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Clinical assessment of the changes in corneal endothelium cell density, IOP and correlated factors after phakic iol implantation

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Background. *Refractive errors are leading pathology of visual organ among active age population. Myopia is one of the main causes of disability and blindness.*

Purpose. *To assess the clinical outcomes of changes in endothelial cell density, intraocular pressure (IOP), and correlated factors after phakic intraocular lens (IOL) implantation in patients with high myopia during the 6-month postoperative period.*

Material and Methods*. In this observational study, 58 eyes of 30 patients were investigated after spheric implantable collamer lens (ICL) implantation. The main clinical outcomes were uncorrected visual acuity, best-corrected visual acuity, endothelial cell density, intraocular pressure, and correlated factors. In this study, all patients' postoperative outcomes were evaluated at 1 day, 1 week, 1, 3, and 6 months after surgery.*

Results. *In total, 58 eyes of 30 patients underwent spheric ICL model implantation at the Republican Specialized Scientific and Practical Medical Center of Eye Microsurgery from January 2023 to June 2023. The mean age of patients was 27.52±6.61. The mean preoperative manifest spherical equivalent was -10.59±3.41 D, respectively, which postoperative spherical refractive measures reduced to -0.92±0.37 D. The mean IOP was 15.9±1.92 mm Hg preoperatively. The mean IOP has changed until 15.86±3.3 mm Hg during the 6-month post-operative period.*

Conclusion. *Implantable collamer lens implantation is a safe, effective, and alternative refractive surgery for correction of high myopia in patients with thin corneas and several contraindications for laser correction.*

Key words:

high myopia, visual acuity, implantable collamer lens, endothelial cells density, intraocular pressure

Introduction

Refractive errors are the leading pathology of the eyes among the population aged 20-45. The prevalence of refractive errors varies from 23% to 36% and even up to 40%. Several studies have indicated that high myopia ranks as the fourth to seventh leading cause of blindness. It is important to emphasize that the progression of refractive abnormalities can lead to serious irreversible changes in the eye and significant loss of vision [1, 2, 3].

One of the most common surgical methods for correcting refractive errors, such as high myopia, is phakic intraocular lens (pIOL) implantation. Phakic IOLs are classified as anterior chamber (AC pIOL) and posterior chamber (PC pIOL). Anterior chamber pIOLs are further subdivided based on the method of fixation to the ocular structures: angle-fixated or iris-fixated. They have commonly been used to treat high myopia because they can correct higher refractive errors compared to corneal refractive procedures [4, 5].

Initially, the implantable lens, made from a biocompatible collagen copolymer, was developed by STAAR Surgical (Monrovia, CA, USA) in 1993 as a sulcus-placed posterior chamber pIOL and was called an implantable collamer lens (ICL). This lens can correct high refractive errors. ICL implantation has several advantages, including faster recovery, more stable refraction, better visual quality, reversibility of the surgical procedure, and exchangeability of the pIOL. However, the first models of ICL had more complications, which were revealed after implantation. Lens development and modification continue by the manufacturer under the supervision of leading scientists [6].

The implantable collamer lens with a central hole (ICL V4c; STAAR Surgical Company, Monrovia, CA, USA) is a new posterior chamber phakic intraocular lens (PC pIOL) designed to allow the natural flow of aqueous humor from the posterior chamber to the anterior chamber through a 360 µm central hole. Notably, this approach does not require preoperative peripheral iridotomy, which is in contrast to the approach necessary for a conventional ICL V4. The ICL V4c has shown excellent clinical and refractive results when used for treating myopia [7, 11].

In 2016, the latest modifications to the spherical (EVO + Visian ICL) VICM5 model for correcting spherical refractive errors were designed and manufactured. This lens has an advanced optic size, ranging from 4.9 to 6.1 mm, which helps reduce night-time visual disturbances, such as halos and glare, in patients who undergo ICL implantation. Corneal endothelial cells are essential for maintaining corneal transparency. The loss of corneal endothelial cells after intraocular surgery, especially lens surgery, may cause dysfunction and lead to corneal edema [12]. The new design of the ICL with a central port changes the aqueous humor flow, which may influence corneal endothelial cells. Previous reports [13, 14, 15] have described that endothelial cell density (ECD) loss ranges from 2% to 9% after ICL and ICL V4c implantation. However, few reports have focused on the correlations between various factors and ECD loss after ICL V4c implantation [16].

