCVA) and best-corrected visual acuity, manifest refraction, spherical equivalent, total astigmatism, IOP, and AC vault (Vault was evaluated using the images obtained from the anterior segment optical coherence tomography taken by an expert technician). Post-surgical complications and their management were registered during follow-up.

ICL calculation

ICL power calculation was performed by STAAR Surgical software based on manifest refraction, keratometry, and ACD. An emmetrope correction was sought in all patients in an attempt to accurately amend the refractive error. ACD and WTW data were

measured with Orbscan IIz and Pentacam and uploaded to STAAR Surgical software, with which ICL sizing was obtained. The lens models used were the ICL V4c model and the Toric (TICL) ICL V4c model.

Surgical technique

Preoperatively, we marked the zero and 180 horizontal corneal axes (TICL cases) while the patient was sitting upright to avoid potential cyclotorsion while lying supine. All surgeries were performed under topical anesthesia; we marked the desired axis in TICL cases with a Mendez degree gauge (Katena Inc., Den-ville, NJ, USA). Two superior and inferior paracentesis incisions were performed, and a cohesive viscosurgical device (Provisc® Sodium Hyaluronate 1%, Alcon, Fort Worth, Texas, USA) was injected into the AC. A temporal clear cornea 3.0 mm incision was then made to inject the ICL or TICL. After the insertion of the lens, we placed the four haptics under the iris with a Batlle ICL manipulator (ASICO LLC, Westmont, IL, USA) and aspirated viscosurgical devices. The correct positioning of the ICL in the center of the pupillary zone was verified after which we used intraocular 1% acetylcholine chloride to achieve miosis. We routinely preferred to use a single 10-0 nylon suture to close the main wound. A 7-day post-operative course of 0.5 % Moxifloxacin 0.5% (Vigamoxi, Alcon Laboratories, Ft. Worth, Texas, USA) and 1 % Prednisolone Acetate (Prednefrin, Allergan, Dublin, Ireland) ophthalmic suspension was indicated.

Statistical analysis

Statistical analysis was performed on RStudio v.4.0.2. Demographic data were analyzed through mean plus standard deviation. The Shapiro–Wilk test was used to assess data normality. Paired t-tests were employed to compare pre-operative and post-operative data for all normally distributed data, while non-parametric equivalents were used for data that did not follow a normal distribution. A $p = 0.05$ or less was considered statistically significant.

Results

This study included a total of 254 eyes of 135 patients who underwent ICL V4c model and the Toric ICL V4c model implantation to manage myopia and myopic astigmatism. Of the 254 eyes, 173 (68%) were from

female patients. The mean age was 27.86 years, ranging from 21 to 47 years. Of the 254 ICLs implanted, 226 (88.97%) were toric. Myopic astigmatism was the most common refractive error, found in 244 eyes, followed by myopia alone in 10 (3.93%) eyes. Mean follow-up was 15.05 ± 15.12 months. Mean WTW was 11.68 ± 0.32 mm (10.8-12.9), and the mean ACD was 3.53 ± 0.32 mm (2.80-4.39).

Mean pre-operative and post-operative spheres were -9.65 ± 4.46 D and 0.07 ± 1.12 D, respectively ($p < 0.001$). Mean pre- and post-operative cylinders were -3.17 ± 1.61 D and -0.96 ± 0.83 D ($p < 0.001$). Pre-operative mean spherical equivalent was -11.24 ± 4.35 D (-25 – $+6.25$ D) and -0.38 ± 1.16 D (-6.75 – $+2.12$ D) postoperatively ($p < 0.001$) (Figs. 1 and 2).

Statistically significant differences were also shown between pre-operative UDVA 1.58 ± 0.44 and post-operative UDVA 0.17 ± 0.17 and between pre-operative 0.15 ± 0.12 and post-operative 0.08 ± 0.09 CDVA ($p < 0.001$) (Figs. 3 and 4). Refraction stability throughout the follow-up can be seen in Fig. 5. Mean pre- and post-operative IOP were 13.02 ± 1.9 mmHg and 13.89 ± 2.97 mmHg, respectively, with $p < 0.001$. Mean ICL vaulting value postoperatively was 562.46 ± 243.12 μ m (range: 130-1400 μ m). Eight patients had a vault lower than 250 μ m, while 40 patients had a vault higher than 750 μ m.

