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Original article

Preliminary results of clinical assessment of correction of high refractive errors with using phakic intraocular lenses

N.N. Zaynutdinov[1], A.F. Yusupov[1], M.Kh. Karimova[1], Kh.M. Kamilov[2]

[1]*Republican Specialized Scientific and Practical Medical Center of Eye Microsurgery, Tashkent, Uzbekistan*
[2]*Center for the Development of Professional Qualifications of Medical Workers, Tashkent, Uzbekistan*

ABSTRACT

Purpose. To evaluate initial clinical outcomes after implantation phakic IOLs (ICL and toric ICL) to patients with high refractive errors during next post-op 6 months period. **Material and methods.** In this retrospective, observational study, 112 eyes of 60 patients had been investigated after implantation VICM5 and VTICM5 models of phakic IOLs. In early stages of investigation, the main clinical outcomes of this study were uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), ICL vault, intraocular pressure, and development of any kind early post-op complications. In this study, safety and efficacy indexes and all patients' postoperative outcomes have been evaluated at 1 day, 1 week, 1, 3 and 6 months in post – operative period. **Results.** Totally 112 eyes of 60 patients had underwent VICM5 and VTICM5 models of PIOL implantation in NAZAR Eye Center from January 2020 to December 2022. These patients had been divided into two groups. The first group A has contained 30 patients with 58 eyes (the mean age of patients was 27.52±6.61). In this group, the mean preoperative manifest spherical equivalent (MSE) was –10.59±3.41 D and manifest cylinder (MC) was –1.29±0.51 D respectively, which postoperative spherical refractive measures reduced to –0.92±0.37 D and cylinder measures reduced to –0.77±0.39 D. The second group B has contained 30 patients with 54 eyes (the mean age of patients was 28.34±6.64). In this group, the mean preoperative manifest spherical equivalent (MSE) was –9.85±2.65 D and manifest cylinder (MC) was –3.19±0.79 D respectively, which postoperative spherical refractive measures reduced to –1.18±0.56 D and cylinder measures reduced to –0.53±0.1 D. The mean IOP was 16.30±1.85 mmHg preoperatively. The mean IOP has changed until 15.44±1.76 mmHg during six months post-op period. **Conclusion.** Spheric models of phakic IOLs VICM5 and and toric VTICM5 ICL implantation are a safe, effective and alternative refractive surgery for correction of high refractive errors (high myopia and myopic astigmatism) for patients with thin cornea and several contraindications for laser correction.

Key words: *high refractive errors, phakic intraocular lens, implantable collamer lens, visual acuity, high myopia, intraocular correction, intraocular pressure*

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Corresponding author: Nazim N. Zaynutdinov, znazim@yandex.ru

Научная статья

Предварительные результаты клинической оценки коррекции высоких аномалий рефракции с использованием факичных интраокулярных линз

Н.Н. Зайнутдинов[1], А.Ф. Юсупов[1], М.Х. Каримова[1], Х.М. Камилов[2]

[1]*Республиканский специализированный научно-практический медицинский центр микрохирургии глаза, Ташкент, Узбекистан*
[2]*Центр развития профессиональной квалификации медицинских работников. Ташкент, Узбекистан*

РЕФЕРАТ

Цель. Оценить результаты имплантации факичных интраокулярных линз (ИОЛ) пациентам с высокими аномалиями рефракции. **Материал и методы.** Ретроспективное исследование проведено на основании результатов факоэмульсификации катаракты у 60 пациентов (112 глаз), которым выполнена имплантация факичных ИОЛ модели VICM5 и VTICM5. Оценивались некорригированная (НКОЗ) и максимальная корригированная острота зрения (МКОЗ), расстояние между линзой и естественным хрусталиком, динамика внутриглазного давления и частота различных ранних послеоперационных осложнений через 1 день, 1 неделю, 1, 3 и 6 месяцев после операции. **Результаты.** Всем 60 пациентам (112 глаз) были имплантированы различные модели факичных ИОЛ VICM5 (сферические) и VTICM5 (торические) в глазном центре NAZAR в период с января 2020 г. по декабрь 2022 г. Пациенты были разделены на две группы. В группу А вошли 30 пациентов (58 глаз), средний возраст 27,52±6,61 года. В этой группе средний дооперацион-

ный сферический эквивалент рефракции (MSE), составляющий 10,59±3,41 дптр, снизился до −0,92±0,21 дптр, а цилиндрический компонент (МС) – с −1,29±0,51 до −0,77±0,15 дптр соответственно. В группе В у 30 пациентов (54 глаза), возраст которых был 28,34±6,64 года, средний MSE снизился с −9,85±2,65 до −1,18±0,56 дптр, а МС – с −3,19±0,79 до −0,53±0,1 дптр соответственно. Через 6 месяцев НКОЗ статистически значимо повысилась в группе А с 0,06±0,03 до 0,66±0,21, а в группе В – с 0,09±0,05 до 0,62±0,18. МКОЗ повысилась в обеих группах: группе А – с 0,44±0,25 до 0,68±0,21, группе В – с 0,43±0,18 до 0,63±0,18. Внутриглазное давление не имело статистически значимой динамики с дооперационными значениями и варьировало от±± 16,30±1,85 до 15,44±1,76 мм рт.ст. в течение всего периода наблюдения. **Заключение.** Имплантация сферической факичной линзы VICM5 и торической VTICM5 является безопасным, эффективным и альтернативным методом коррекции высоких аномалий рефракции, позволяя повысить остроту зрения в 8–11 раз у пациентов с тонкой роговицей и наличием противопоказаний к лазерной коррекции зрения.
Ключевые слова: *высокая аномалия рефракции, факичная интраокулярная линза, острота зрения, миопия высокой степени, интраокулярная коррекция, внутриглазное давление*

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Автор, ответственный за переписку: Назим Н. Зайнутдинов, znazim@yandex.ru

INTRODUCTION

Myopia is one of the most common ametropic diseases. The high prevalence of refractive errors are the leading pathology of the eye among the population at a capable age. According to a number of epidemiological studies, the frequency of propagation of refractive errors varies from 23 to 36% and even up to 40% [1–2].