Aim of the study. To evaluate the initial clinical results and correlated factors related to changes in ECD and IOP during the 6-month postoperative period after implantation of spherical ICL in patients with high myopia for the first time in Uzbekistan.

Material and methods

This retrospective, consecutive, and observational study included 58 eyes of 30 patients with high myopia who underwent implantation of spherical ICL (VICM5 model) from January 2023 to June 2023 at the Republican Specialized Scientific and Practical Medical Center of Eye Microsurgery, Tashkent, Uzbekistan. The study included patients for whom LASIK surgery was contraindicated due to thin corneas and myopia range greater than -6.0 diopters (D). All patients had stable refractions within ±0.75 D for 1 year prior to surgery. Each patient underwent specialized ophthalmic examinations, including bio-ophthalmoscopy with dilated pupils using a 90 D aspheric lens (Volk Inc., USA), A and B ultrasound scanning of the eye globe (Tomey, Japan), non-contact tonopachymetry (Topcon, Japan), autorefkeratometry (Topcon, Japan), keratotopography (Pentacam, O culus, Germany), and anterior and posterior segment OCT (DRI OCT Triton Plus, Topcon, Japan). Based on the keratopachymetric and ACD results, we paid particular attention to the depth of the anterior chamber from the endothelium to the anterior surface of the clear natural lens. This measurement cannot be less than 2.80 mm. Patients with peripheral retinal tears and lesions were treated with a green laser coagulator (Novus Spectra, Lumenis, USA). The exclusion criteria were lens opacities, peripheral retinal detachments, history of uveitis, glaucoma, shallow anterior chamber, and corneal pathology. Written informed consent was obtained from each patient. In all cases, intraocular pressure (IOP) measurements and gonioscopy were performed to ensure wide-open angles. Best-corrected visual acuity (BCVA) and uncorrected visual acuity (UCVA) were recorded preoperatively and postoperatively. The White-to-White (WTW) diameter was measured using a digital biometric ruler-digital caliper. Endothelial cell density (ECD) was measured using a specular microscope (SP-P1, Topcon, Japan). The ICL power was calculated using the STAAR Surgical OCOS system (Online calculation and order system) https://evo-ocos.staarag.ch/Live/. Each eye was examined using anterior segment optical coherence tomography (DRI OCT Triton Plus, Topcon, Japan) to determine the vault (the distance between the ICL and the anterior surface of the clear natural lens) in the postoperative period at 1 day, 1 week, and at 1, 3, and 6 months.

Surgical technique

On the day of surgery, patients were administered dilating and cycloplegic agents. Pupillary dilation was achieved using a combination of Sol. Mydoptic (phenylephrine) 2.5% and Sol. Tropicamide 1% eye drops, administered three times at 15-minute intervals, 1 hour prior to surgery. All surgeries were performed under topical and subtenon anesthesia by a single highly experienced surgeon using a standardized technique. Two clear corneal 1-mm paracenteses were made, and hydroxypropylmethylcellulose 1% (viscoelastic device) was injected into the anterior chamber. The spherical ICL (VICM5 model) was implanted through a 2.8-mm temporal clear corneal incision using an injector and cartridge system from STAAR Surgical. The ICL was placed and positioned in the posterior chamber using a Vukich ICL manipulator. The viscoelastic device was completely washed out of the anterior chamber with balanced salt solution, and a miotic agent was instilled. All surgeries were completed successfully, and no intraoperative complications were observed. After surgery, a combined agent (antibiotic + steroid) Sol. Tobradex 5 ml 4 times a day and Sol. Timolol 0.5% 5 ml eye drops twice a day were administered topically for 2 weeks, with a gradual reduction in dosage thereafter.