The complication rate was 13.38 % (34 eyes), with elevation of IOP as the most common complication, observed in 19 eyes, most of which responded well to topical antihypertensives in an average of 48 h. Only one eye presented a pupillary block and had to undergo ICL removal. Other documented complications included ICL rotation in 9 eyes, one of them secondary to ocular trauma, persistent mydriasis in 1 eye resolved with intraocular application of 0.01% Carbachol (Miostat, Alcon, Fort Worth, Texas, USA), residual esotropia in 2 eyes, and iris trapping in the main wound in 1 eye. In addition, 2 patients had rhegmatogenous retinal detachment unrelated to the surgical procedure, one case 6 months after ICL implantation and the other 2 years after. Throughout the follow-up, none of the patients developed clinically significant lens opacity.

Discussion

pIOLs have gained popularity throughout the years, due to their many reported benefits, such as rapid visual recovery, the ability to remove or reposition the lens, a wider range of correction of refractive errors,

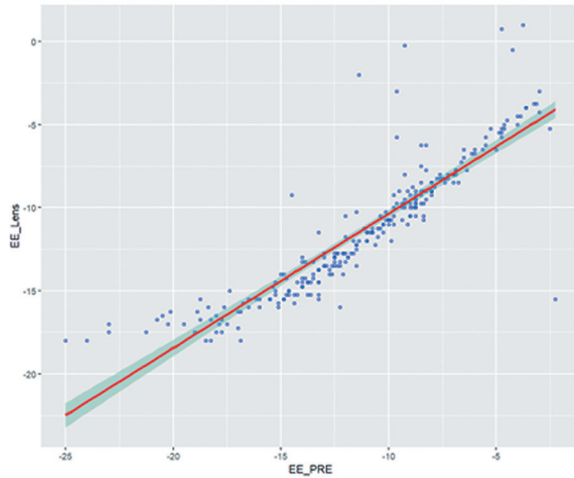


Figure 1. Line plot showing correlation between Spherical Equivalent before surgery (x-axis) and Spherical Equivalent of the lens implanted (y-axis).

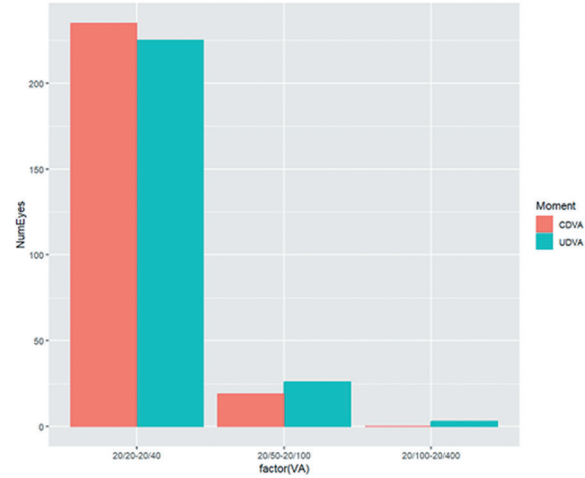


Figure 3. Bar chart showing the number of eyes in categories for corrected distance visual acuity before surgery and uncorrected distance visual acuity after implantable Collamer lens implantation.

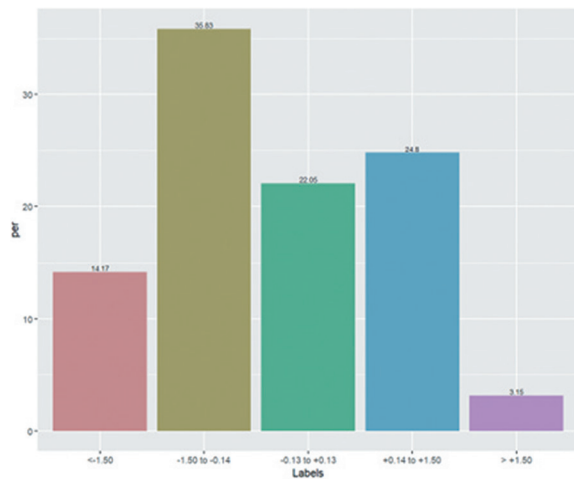


Figure 2. Bar chart showing categories for residual spherical equivalent after implantable Collamer lens implantation by cumulative percentage of eyes.