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. Mainly in ophthalmic practice eyeglasses, contact lenses and surgical methods (radial keratotomy, photo refraction, excimer laser surgery of the cornea, clear lens extraction, etc.) are used to correct the refractive anomalies. A number of studies indicate that high myopia and myopic astigmatism is the fourth to seventh disease accounting for blindness [3–4].

The surgical correction of refractive errors such as high myopia and myopic astigmatism includes keratorefractive surgery, refractive clear lens extraction and phakic intraocular lens (pIOL) implantation. Phakic intraocular lenses 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 than corneal refractive procedures [5–6].

Posterior chamber phakic IOLs offer several advantages for correction of high-degree myopia: reversibility, a greater amount of correction, a minimally invasive, precise predictable, preservation of accommodation and corneal endothelial protection. In recent years, anterior chamber phakic IOls implantation has gradually been replaced by posterior chamber pIOLs implantation [7].

Initially, implantable lens consisting of a biocompatible collagen copolymer was developed by STAAR Surgical, (Monrovia CA, USA) in 1993 as a sulcus-placed posterior chamber pIOL and was called ICL. This lens can correct high refractive errors. ICL implantation has several advantages, including faster recovery, more stable refraction, and better visual quality, reversibility of the surgical procedure and exchangeability of the pIOL. However, the first models of ICL had more complications such as poor predictability, and higher risk for developing glaucoma and cataract, which were revealed after implantation. Lens development and modification continues by manufacturer under supervising major scientists [8].

In 2016, last modifications of (EVO + Visian ICL) VICM5 and VTICM5 models for correction of spherical and toric refraction errors were designed and manufactured. This lens has advanced optic size from 4.9 to 6.1 mm, which allows decreasing night light complaints such as halos and glare, on patients who underwent ICL implantation. These lenses already have been registered and certified to use in medical practice by The State Drugs and Equipments, Quality Control and Registration Committee of Uzbekistan.

PUSPOSE

To evaluate clinical outcomes during 6 months post-op period, after implantation of spheric and toric ICL pIOLs to patients with high myopia and myopic astigmatism.

MATERIAL AND METHODS

This study is composed of 112 eyes of 60 patients with high myopia and myopic astigmatism who underwent implantation of spheric and toric ICL (VICM5 and VTICM5 models) from January 2020 to December 2022 at NAZAR Eye Center, Tashkent, Uzbekistan. Those patients in whom LASIK surgery was contraindicated because of thin cornea and range of myopia was higher than – 6.0 diopters (D) and myopic astigmatism more than – 2.0 diopters. All patients had stable refractions within ±0.75 D for 1 year before surgery. Each patient had undergone specialized ophthalmic examination such as; bio ophthalmoscopy with dilated pupil by using 90 D aspheric lens (Volk Inc., USA), A & B ultrasound scanning of eye globe, non-contact tonopachymetry (Topcon, Japan), autorefkeratometry (Topcon, Japan), keratotopography

(ORBSCAN III, ZYWAVE3, Germany), anterior and posterior segment OCT (HD – Cirrus 4000, Zeiss, Germany). IOL power calculation performed based on cycloplegic refraction, keratometry, axial length, anterior chamber depth (ACD) and lens thickness. Depends on keratopachymetric and ACD results we gave attention to anterior chamber depth from endothelium to the anterior surface of clear natural lens. This measure could not be less than 2.80 mm. Patients with peripheral retinal tears and lesions were treated by green laser coagulator (Novus spectra, Lumenis, USA).

Exclusion criteria included lens opacities, peripheral retinal detachments, history of uviets, glaucoma, shallow anterior chamber, corneal pathology etc. Informed and written consents were obtained in each case. In all cases intraocular pressure measurements and gonioscopy had been done 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. The ICL power was calculated by using the STAAR Surgical OCOS system (Online calculation and order system) https://evo-ocos.staarag.ch/Live/. Each eye had been examined by using anterior segment optic coherent tomography (OCT HD – Cirrus 4000, Zeiss, Germany) to determine (the vault) distance between ICL and anterior surface of clear natural lens in postoperative period at 1 day, 1 week and 1,3, 6 months.

Surgical technique

On the day of surgery, all patients were administered dilating and cycloplegic agents. Pupillary dilation was achieved by using combination of Sol. Mydoptic (phenylephrine) 2.5% and Sol. Tropicamide 1% eye drops, administered three times at 15 minutes interval, 1 hour prior to surgery. All surgeries performed under topical and subtennon anesthesia by a single high experienced surgeon by using standardized technique. Two clear corneal 1 mm paracentesis were made and injected into AC hydroxypropylmethyl cellulose 1% – viscoelastic. VICM5 and VTICM5 models of ICL were implanted through a 2.8 mm temporal clear corneal incision by using injector and cartridge system from STAAR Surgical. ICLs were placed and positioned into the posterior chamber by using Vukich ICL manipulator. Viscoelastic device was completely washed out of the anterior chamber with balanced salt solution (BSS), and myotic agent (Carbacholin) was instilled. Only while implanting toric ICL we had an attention to axis and marked preoperatively to limb side by using sterile pen on biomicroscope. Then during axis correction procedure, we gave more attention to make a right position toric ICL by limb marked points in 0° and 180°. All surgeries were sucsessfully ended and no intraoperative complication was observed. After surgery, 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 during 2 weeks, then the dose of medications being reduced gradually by 1 month.