Statistical analysis

Statistical analysis was performed using Microsoft Excel (2016 version, Microsoft Corporation, Redmond, WA, USA). Preoperative vs. postoperative data were compared using Student's t-test. Pearson's correlation analysis was used to identify variables correlated with changes in ECD. The safety index (defined as the ratio between postoperative BCVA and preoperative BCVA) and efficacy index (defined as the ratio between postoperative UCVA and preoperative BCVA) were calculated based on Snellen decimal visual acuity values. The results were expressed as mean ± standard deviation (SD), and a p-value of <0.05 was considered statistically significant.

Ethical consideration

Ethical approval was obtained from the research ethics committee of the Center for the Development of Professional Qualifications of Medical Workers in Tashkent, Uzbekistan. This study adhered to the principles of the Declaration of Helsinki and was registered as an innovative scientific research project with the institutional scientific board. Each patient signed an informed written consent before the surgical intervention and received agreement from accompanying personnel and clinical staff.

Results

The results showed a minimal increase in manifest residual refraction during follow-up. The manifest residual refraction increased depending on the accommodative function of the natural lens. After surgery, some younger patients had difficulty working at near distances. Therefore, while their visual acuity remained stable, the refractive measure increased less. In patients with even mild refractive amblyopia, high visual performance was observed during the postoperative follow-up period. Visual acuity improved 6 months after the telescopic effect of the phakic IOL and activation of the eye's visual function. The mean changes in manifest spherical refraction from Day 1 to 6 are shown in Figure 1.

Preoperative demographic data are presented in Table 1.

All patients who underwent spheric ICL implantation were observed postoperatively and follow–up data are presented in Table 2.

The safety and efficacy indices were 1.39 and 1.28, respectively. We found a significant difference between preoperative UCVA and BCVA, and 6 months postoperative UCVA and BCVA ($p < 0.001$, Student's paired t-test) (Fig. 2). The remaining manifest spherical equivalent (SE) correction at follow-up showed that 95% of eyes were within ±0.75 D of the attempted

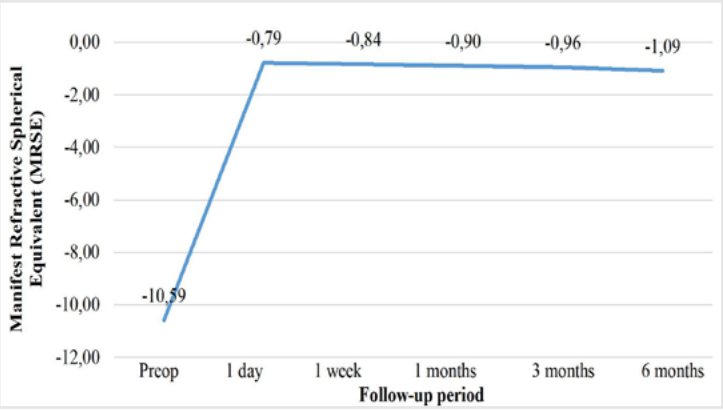

Figure 1. Changes in mean spherical equivalent during 6 months postop period

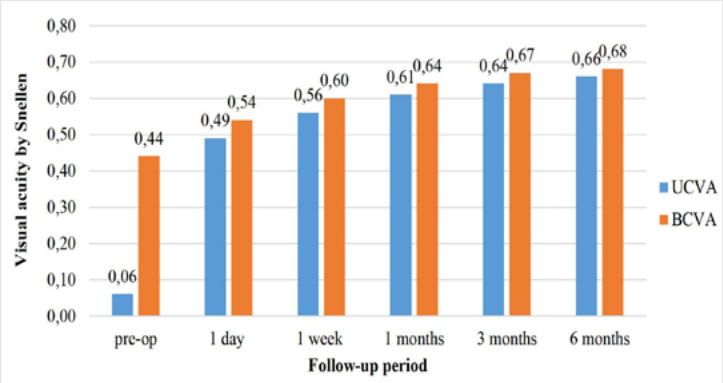

Figure 2. Changes in UCVA and BCVA during 6 months postop period

Table 1. Preoperative patient demographic data and pIOL characteristics (n= 58 eyes)

