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Long-term results of late "in-the-bag" IOL dislocation surgery

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BACKGROUND: Intraocular lens (IOL) repositioning and IOL exchange are the main methods of surgical treatment of late "in-the-bag" IOL dislocation.

AIM: To evaluate refraction, induced corneal astigmatism and IOL tilt after surgical treatment of late "in-the-bag" IOL dislocation by transscleral suture fixation and exchange to "iris-claw" IOL with retropupillary fixation.

MATERIALS AND METHODS: 78 of patients with late "in-the-bag" IOL dislocation were included. Transscleral suture IOL fixation was performed in group I (38 eyes), exchange to "iris-claw" IOL was performed in group II (40 eyes). Refractometry, keratotopography and optical coherence tomography of anterior segment were performed before surgery, 1 week, 1, 3 and 6 months after surgery.

RESULTS: The groups did not differ in subjective and objective refraction. But there was significant variability of data in the group I 3 and 6 months after surgery. There was no difference in corneal astigmatism in both groups during 3 months, but a significant increase was found in group II 6 months after surgery. There was no difference in IOL tilt between groups before surgery. Decrease of IOL tilt in 180 degrees plane was observed after 1 month in group II, while there was no difference in 90 degrees plane between groups.

CONCLUSIONS: Both methods of late "in-the-bag" IOL dislocation treatment allow to receive good refractive result, but refraction is less predictable after trans-scleral suture IOL fixation. Surgically induced astigmatism is higher in IOL exchange group due to large sclerocorneal tunnel incision. Transscleral suture IOL fixation does not cause clinically significant IOL tilt.

Keywords: IOL dislocation; AS-OCT; IOL exchange; IOL fixation; IOL tilt.

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Оценка отдалённых результатов хирургического лечения поздней дислокации комплекса «интраокулярная линза — капсульный мешок»

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Актуальность. Основные способы хирургического лечения поздней дислокации комплекса «интраокулярная линза (ИОЛ) – капсульный мешок»: склеральная фиксация ИОЛ и замена на другую ИОЛ с различными видами фиксации.

Цель — оценить рефракцию, роговичный астигматизм, угол наклона ИОЛ после хирургического лечения поздней дислокации комплекса «ИОЛ – капсульный мешок» методами транссклеральной шовной фиксации ИОЛ и замены на «ирис-клоу»-ИОЛ с ретропупиллярной фиксацией.

Материалы и методы. В исследование включены 78 пациентов: в группе I (38 глаз) выполнена транссклеральная шовная фиксация ИОЛ, во группе II (40 глаз) — замена на «ирис-клоу»-ИОЛ с ретропупиллярной фиксацией. До операции и через 1 нед., 1, 3 и 6 мес. после нее пациентам проводили рефрактометрию, кератотопографию и измерение угла наклона ИОЛ методом оптической когерентной томографии.

Результаты. Между группами сравнения не было достоверной разницы по величине субъективной и объективной рефракции, однако в отдалённые сроки в группе I выявлен значительный разброс данных. В течение 3 мес. группы не отличались по роговичному астигматизму, через 6 мес. обнаружено значимое его увеличение у пациентов группы II. Группы не отличались по углу наклона ИОЛ до операции. Через 1 мес. после операции и далее отмечалось его уменьшение в группе II в меридиане 180°, в то время как в меридиане 90° достоверных различий между группами не выявлялось.

Заключение. При выполнении транссклеральной шовной фиксации ИОЛ вероятность развития хирургически индуцированного астигматизма ниже, чем при замене на «ирис-клоу»-ИОЛ с ретропупиллярной фиксацией. Оба метода дают возможность получить хороший рефракционный результат, однако при замене ИОЛ конечная рефракция более предсказуема. Метод транссклеральной шовной фиксации не приводит к клинически значимому наклону ИОЛ.

Ключевые слова: интраокулярная линза; дислокация ИОЛ; оптическая когерентная томография переднего отрезка; замена ИОЛ; фиксация ИОЛ; угол наклона ИОЛ.