Statistical analysis

All statistical analysis were performed using Microsoft Excel (2016 version, Microsoft Corporation, Redmond, WA, USA). The Student`s t-test was used to perform in both groups the preoperative – vs – postoperative data comparison. The efficacy index (defined as the ration between postoperative UCVA and preoperative BCVA) and safety index (defined as the ratio between postoperative BCVA and preoperative BCVA) were calculated based on Snellen decimal visual acuity values. The results were expressed as mean±standard deviation (SD), and value of $p<0.05$ was considered statistically significant.

RESULTS

Totally 112 eyes of 60 patients (52 bilateral and 8 unilateral ICL implanted patients) were recruited in this study. These eyes depends on refractive errors had divided into two groups. The first group A has 30 patients with 58 eyes who had only undergone spheric ICL (VICM5 model) implantation to correct high myopia. The second group B has 30 patients with 54 eyes who had toric ICL (VTICM5 model) implantation to correct high myopia and myopic astigmatism. All patients had pIOL implantation in an eye center by one surgeon during 2 years. Preoperative demographic data are listed in *Table 1*. All eyes had successful surgery and there were few intraoperative and early postoperative complications encountered. The mean follow-up period was 6.5±1.2 months.

As shown in *Table 1*. The mean age of patients in Group A was 27.52±6.61 and in Group B was 28.34±6.64. Gender proportion was 13:17, male 43.3% and female 56.7% to 14:16, male 46.7% and female 53.3% respectively. The mean SE in Group A was –10.59±3.41 and in Group B was –9.85±2.65 D, UCVA and BCVA by Snellen were 0.06±0.03, 0.44±0.25 to 0.09±0.05, 0.43±0.18 respectively. The horizontal white-to-white distance in Group A was 11.43±0.42 and in Group B was 11.59±0.49 mm.

The mean anterior chamber depth was 3.02±0.16 to 3.02±0.15 mm, and keratometric readings were in Group A, K1: 42.53±2.16 D and K2: 43.90±2.21 D, in Group B were K1: 42.04±1.52 D and K2: 45.00±1.66 D.

The mean axial length in Group A was 27.59±1.34 mm, central corneal thickness was 501.07±34.2 μm, and IOP was 15.9±1.92 mm Hg. The mean axial length in Group B was 27.18±1.23 mm, central corneal thickness was 497.37±30.1 μm, and IOP was 16.3±1.85 mm Hg. Intra operatively had been implanted totally 112 ICL and TICL pIOLs: spheric ICL model (VICM5) to 58 eyes and toric ICL model (VTICM5) to 54 eyes. The mean implanted pIOL spherical power in Group A was –11.11±3.19 D and size was 12.83±0.35 mm, in Group B was –10.47±2.3 D, toric power was 2.74±0.6 D and size was 12.91±0.46 mm respectively.

All patients who underwent pIOL implantation surgery had been observed postoperatively at 1st day, 1st week, 1st, 3rd and 6 months periodically in NAZAR Eye Center. Postoperative examinations included UCVA, BCVA, and manifest residual refraction (residual sphere and cylinder), IOP measures, CCT and central vault volume (distance between the pIOL and anterior surface of crystalline). Group A patients postoperative follow-up data are shown in *Table 2*.

In both group, we found significant increase of manifest residual refraction during 6 months post-op period. In Group A manifest residual spherical component of refraction at different periods from 1st day to 6th months

Table 1

Preoperative patient demographic data and pIOL characteristics (n=112 eyes)

Таблица 1

Предоперационные демографические данные пациентов и характеристики ФИОЛ (n=112 глаз)

Characteristic Показатели		Mean ± SD (range) Среднее значение ± стандартное отклонение (диапазон)		Student`s (t-test) Тест Стьюдента
		Group A (58 eyes) Группа А (58 глаз)	Group B (54 eyes) Группа В (54 глаза)	p
Age (years) Возраст (лет)		27.52±6.61 (21 to 44)	28.34±6.64 (20 to 42)	0.628
Gender (male:female), n (%) Пол (муж/жен), n (%)		13:17 (43.3%:56.7%)	14:16 (46.7%:53.3%)	
Manifest spherical equivalent (D) Сферический эквивалент рефракции (дптр)		−10.59±3.41 (−6.25 to −19.75)	−9.85±2.65 (−6.25 to −18.00)	0.206
Manifest cylinder (D) Цилиндрический компонент (дптр)		−1.29±0.51 (−0.25 to −2.00)	−3.19±0.79 (−1.75 to −5.50)	0.000
UCVA by Snellen НКОЗ по таблице Снеллена		0.06±0.03 (0.01 to 0.15)	0.09±0.05 (0.03 to 0.25)	0.000
BCVA by Snellen МКОЗ по таблице Снеллена		0.44±0.25 (0.10 to 1.00)	0.43±0.18 (0.10 to 0.80)	0.855
Horizontal white-to-white distance (mm) Расстояние от лимба до лимба в горизонтальном меридиане (мм)		11.43±0.42 (10.5 to 12.5)	11.59±0.49 (10.4 to 12.6)	0.069
Anterior chamber depth (mm) Глубина передней камеры (мм)		3.02±0.16 (2.80 to 3.32)	3.02±0.15 (2.80 to 3.35)	0.842
Axial length (mm) Аксиальная длина (мм)		27.59±1.34 (24.85 to 31.12)	27.08±1.22 (25.19 to 30.23)	0.222
Central corneal thickness (μm) Толщина центральной зоны роговицы (нм)		501.07±34.2 (432 to 596)	497.37±30.1 (429 to 559)	0.544
Keratometric readings (D) Показатели кератометрии (дптр)	K1	42.53±2.16 (38.00 to 48.50)	42.04±1.52 (39.00 to 46.75)	0.163
	K2	43.90±2.21 (39.50 to 49.75)	45.00±1.66 (41.50 to 49.50)	0.003
Intraocular pressure (mm Hg) ВГД (мм рт.ст.)		15.9±1.92 (13 to 22)	16.3±1.85 (14 to 21)	0.264
Implanted pIOL spherical power (D) Сила имплантированной сферической ИОЛ (дптр)		−11.11±3.19 (−6.00 to −18.00)	−10.47±2.3 (−7.00 to −14.00)	0.225
Implanted pIOL toric power (D) Сила имплантированной торической ИОЛ (дптр)		N/A	2.74±0.6 (1.5 to 4.00)	
Implanted pIOL size (mm) Размер имплантируемой ИОЛ (мм)		12.83±0.35 (12.1 to 13.2)	12.91±0.46 (12.1 to 13.7)	0.341