Characteristic		Mean ± SD	Range
Age (years)		27.65±6.8	(21 to 44)
Gender (male:female)		13 : 17, 43.3% : 56.7%	
Manifest spherical equivalent (D)		-10.59±3.44	(-6.25 to - 19.75)
Manifest cylinder (D)		-1.29±0.52	(-0.25 to -2.00)
UCVA by Snellen		0.06±0.03	(0.01 to 0.15)
BCVA by Snellen		0.44±0.25	(0.10 to 1.00)
Horizontal white-to-white distance (mm)		11.43±0.42	(10.5 to 12.5)
Anterior chamber depth (mm)		3.02±0.16	(2.80 to 3.32)
Axial length (mm)		27.39±1.42	(24.85 to 31.12)
Central corneal thickness (μm)		501.07±34.2	(432 to 596)
Keratometric readings (D)	K1	42.53±2.16	(38.00 to 48.50)
	K2	43.90±2.21	(39.50 to 49.75)
Intraocular pressure (mmHg)		15.9±1.92	(13 to 22)
Endothelial cell density (cells/mm^2)		3053±107	(2814 to 3237)
Implanted pIOL spherical power (D)		-11.11±3.19	(-6.00 to -18.00)
Implanted pIOL size (mm)		12.83±0.35	(12.1 to 13.2)

Note. UCVA – uncorrected visual acuity; BCVA – best corrected visual acuity; SD – standard deviation.

Table 2. Postoperative patient demographic data: 6 months follow–up period. (Mean ± SD)

Characteristic		Postoperative follow-up period:				
		1 day	1 week	1 month	3 months	6 months
Manifest refraction (D)	Sph	-0.7±0.33 (p<0.001)	-0.84±0.33 (p<0.001)	-0.90±0.37 (p<0.001)	-0.96±0.41 (p<0.001)	-1.09±0.40 (p<0.001)
	Cyl	-0.78±0.41 (p<0.001)	-0.77±0.39 (p<0.001)	-0.77±0.39 (p<0.001)	-0.76±0.37 (p<0.001)	-0.78±0.37 (p<0.001)
UCVA by Snellen		0.49±0.25 (p<0.001)	0.56±0.23 (p<0.001)	0.61±0.22 (p<0.001)	0.64±0.21 (p<0.001)	0.66±0.21 (p<0.001)
BCVA by Snellen		0.54±0.25 (p<0.001)	0.60±0.19 (p<0.001)	0.64±0,21 (p<0.001)	0.67±0.21 (p<0.001)	0.68±0.21 (p<0.001)
Intraocular pressure (mmHg)		16.98±4.21 (p<0.051)	16.50±4.39 (p<0.330)	15.93±3.48 (p<0.947)	14.98±2.26 (p<0.008)	14.90±2.18 (p<0.006)
Endothelial cell density (cells/mm²)		N/A	N/A	3006±107 (p<0.001)	2930±113 (p<0.001)	2889±113 (p<0.001)
Central corneal thickness (μm)		498.2±34.6 (p<0.001)	502.3±34.69 (p<0.036)	505.4±34.06 (p<0.001)	507.2±34.54 (p<0.001)	505.1±34.83 (p<0.001)
Vault (μm)		428±138.2	452.4±134.6 (p<0.001)	469.3±134.4 (p<0.001)	479.9±131.2 (p<0.001)	483.5±127.7 (p<0.001)

Note. UCVA – uncorrected visual acuity; BCVA – best corrected visual acuity; SD – standard deviation Student`s t-test, P – probability (p ≤ 0.05).