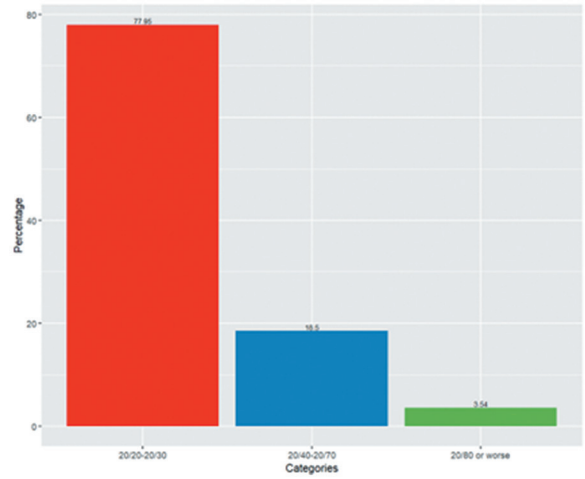


Figure 4. Bar chart showing categories by percentage of eyes for uncorrected distance visual acuity after implantable Collamer lens implantation.

less post-surgical dry eye, and fewer induced higher-order aberrations compared to laser refractive surgery.^{11,12} Although posterior chamber pIOL implantation has been reported to be safe and effective for the correction of myopia and myopic astigmatism throughout a long-term follow-up period,¹³ certain risks attributed to the procedure still remain. The most common challenges refractive surgeons encounter with this procedure include the accurate placement of the lens, achieving rotational stability, dealing with residual astigmatism, and IOP management. However,

previous literature reviews have revealed promising visual and refractive results with the use of Spherical and Toric ICLs in patients with considerably high refractive disorders, including high astigmatism,^{14,15} which has not been proven as so with laser refractive procedures.

This study demonstrates a high rate of visual and refractive success among patients with ICL and toric ICL V4c models. Myopic astigmatism was the most common refractive error found in our population. 209 eyes (82.28 %) presented with high myopias (≥ 6.00 D)

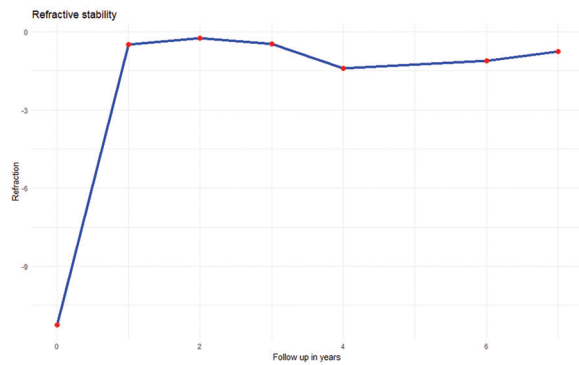


Figure 5. Line plot showing refraction stability for all eyes through follow-up.

which made complete treatment with any type of laser refractive procedure difficult, whereas ICLs can achieve correction of up to -23.00 D of myopia. We observed a significant improvement in the mean pre- and post-operative sphere, with a mean spherical residual of 0.07 ± 1.12 D ($p < 0.001$). The same goes for significant grades of astigmatism (considered as ≥ 2.00 D),¹⁶ present in 202 eyes (79.52%), in which cases a toric ICL was used, with a significant difference in the pre and postsurgical cylinder and a mean residual of -0.96 ± 0.83 ($p < 0.001$). This refractive outcome translated well in the UCVA, which improved significantly from a mean of 1.58 ± 0.44 in logMar scale (approx. 20/800 Snellen) to 0.17 ± 0.17 (20/30 Snellen) ($p < 0.001$). Corrected visual acuity also exhibited an important improvement, going from 0.15 ± 0.12 (20/30 Snellen) pre-operative to 0.08 ± 0.09 (0-0.54 D) (20/25 Snellen) post-operative ($p < 0.001$). These results confirm an outstanding outcome in refractive and visual parameters for patients who undergo ICL V4c implantation, with both clinical and statistical significance. They also demonstrate that this ICL model provides accurate and predictable refractive error correction, even in patients with high refractive disorders. It is important to point out that these outcomes were sustained throughout monitoring visits, including in patients who had up to 6 years of follow-up, demonstrating that the visual results provided by the V4c ICL model are not only adequate but also sustainable, as reported in previous studies (Table 1).