was: −0.79±0.33, −0.84±0.33, −0.90±0.37, −0.96±0.41, −1.09±0.40, respectively. Residual cylindric component at the same period was: −0.78±0.41, −0.77±0.39, −0.77±0.39, −0.76±0.37, −0.78±0.37.

In Group B manifest spherical component of refraction at the following period was −0.97±0.58, −1.1±0.58, −1.17±0.55, −1.27±0.57, −1.37±0.52 and residual cylinder was −0.82±0.36, −0.88±0.37, −0.96±0.38, −0.99±0.41, −1.00±0.42 in 1 day, 1 week and 1,3,6 months post-op period, respectively ($p<0.001$). The mean changes in manifest spherical refraction from 1 day to 6 months were shown in *Figure 1*.

The mean changes in manifest cylinder refraction during 6 months post-op period were shown in *Figure 2*. Postoperatively, In Group A, UCVA by Snellen was 0.49±0.25, 0.56±0.23, 0.61±0.22, 0.64±0.21, 0.66±0.21 and BCVA by Snellen was 0.54±0.25, 0.60±0.19, 0.64±0.21, 0.67±0.21, 0.68±0.21 in 1 day, 1 week, and 1, 3 and 6 months after surgery, respectively. We found a significant difference between preoperative UCVA and BCVA, with 6 month postoperative UCVA and BCVA ($p<0.001$, Student`s paired t-test) *(Fig. 3)*. The safety index for group A was 1.43 and efficacy index was 1.34.

Table 2

Group A patient preoperative and postoperative demographic data: 6 months follow-up period (Mean ± SD)

Таблица 2

Дооперационные и послеоперационные демографические данные в группе А: период наблюдения 6 месяцев (среднее значение ± стандартное отклонение)

Characteristic Показатели		Pre op values До операции	Postoperative follow-up periods Сроки наблюдения после операции				
			1 day 1 день	1 week 1 неделя	1 month 1 месяц	3 months 3 месяца	6 months 6 месяцев
Manifest residual refraction (D) Остаточная рефракция (дптр)	Sph	−10.59±3.41	−0.79±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	−1.29±0.51	−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 НКОЗ по таблице Снеллена		0.06±0.03	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 МКОЗ по таблице Снеллена		0.44±0.25	0.54±0.25 (p<0.013)	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 (mm Hg) ВГД (мм рт.ст.)		15.9±1.92	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)
Central corneal thickness (μm) Толщина центральной зоны роговицы (нм)		501.07±34.2	498.2±34.64 (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) Расстояние между ИОЛ и хрусталиком (нм)		N/A	428±138.2 n/a	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)

Table 3

Group B patient preoperative and postoperative demographic data: 6 months follow-up period (Mean ± SD)

Таблица 3

Дооперационные и послеоперационные демографические данные в группе В: период наблюдения 6 месяцев (среднее значение ± стандартное отклонение)

Characteristic Показатели		Pre op values До операции	Postoperative follow-up periods Сроки наблюдения после операции				
			1 day 1 день			1 day 1 день	
Manifest residual refraction (D) Остаточная рефракция (дптр)	Sph	−9.85±2.65	−0.97±0.58 (p<0.001)	−1.1±0.58 (p<0.001)	−1.17±0.55 (p<0.001)	−1.27±0.57 (p<0.001)	−1.37±0.52 (p<0.001)
	Cyl	−3.19±0.79	−0.82±0.36 (p<0.001)	−0.88±0.37 (p<0.001)	−0.96±0.38 (p<0.001)	−0.99±0.41 (p<0.001)	−1.00±0.42 (p<0.001)
UCVA by Snellen НКОЗ по таблице Снеллена		0.09±0.05	0.47±0.19 (p<0.001)	0.51±0.19 (p<0.001)	0.56±0.18 (p<0.001)	0.60±0.18 (p<0.001)	0.62±0.18 (p<0.001)
BCVA by Snellen МКОЗ по таблице Снеллена		0.43±0.18	0.54±0.19 (p<0.001)	0.58±0.19 (p<0.001)	0.60±0.18 (p<0.001)	0.63±0.18 (p<0.001)	0.63±0.18 (p<0.001)
Intraocular pressure (mm Hg) ВГД (мм рт.ст.)		16.3±1.85	16.91±3.1 (p<0.102)	15.74±1.92 (p<0.05)	15.07±1.37 (p<0.001)	14.83±1.26 (p<0.001)	14.69±1.16 (p<0.001)
Central corneal thickness (μm) Толщина центральной зоны роговицы (нм)		497.37± 30.1	493.6±30.44 (p<0.006)	495.9±30.68 (p<0.325)	499.3 ±30.18 (p<0.224)	500.2±29.97 (p<0.113)	498.8±29.76 (p<0.461)
Vault (μm) Расстояние между ИОЛ и хрусталиком (нм)		N/A	427±141.7 n/a	463.2±142.6 (p<0.001)	485.5±138.6 (p<0.001)	492.2±133.7 (p<0.001)	490.9±131 (p<0.001)