SE correction. The manifest SE significantly decreased from -10.59±3.44 D preoperatively to ±0.75 D postoperatively (p<0.001, Student's paired t-test). The changes in manifest refraction from Day 1 to 6 are shown as a scatter plot in Figure 3. The mean postoperative IOP was 15.86±3.3 mm Hg, as shown in Figure 4. On the first day of the postoperative period, high intraocular pressure was observed in 4 (6.9%) eyes, with IOP reaching 28.00 mm Hg. We immediately prescribed eye drops (Sol. Timolol 0.5%, 5 ml, twice a day for 1 week). The increased IOP gradually decreased to 18.00 mm Hg over the course of 1 week. No cases of secondary glaucoma were observed during the observation period. The mean vault data are shown in Figure 5. In all cases, the minimal vault was 101 μm and the maximal vault was 752 μm. The mean vault was 462.63±106.3 μm, with a mean minimum vault of 167.4 μm and a mean maximum vault of 737.8 μm during the 6-month period. These measures showed no significant changes during the follow-up. The mean values of endothelial cell density (ECD) were 3053±107 cells/mm² preoperatively. The preoperative and 6-month postoperative ECD values significantly changed from 3053±107 cells/mm² to 2889±113 cells/mm² (p<0.001, Student's paired t-test), respectively. The mean percentage of endothelial cell loss was 5.68% at 6 months after implantation. However, none of the eyes showed a decrease in ECD to less than 2000 cells/mm², and none of the eyes experi-

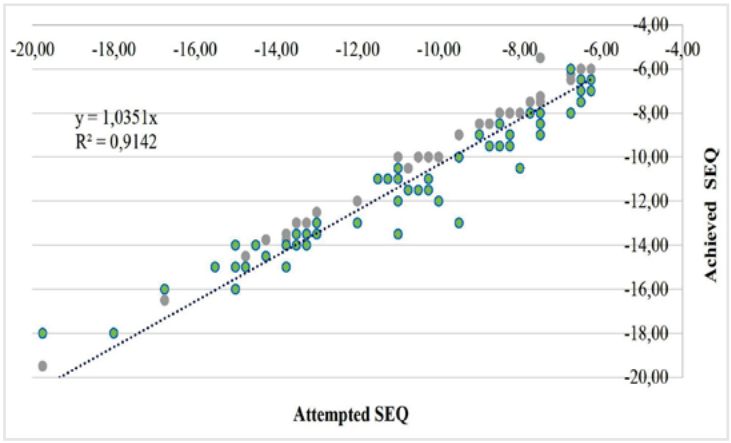

Figure 3. Spherical equivalent refraction attempted vs achieved

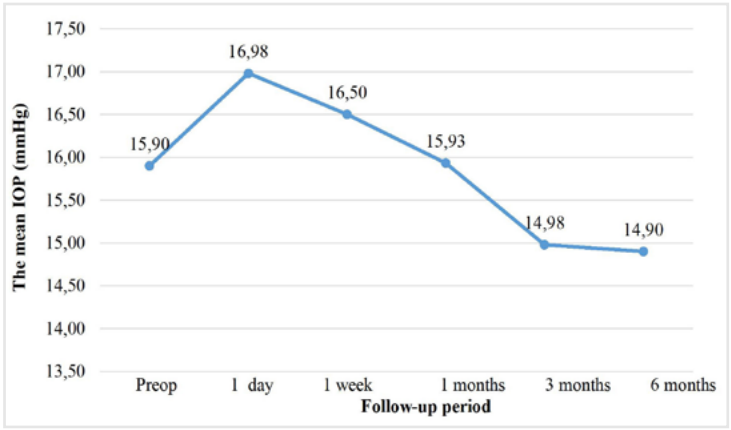

Figure 4. Changes in mean IOP during postop 6 months postop period

enced a significant loss of over 30%. No eyes showed corneal edema on the first postoperative day. The mean changes in ECD during the preoperative and postoperative follow-up periods are shown in Fig. 6.

As mentioned above, changes in ECD significantly affected other postoperative measures. Therefore, we identified pre- and postoperative variables correlated with changes in ECD using Pearson's correlation test. There was a strong positive significant correlation between preoperative ECD value and postoperative 6-month follow-up ECD value (r=0.969, p<0.001), as shown in Figure 7. We also observed a weak negative significant correlation between postoperative 6-month follow-up IOP measures and postoperative 6-month follow-up ECD value (r= -0.135, p<0.001), as shown in Figure 8.