Regarding the ICL vault depth, we obtained WTW and ACD presurgical measurements with Orbscan II and Pentacam topography, which are required for ICL vault determination. Mean WTW and ACD values

were 11.68 ± 0.32 and 3.53 ± 0.32 , respectively. Post-operatively, we performed ICL vault measurements at each visit with the same devices. Our patients showed a mean vaulting value postoperatively of 562.46 ± 243.12 μ m, ranging from 130 μ m the lowest and 1400 μ m the highest. While vaults lower than 250 μ m are associated with increased contact of the ICL posterior surface and the crystalline lens anterior capsule, leading to cataract formation, vaults higher than 750 μ m can elicit an acute angle-closure glaucoma secondary to pupillary block.¹⁷ In our study population, only 8 patients (3.14%) presented with a vault < 250 μ m, and 40 patients (15.74%) with a vault > 750 μ m. Although more patients presented with a higher vault versus a lower one, we did not experience a significant difference in the aforementioned complications due to the fact that this particular ICL model allows for aqueous humor circulation through the central port, compensating and frankly reducing the incidence of pupillary block, a known complication of increased vaulting we experienced in only one patient (Fig. 6).

Our review found that post-operative elevation of IOP represented the most common complication, observed in 7.48% of our study population. This occurred only in early visits of the post-op period and in the majority of cases was resolved with the use of short courses of topical antihypertensive agents. In their study regarding ICL V4c implantation and its correlation with ICL vault and IOP, Eissa et al.¹⁰ describe a statistically significant increase in IOP at 1 month postoperatively, going from a mean baseline IOP of 11.69 ± 2.15 to a mean value of 16.07 ± 4.12 , 16.07 ± 4.10 , and 16.07 ± 4.13 , at 6 and 18 months, respectively, and 7 out of 54 (12.96%) eyes with an IOP higher than 20 mmHg at the 1 month. However, they reported no eyes with IOP's 10 mmHg or more above the presurgical IOP measurement at the 18-month post-op period. They, along with Kohlhaas and Druschel,¹⁸ attributed the initial rise in IOP to the inflammatory effect of the surgery itself, along with trabeculitis and the use of topical steroids. This goes along with our own findings, where the majority of our patients did not present with persistent IOP elevation throughout their follow-up and resolved with a short course of antihypertensive agents. Only one patient, in one eye, presented with a marked IOP elevation, up to 50 mmHg by Goldmann tonometry, which did not solve until the ICL was surgically removed. This was probably associated with a high vaulting in the post-operative period, reaching up to 1390 μ m. This generated a

Table 1. Clinical studies reporting data for the V4c ICL model

Authors	Year	Follow-up (Months)	Eye (N)	SE (D)	UDVA (logMAR)
Fernández-Vigo et al. ²⁵	2017	24	54	-8.48 ± 4.03	0.02 ± 0.10
Fernández-Vega-Cueto et al. ²⁶	2018	36	184	-8.30 ± 2.98	0.08 ± 0.12
Alfonso et al. ²⁷	2019	60	147	-9.20 ± 3.02	0.13 ± 0.18
Sachdev et al. ²⁸	2019	12	203	-8.37 ± NR	0 ± NR
Chen et al. ²⁹	2020	12	26	-12.48 ± 3.78	NR
Fernández-Vega-Cueto et al. ³⁰	2021	84	84	-9.35 ± 2.90	0.17 ± 0.23
Chen et al. ³¹	2021/2022	60	78	-15.10 ± 4.32	0.22 ± 0.26
Lin et al. ³²	2022	6	32	-7.56 ± 2.55	NR
Chen et al. ³³	2023	69	114	-8.66 ± 1.97	NR
Present study	2024	15	254	-11.24 ± 4.35	0.17 ± 0.17

ACD: anterior chamber depth; NR: no reported; SE: pre-operative spherical equivalent; ICL: implantable Collamer lens; UDVA: post-operative uncorrected distance visual acuity.