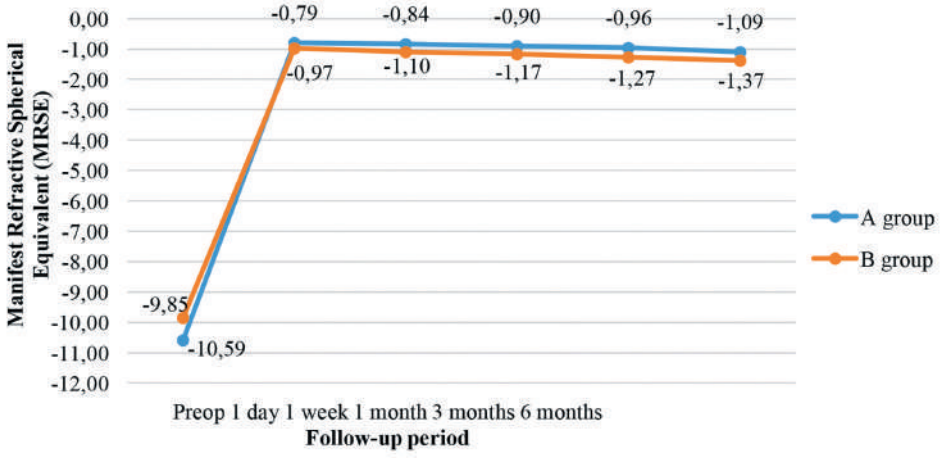

Fig. 1. Changes in mean spherical equivalent during 6 months postop period

Рис. 1. Динамика среднего показателя сферического эквивалента рефракции в течение 6 месяцев после операции

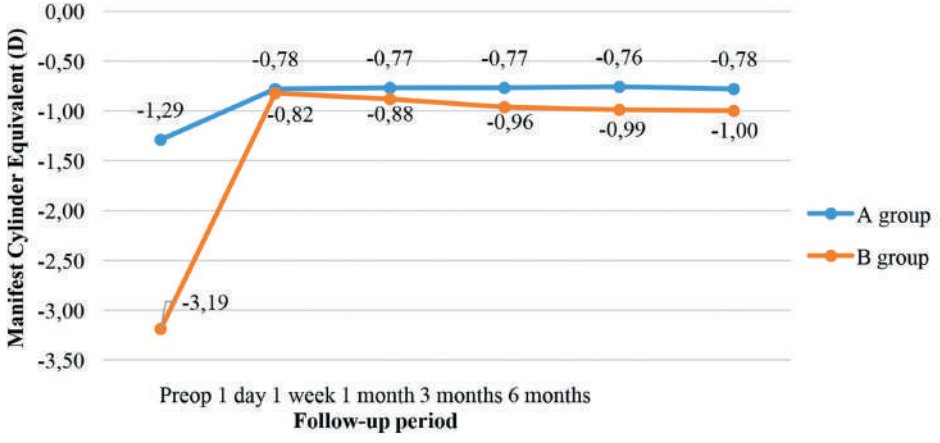

Fig. 2. Changes in mean cylinder equivalent during 6 months postop period

Рис. 2. Динамика среднего показателя цилиндрического компонента рефракции в течение 6 месяцев после операции

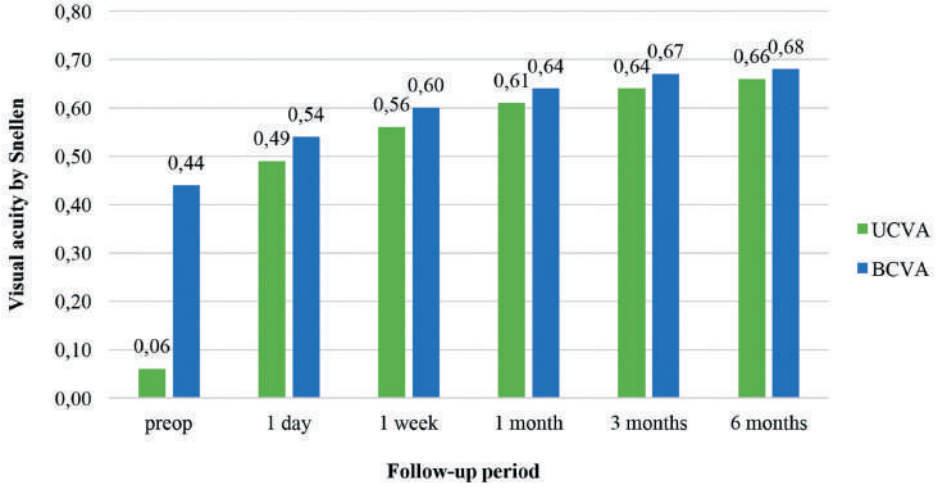

Fig. 3. Changes in UCVA and BCVA during 6 months postop period

Рис. 3. Динамика показателей НКОЗ и МКОЗ в течение 6 месяцев после операции (группа А)