There were no intraoperative complications, although we needed to re-implant 3 (5.17%) eyes with a phakic IOL into the anterior chamber through the main clear corneal temporal incision. In these cases, while injecting the ICL, the position of the ICL was reversed, and the optic side touched the anterior surface of the crystalline lens. We carefully removed the ICL and gently reinjected it. At the end of the implantation procedure, the PIOL was positioned correctly. During the 6-month follow-up, no anterior subcapsular cataracts were detected in the phakic IOL-implanted eyes.

Discussion

The current study focused on changes in endothelial cell density (ECD) during the 6-month postoperative period given that ECD remains an important concern for patients undergoing intraocular procedures such as lens implantation surgery. This study aimed to investigate the safety, efficacy, predictability, and stability of the surgery, as well as changes in corneal endothelial cells during the 6-month follow-up period after implantation of VICMO and VICM5 spherical ICL models in patients with high myopia.

Regarding the safety and efficacy of the procedure, spherical ICL implantation was both safe and effective for the correction of high myopia, and the results are consistent with those of previous studies. As shown in this study, the efficacy index was 1.28, and the safety index was 1.39 at the last follow-up visit. Miao et al. [17] reported an efficacy index of 1.14 and a safety index of 1.33 at 3 months after ICL V4c implantation for moderate-to-high myopia. Furthermore, Yan et al. [18] reported