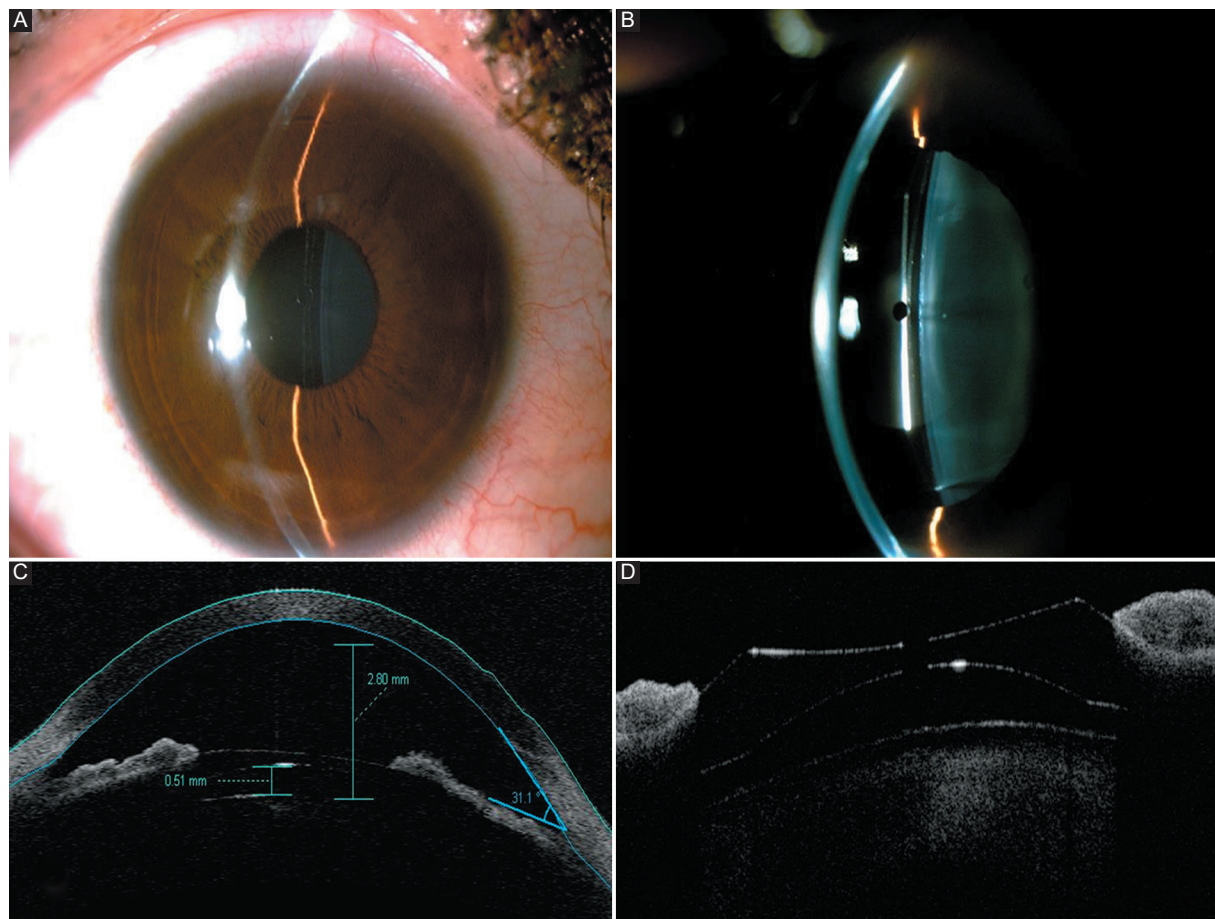


Figure 6. A: slit-lamp photograph of the eye with implantable Collamer lens (ICL) V4c model. **B:** ICL Central port, the KS-Aquaport. **C and D:** anterior segment optical coherence tomography of the same eye showing measurement of the ICL vault.