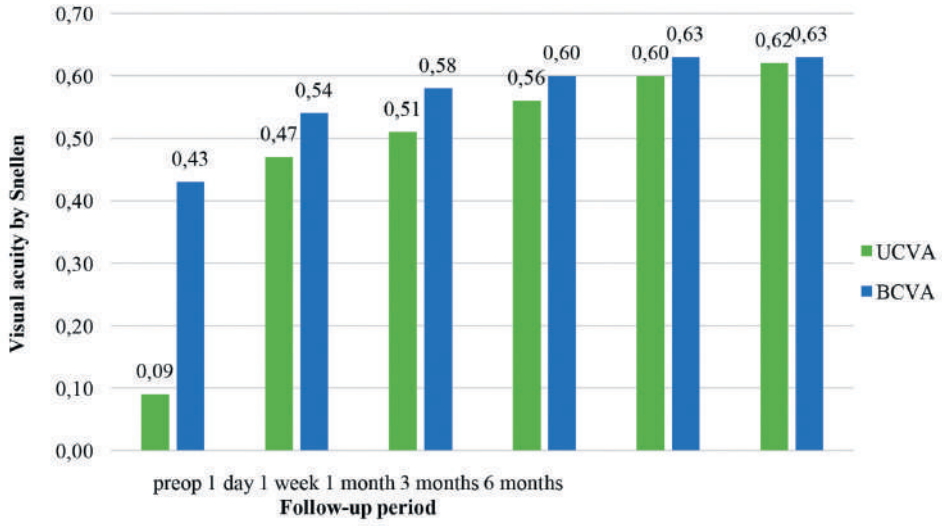

Fig. 4. Changes in UCVA and BCVA during 6 months postop period

Рис. 4. Динамика показателей НКОЗ и МКОЗ в течение 6 месяцев после операции (группа В)

In Group B, UCVA by Snellen was 0.47±0.19, 0.51±0.19, 0.56±0.18, 0.60±0.18, 0.62±0.18 and BCVA by Snellen was 0.54±0.19, 0.58±0.19, 0.60±0.18, 0.63±0.18, 0.63±0.18 in 1 day, 1 week, and 1, 3 and 6 months after surgery, respectively. We found a statistically significant difference between preoperative UCVA and BCVA, with 6 month postoperative UCVA and BCVA (p<0.001, Student`s paired t-test) *(Fig. 4)*. The safety index for group B was 1.39 and efficacy index was 1.28.

The remained manifest spherical equivalent (SE) correction in one day 1 week, 1, 3 and 6 months after surgery 95% of eyes were within ±0.75 and ±1.0 D, respectively, of the attempted SE correction. The manifest SE in Group A and Group B were significantly decreased from −10.59±3.41 D and −9.85±2.65 D preoperatively to −0.5±1.0 D postoperatively (p<0.001, Student`s paired t-test). IOP is one of the most important parameters that should be evaluated in those patients implanted with this phakic IOLs. As mentioned above, the central port facilitates aqueous flow, which helps keep IOP at appropriate levels. In this study, IOP values carefully had been analyzed.

In Group A, the IOP was 16.98±4.21, 16.50±4.39, 15.93±3.48, 14.98±2.26 and 14.90±2.18 mm Hg. The mean post-op IOP was 15.86±3.30 mm Hg and in opposite Group B, the IOP was 16.91±3.1, 15.74±1.92, 15.07±1.37, 14.83±1.26 and 14.69±1.16 mm Hg at 1 day, 1 week, 1.3 and 6 months after surgery. The mean IOP in Group B was 15.44±1.76 mmHg. Respectively. These data are shown in *Figure 5*. These changes are not statistically significant (p<0.947).

In early the 1st day of post-up period had revealed high intraocular pressure in 7 (6.25%) eyes from total 112 eyes. IOP was increased up to 38.00 mm Hg. Immediately we prescribed eye drops Sol. Timolol 0.5% – 5 ml, twice a day for 1 week. Increased IOP slowly went down until 16.00 mmHg during 1 week, respectively. Any secondary glaucoma case had been revealed during observation period in both group.

In Group A, the mean vault was 428±138.2, 452.4±134.6, 469.3±134.4, 479.9±131.2 and 483.5±127.7 μm, and changes from minimal to maximal measures postoperatively (p<0.001, Student`s paired t-test); In all cases, we revealed the minimal mean vault 101 μm and the maximal mean vault 752 μm. These measures showed no significant changes between 1 day, 1 week and 1, 3 and 6 months results.

In Group B, the mean vault was 427±141.7, 463.2±142.6, 485.5±138.6, 492.2±133.7 and 490.9±131 μm, and changes from minimal to maximal measures postoperatively (p<0.001, Student t-test); In all cases, we revealed the minimal mean vault 189 μm and the maximal mean vault 767 μm. These measures showed few significant changes between 1 day, 1 week and 1.3 and 6 months results. These data are shown in *Figure 6*.

There were no intraoperative complications but while implanting we should re-implanted 6 (5.36%) eyes from total 112 eyes pIOL again into AC through main clear corneal temporal incision. While injecting ICL was reversed its position and optic side was touched to anterior surface of crystalline. In these cases, we got the ICL back gently and carefully reinject it. At the end of this implantation procedure PIOL was in right position. Only in 2 (3.7%) eyes from 54 eyes we should repositioned toric ICL cylinder axis position to correct place which axis rotation was over than 12°. During 6 months of observation after surgery, only in one eye (0.89%) from total 112 eyes anterior subcapsular lens opacity was found in the 3rd month of post-op period. Only in one eye (0.89%) had appeared retinal detachment after 6 months post-op period.

DISCUSSION

The main findings of this study showed that, in all measures of safety, efficacy, predictability and stability we achieved expected refractive outcomes after implantation of