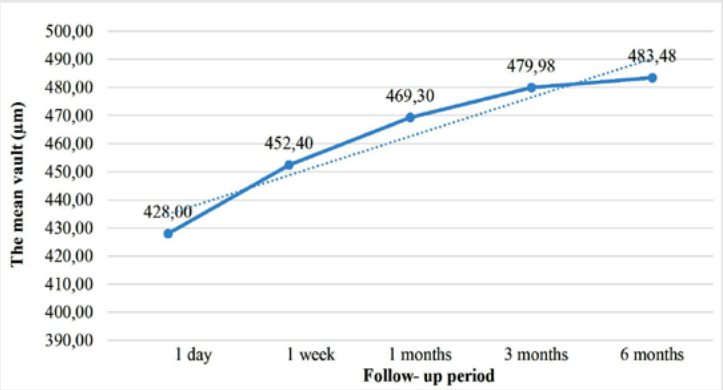

Figure 5. Changes in pIOL vault during 6 months postop period

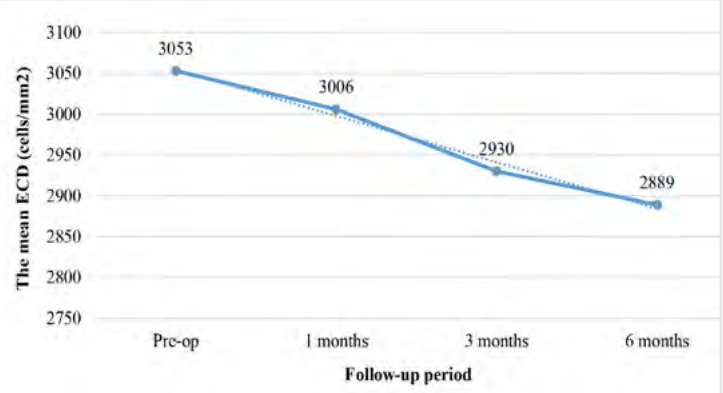

Figure 6. Changes in mean ECD during 6 months postop period

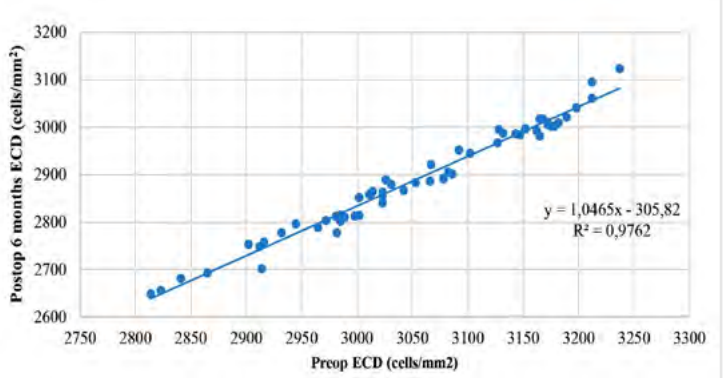

Figure 7. Correlation between preop ECD and postop 6 months ECD value

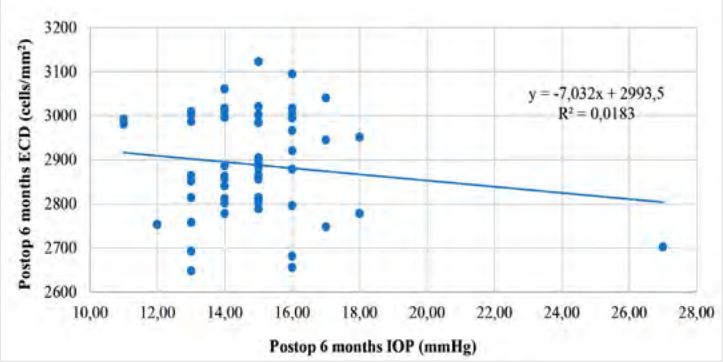

Figure 8. Correlation between postop IOP and postop 6 months ECD value

an efficacy index of 1.03 and a safety index of 1.24 after 2 years after surgery.

Regarding predictability and stability, this procedure performed through a 2.8-mm temporal clear corneal incision, regardless of the amount of myopic correction, had negligible effect on refractive outcomes, and this surgical technique is less subject to the wound healing responses of the cornea [19]. In this study, the mean preoperative manifest SE was -10.59±3.44 D, and 95% of eyes had manifest SE correction within ±0.75 D after surgery during the 6-month follow-up period.

One of the first studies on the ICL model with central flow technology (V4c model with a central hole) was performed by Shimizu et al. [20] (2012) in 20 myopic eyes (mean SE -7.36±2.13 D). They reported that 95% and 100% of eyes were within ±0.50 D and ±1.00 D, respectively, of the target correction. The change in manifest refraction from 1 week to 6 months was 0.06±0.28 D. The safety index was 1.13, and the ECD loss was 2.8% at 6-month follow-up.

Kamiya et al. [21] (2017) reported high results, with 100% of eyes being within ±0.50 D and ±1.00 D of the target correction, with SE of -0.08±0.17 D. Chen et al. [22] (2020) evaluated 22 eyes of 22 patients with high myopia over 6 months. The mean SE was -9.43±5.01 D, the mean age of patients was 26.5±5.8 years, and the mean ACD was 3.42±0.31 mm. Cao et al. [23] (2016) also followed up 41 patients (78 eyes) after ICL implantation over a 6-month postoperative period. In this study, the mean age of patients was 29.1±8.3 years, and the mean SE was -12.55±2.98 D. The mean WTW measure was 11.4±2.98 mm. The safety index was 1.42, and ECD loss was 2.0% at 6-month follow-up.

Pjano et al. [24] (2017) evaluated 28 myopic eyes (mean SE -9.52±3.69) of 16 patients, and favorable postoperative visual results were obtained. The UCVA was 0.76±0.16 (Snellen) and corrected visual acuity was 0.79±0.14 (Snellen) within the 1-year follow-up period after pIOL (ICL) implantation. The safety index was 1.25, and ECD loss was 5.5% at 12 months postoperatively.