pseudo-phacomorphic mechanical angle closure by the iris-corneal apposition in the periphery which did not solve until the ICL was surgically removed. Posterior to removing the ICL, the patient's CVDA remained at 20/20 by Snellen and IOP was lowered to 14 mmHg at the last recorded visit. This patient is to undergo laser refractive surgery, with close follow-up of the contralateral eye, which also presented with an elevated vault of 1030 μm , but no signs of other alterations to date. There have been some cases reporting this issue. Grover et al.¹⁹ published the first case report of pupillary block secondary to obstruction of the central Aquaport with viscoelastic and inflammatory debris in a 28-year-old patient with a high myopic refractive error, who underwent ICL removal which successfully lowered IOP and visual acuity remained 20/30 at the 1-year follow-up visit, but the pupil remained permanently dilated and fixed because of extensive sphincter atrophy as a result of the acute pupillary block. Mimouni et al.²⁰ also reported a case of AquaPORT occlusion leading to pupillary block in a patient with toxic anterior segment syndrome (TASS), where strands of fibrin were found to block the central ICL hole, where ICL removal was required but a persistent atonic, hyporeflexive pupil remained as a complication. These findings, along with our own, suggest the need for close follow-up in patients who undergo ICL V4c implantation, because the central port, although it reduces the incidence, does not completely eliminate the risk of pupillary block and its inevitable consequences for patient vision if not treated promptly.

To this day, literature regarding crystalline lens opacification after ICL implantation reports rates of 7-13% at 5 years,^{14,21} 20% at 8 years,²² and 28% at 10 years.²³ Guber et al.²⁴ describe that the rates of lens opacity and phacoemulsification increase with time, with approximately one-fifth of patients undergoing cataract extraction at the 10-year mark, and observed lens opacification in 40.9% and 54.8% at 5 years and 10 years, respectively. No cases of cataract were observed in this cohort, including those patients whose follow-up surpassed the 5-year mark in which cataract formation is reported to become significant. Certain situations, such as an unsatisfactory ICL fit, have been associated with early cataract onset (< 1-year post-op),²⁴ and we did not encounter any in the patients with a shorter period of monitoring. Another significant factor in cataract formation is older age, since age-related lens opacification begins approximately at 40 years of age, as well as lower vaulting (< 250 μm). Our study included 13 eyes

(5.11%) of patients over 40 years old, as well as 8 patients (3.14%) with low vault height, in whom we did not observe lens opacity during post-operative check-ups. Further monitoring of this cohort will give insight into further cataract formation rates among our population with this ICL V4c model.

Other infrequent but possible complications that have been reported before with the V4C model (as well as with previous models), such as TASS, pigment dispersion syndrome, and endophthalmitis, none of which were observed in any patients in this cohort, which supports the procedure's safety when performed in well-selected patients and under carefully planned surgical conditions.

Limitations in this study include a variable follow-up period of our studied group, which can be attributed to many factors: a lack of patient attendance at regularly scheduled check-ups, the fact that many of the patients included were operated on at the beginning of the COVID-19 pandemic and therefore could not or did not want to attend hospital appointments, and also that some of the patients included have had surgery in recent years; hence, their monitoring period to this day has been short. There are some variables which we could have included in this study such as endothelial cell loss by specular microscopy, although no clinical signs of corneal decompensation have been observed in any patient.

Conclusions

This study showcases a noteworthy level of visual and refractive efficacy in individuals who underwent implantation of both spherical and toric ICL V4c models. The surgical procedure proved to be highly effective and safe for correcting myopia and astigmatism.

Funding

The authors declare that they have not received funding.

Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of human subjects and animals. The authors declare that no experiments on humans or animals were performed for this research.

Confidentiality, informed consent, and ethical approval. The authors have obtained approval from the Ethics Committee for the analysis of routinely collected and anonymized clinical data; therefore, individual informed consent was not required. Relevant ethical recommendations have been followed.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing or creation of the content of this manuscript.

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