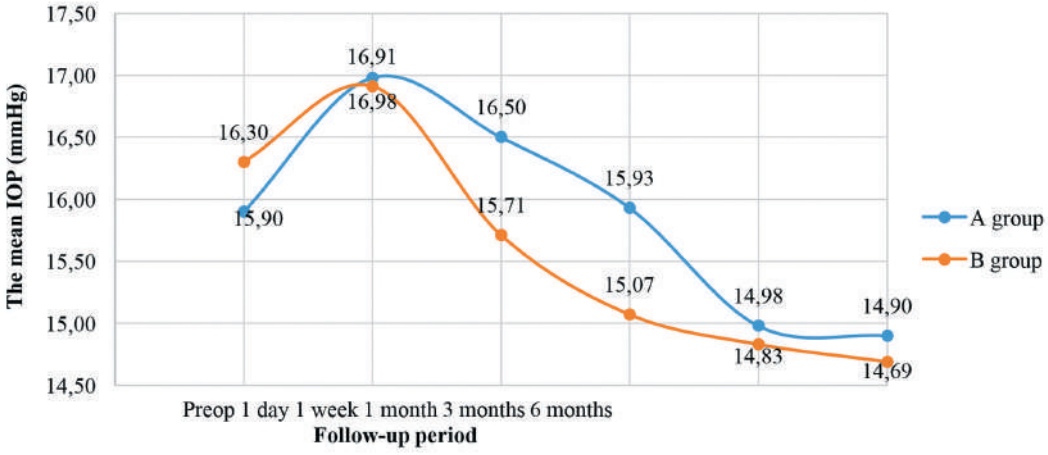

Fig. 5. Changes in IOP during 6 months postop period

Рис. 5. Динамика ВГД в течение 6 месяцев после операции

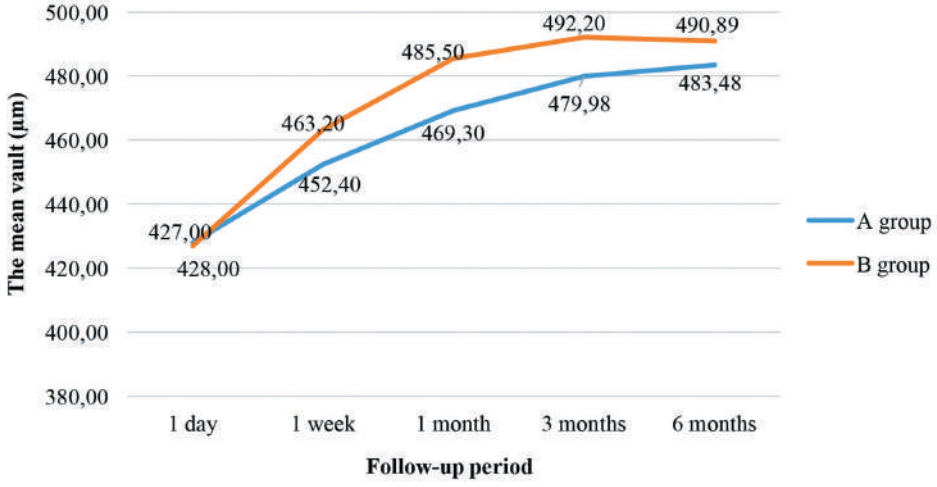

Fig. 6. Changes in vault during 6 months postop period

Рис. 6. Динамика показателей «свода» (расстояние между ИОЛ и хрусталиком) в течение 6 месяцев после операции

VICM5 and VTICM5 ICL models to patients with high myopia and myopic astigmatism during 6 months follow-up period.

Concerning to the safety and efficacy of the procedure, ICL implantation was safe and efficacy for the correction of high myopia and myopic astigmatism with finding results that were matched in previous studies [9].

Concerning to predictability and stability, this procedure through a 2.8 mm temporal clear corneal incision. Regardless of the amount of myopic correction, has negligible effect on refractive outcome, and that this surgical technique is less subject to the wound healing responses of the cornea [10]. About complications of the surgical technique, we found no significant rise of IOP during 6 months of post-op follow-up period. As mentioned above only in 7 (6.25%) eyes from total 112 eyes we found increasing of IOP at 1 day and 1 week post-op follow-up period and we reached to safe IOP values by using hypotensive eye drops. In any case, we did not find pigment dispersion symptoms in anterior segment of the eye during 6 months follow-up period.

One of the first study of ICL model with central flow technology (V4c model with central hole) performed by Shimizu et al. [11] (2012) 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. Change in manifest refraction from 1 week to 6 months was 0.06±0.28 D. The mean IOP was 13.00±3.0 mm Hg, the mean ECD was 2720±268 (2.8% loss) and the mean vault value not reported.

Alfonso et al. [12] (2013) reported his results after implanting ICL to 138 eyes of 70 patients during 6 months post-op period. The mean age of patients were 30.5±4.8, the mean SE was –8.73±2.54 D (–3.00 to 17.50 sph, –0.25 to –3.00 cyl) and the mean WTW was 11.99±0.44 mm. The mean CCT value was 539±36 μm and the mean ACD was 3.31±0.25 mm. The mean ICL size was 13.16±0.34 mm and the mean ICL power was –9.52±2.60 D (–3.50 to –18.0). The mean IOP was 12.4±1.5 mm Hg, the mean ECD was 2533 (8.5% loss) and the mean vault value was 482.7±210.5 (90 to 970) μm. Once again, Alfonso et al. (2019) reported his study results. The mean IOP value was 13.00±2.03 mmHg. The mean ECD was 2645±359 (0.43% loss) and the mean vault value was 340±163 μm. Kamiya et al. [13] (2017) reported high level of results as 100% of eye being within ±0.50 D and ±1.00 D, respectively, of the target correction with SE –0.08±0.17 D. The mean IOP value was 13.6 mmHg. Chen et al. [14] (2020) evaluated 22 eyes of 22 patients with high myopia and myopic astigmatism during 6 months. The mean SE was –9.43±5.01 D and the mean cylinder was –3.75±1.50 D. The mean age of patients were 26.5±5.8 and the mean ACD was 3.42±0.31 mm. The mean IOP value was 15.52±2.87 mm Hg. The mean ECD was 3261.4±355.1 (0.35% loss). The mean vault was not reported. In this study were implanted Toric ICL with the mean SE power –12.4±0.8 D and the mean cylinder 4.50±1.00 D. Chen et al. (2016) reported these study results. The mean IOP value was 16.00±2.2 mmHg and the mean vault was 542.8±45.3 μm. Cao et al. [15] (2016) also followed-up 41 patients with 78 eyes after ICL implantation during 6 months post-op period. In his study, the mean age of patients were 29.1±8.3 and the mean SE was –12.55±2.98 D. The mean WTW measures were 11.4±2.98 mm. The mean IOP value was 14.9±2.0 mm Hg. The mean ECD was 2633±310 (2% loss) and the mean vault value was 499.7±244.3 (120 to 980) μm.