During the 6-month follow-up, we evaluated the ECD values and compared them with the preoperative values. No significant difference was observed between the preoperative ECD value and the value at 1 and 3 months. However, the preoperative and last follow-up endothelial cell density significantly changed from 3053±107 cells/mm² to 2889±113 cells/mm² during the 6-month postoperative period ($p<0.001$, Student's paired t-test). The mean percentage of endothelial cell loss was 5.68% at 6 months after implantation. Bhandary et al. [25] reported that the ECD reduction was 6.1% at 9 months after surgery, and Lee et al. [26] reported a 7.8% ± 8.3% reduction in ECD at least 5 years after ICL implantation. Alfonso et al. (2013) reported 8.5% ECD loss in 138 eyes during the 6-month postoperative follow-up period, and Liu et al. (2016) reported a 4.83% ECD reduction in 82 eyes during the 5-month postoperative follow-up period [4]. Physiological age-related ECD loss was reported to decline by approximately 0.6% per year in Bourne et al.'s [27]. The reduction in ECD in our study is similar to that of previous studies. However, the ECD loss should be evaluated in long-term follow-up periods.

Regarding complications of the surgical technique, no significant increase in IOP was observed during the 6-month postoperative follow-up. As mentioned above, only in 4 cases did we find an increase in IOP on the 1st day and 1st week after surgery, and we were able to achieve safe IOP values using hypotensive eye drops. We did not observe any pigment dispersion symptoms in the anterior segment of the eye during the 6-month follow-up period.

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 VICM0 and VICM5 models, such as causing halos and glare that could decrease the patient's visual performance. However, previous studies have concluded that the hole in the ICL provides excellent optical quality, which is equivalent to that of conventional ICLs without a hole. An animal model study by Shiratani et al. [7] reported comparable optical quality outcomes for pIOLs with and without a central hole.

We found that, in our study, the minimal vault was 101 μm and the maximal vault was 752 μm. The mean vault was 462.63±106.3 μm, the mean minimum vault was 167.4 μm, and the mean maximum vault was 737.8 μm during the 6-month follow-up period. Choi et al. [28] has described an ideal pIOL vault as between 250 and 750 μm. These values are much closer to the recommended vault range.

Correlated factors related to ECD changes affect other postoperative measures. We found a strong positive correlation between preoperative and postoperative ECD values. Additionally, a weak negative correlation was observed between preoperative and postoperative IOP measures and ECD changes. These correlations provide valuable insights for analyzing further changes related to ECD values during long-term postoperative follow-up.

The main advantage of the VICM5 model is its expanded optic size. The optic size in the V4c model ranges from 4.9 to 5.8 mm, while the EVO+ new spherical ICL VICM5 model optic size ranges from 5.0 to 6.1 mm. In this study, we found no significant difference after the implantation of these lenses. Patients were satisfied with the results, and their visual complaints, such as halos and glare at nighttime, significantly decreased.

Conclusion

In summary, the clinical results of our study indicate that the implantation of two new spherical implantable collamer lens (ICL) models is safe and effective and provides predictable and stable refractive outcomes in the correction of high myopia in Uzbekistan. The effectiveness of this surgical method is demonstrated by the improvement in visual performance during the 6-month postoperative

period. Amblyopic eyes showed significant improvement in visual acuity due to the telescopic effect of the phakic intraocular lens. This visual function, along with the patient's quality of life, continued to improve throughout the follow-up period.

Additionally, preoperative endothelial cell density (ECD) values significantly changed during the follow-up. The mean percentage of endothelial cell loss was 5.68% at 6 months after implantation. This value should be monitored for the next 12 months as it can help predict the long-term condition of corneal endothelial cells.

In our opinion, the lens design with an expanded optic size and central hole significantly reduces the incidence of halos and glare during nighttime. We believe and recommend that this procedure is a safe and effective alternative for patients with high myopia, although further investigations with long-term follow-up are needed after implantation of a spherical implantable collamer lens.

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Abbreviation. *UCVA – uncorrected visual acuity; BCVA – best corrected visual acuity; ECD – endothelial cell density; ICL – implantable collamer lens; IOP – intraocular pressure; PIOL – phakic intraocular lens; AC Piol – anterior chamber phakic intraocular lens; PC Piol – posterior chamber phakic intraocular lens; OCT – optic coherent tomography; CCT – central corneal thickness; SE – spherical equivalent; SD – standard deviation*