Pjano et al. [16] (2017) evaluated 28 myopic eyes (mean SE –9.52±3.69) of 16 patients and gained favorable post-op visual results UCVA (0.76±0.16 by Snellen) and corrected visual acuity was (0.79±0.14 by Snellen) within 1 year follow-up period after pIOL (ICL) implantation. In his study the mean IOP value was 14.96±1.7 mmHg and the mean ECD was 2512±127 (5.5% loss). The mean vault value was not reported.

Lee et al. [17] (2018) reported his study results after implantation of ICL to 236 eyes of 236 patients during 6 months postop period. The mean age of patients was 28.2±5.1 (20 to 44), the mean SE was –9.19±2.36 (–4.00 to –19.13) and the mean WTW measure was 11.46±0.28 mm (10.85 to 12.80). The mean ACD value was 3.35±0.20 mm, the mean ICL size was 12.6 mm and the mean implanted ICL power was –11.2±2.2 (–5.5 to –18.00). The mean vault value was 519±112.8 (250 to 740) μm. 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 VICM5 and VTICM5 models. For example halos and glare decreasing the patient`s visual performance.

However, previous studies concluded that the hole ICL provided excellent optical quality that was essentially equivalent to that of none hole conventional ICL. An animal model study by Shiratani et al. has reported good and comparable optical quality outcomes of pIOL with and without a central hole. Except for rare complications, cataract formation is the most frequently revealed problem, which is related to ICL implantation (Fernandes et al. 2011). In fact, the prevalence of cataract formation has been widely studied in the context of different ICL models, and different studies indicated that it is more common in older patients and patients with higher myopia (Sanders 2008; Schmidinger et al. 2010; Alfonso et al. 2015). In a study analyzing 781 eyes implanted with V4c ICL model (range 3 – 24 months), Alfonso et al. [5] (2015) found any cases of cataractous eyes.

Similarly, meta-analysis study (Packer 2018) described zero incidence of asymptomatic anterior subcapsular cataract formation. Other analysis indicates that Karandikar et al. [18] (2015), Bhandari et al. (2016), Rizk et al. [19] (2019) and Sachdev et al. [20] (2019) reported only in one eye had revealed cataract formation. This complication mainly occurred in 9 months, one year or two years post-op follow-up periods. One of other complications is uncorrected or over corrected rotation of the pIOL. Rotation of lens more than 30° was reported in several studies (Karandikar et al. 2015; Bhandari et al. 2016; Ganesh et al. 2017; Pjano et al. 2017 and Kamiya et al. 2018). This event required re-rotation or lens exchange surgery. A comparative study of rotational stability between spheric and toric models of ICL concluded that both lenses have similar rotational stability (3.39° versus 4.17°, respectively; Hyun et al. 2017) [21].

In this study, we investigated first 112 eyes in which were implanted VICM5 (58 eyes) spheric ICL and VTICM5 (54 eyes) toric ICL models to patients with high myopia and myopic astigmatism in Uzbekistan. The main privilege of these lenses are expended optic size. The optic size in V4c is ranges from 4.9 to 5.8 mm. EVO+ new ICL VICM5 and toric ICL VTICM5 models optic size range from 5.0 to 6.1 mm. In this study, we found any significant difference after implantation of this lens. Patients have satisfied results and significantly have decreased halo and glare visual complaints at nighttime.

CONCLUSION

In summary, initial results of our study indicate that implantation of VICM5 spheric and VTICM5 toric ICL new models with expanded optic size is safe, effective and provides predictable and stable refractive results in the correction of eyes with high myopia and myopic astigmatism. In our opinion, the lens design with expanded optic size and with central hole significantly decreases of complaints on nighttime such as halo and glare. Also adequate patient selection, accurate measurement of all parameters that are required to calculate spheric and toric ICL size and power are all extremely important to achieve good postoperative results in follow-up period. Patient with spheric and toric refraction would get high visual performance and had increased quality of life during short and long post-op period time. We believe and recommend that this procedure is alternative and safe method to patients who has high refractive errors and requires more investigations for long follow-up period after implantation of both ICL models.

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Information about the authors
Nazim N. Zaynutdinov – PhD, doctoral student of RSSPMCEM, Uzbekistan, znazim@yandex.ru
Azamat F. Yusupov – Professor, director of RSSPMCEM, Uzbekistan
Muyassar Kh. Karimova –Professor, deputy director for research works in RSSPMCEM, Uzbekistan
Khalidjan M. Kamilov – Professor, head of ophthalmology department in CDPQMW, Uzbekistan

Информация об авторах
Назим Н. Зайнутдинов – к.м.н., докторант РСНПМЦМГ, Узбекистан, znazim@yandex.ru
Азамат Ф. Юсупов – д.м.н., профессор, директор РСНПМЦМГ, Узбекистан
Муяссар Х. Каримова – д.м.н., профессор, заместитель директора по научной работе РСНПМЦМГ, Узбекистан
Халиджан М. Камилов – д.м.н., профессор, заведующий кафедрой офтальмологии ЦРПКМР, Узбекистан

Authors` contribution:
Zaynutdinov N.N. – collection of clinical materials, work with text.
Yusupov A.F. – design and organization of the study.
Karimova M.Kh. – statistical processing work with tables and graphs.
Kamilov Kh.M. – work with text.

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Зайнутдинов Н.Н. – сбор клинического материала, работа с текстом.
Юсупов А.Ф. – дизайн и организация исследования.
Каримова М.Х. – статистическая обработка, работа с таблицами и графиками.
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