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BACKGROUND

Cataract is a progressing age-related disease, and more than 50% of people elder than 75 years suffer from it [1]. The leading treatment method for cataract currently is phacoemulsification with intraocular lens implantation (PE + IOL) One of the severe complications of this method is the IOL dislocation. IOL dislocations are divided into two groups: that of the IOL-capsular bag complex ("in-the-bag" dislocation) and that to the outside of the capsular bag ("out-of-the-bag" dislocation). The "inthe-bag" dislocation occurs mostly in 6-12 years after surgery, and is related with zonular weakness; the prevalence of this complication of the PE + IOL procedure is 0.5-3% [2]. The most prevalent cause (up to 50% of cases) of the late "in-the-bag" dislocation is the pseudoexfoliative syndrome [3-5]. Among other frequent predisposing factors are sex, age, axial myopia, primary glaucoma, injuries, history of vitreoretinal surgery, chronic uveitis, pigment retinitis, connective tissue disorders, and intracapsular ring implantation at phacoemulsification surgery [2, 6, 7].

The pseudoexfoliative syndrome is a systemic disease, progressing with age and presenting as production and accumulation in tissues of several organs of an extracellular fibrillar material. The accumulation of the pseudoexfoliative material on zonules and ciliary body processes leads to the stability impairment of the zonular lens support [8].

There are two main approaches to the treatment of the "in-the-bag" dislocation: scleral IOL fixation and exchange to an IOL with various fixation types. In the present study, we compare the results of transscleral suture technique of IOL fixation with IOL exchange to the IOL with retropupillar fixation to the iris stroma ("iris-claw"). As a benefit of such exchange, the possibility to regulate the postoperative refraction is assumed, but large corneal or limbal incisions needed to replace the IOL, lead to more significant surgically induced astigmatism [9–11]. To perform the transscleral IOL fixation by sutures smaller incisions are needed, but when using this method, the refractive result depends on the position of haptics and on the "IOL-capsular bag" complex insertion into the initial position.

It is possible to assume that the IOL's tilt influences the quality of vision after surgical treatment of the "IOL-capsular bag" complex dislocation as well. The anterior segment optical coherence tomography (AS-OCT) of the eyeball ensures high resolution imaging, which allows estimating the IOL's tilt angle.

Aim — to evaluate the induced corneal astigmatism, resulting refraction, IOL's tilt angle change, and complication profile at different terms after surgical treatment of the "IOL-capsular bag" complex dislocation by transscleral suture fixation and by exchange to "iris-claw" IOL.

MATERIALS AND METHODS

Into the study, 78 patients (78 eyes) were included, who have been admitted to the hospital from September, 2018 through January, 2020, for a surgical treatment of the "IOL—capsular bag" complex dislocation of 2nd and 3rd degree according to the classification proposed by N.P. Pashtaev [12]. Depending to the treatment method, patients were divided into two groups: the group I — patients in whom a transscleral IOL fixation by sutures was performed (38 patients, 38 eyes), the group II — patients in whom an exchange to an "iris-claw" IOL with retropupillar fixation was done (40 patients, 40 eyes).

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Exclusion criteria:

- · refractive error of high degree;
- IOL luxation into the vitreous;
- · moderately severe and severe dry eye syndrome;
- history of corneal surgery, of keratitides, of keratectasias, of corneal degenerations and dystrophies;
- · history of uveitides;
- · iris diseases.

The mean age of patients was 78.89 ± 9.33 years in the group I and 83.3 ± 5.29 years in the group II (p > 0.05). Groups did not vary in the distribution of male and female patients in them (p > 0.05). The time since PE + IOL procedure in average was 8.0 ± 2.98 years in the group I and 8.0 ± 5.01 years in the group II (p > 0.05).

In the group I, there were 50% of patients with glaucoma, in the group II — 40%. In 68% of the group I patients and in 72% among those of the group II, the pseudoexfoliative syndrome was diagnosed.

All surgeries were performed by one surgeon. In the group I patients, transscleral IOL fixation by sutures was done using limbal mini-pockets (patent No. 2698174 from August 22, 2019). In the transparent limbal area, at opposite meridians, a preliminary incision involving the half of its thickness of about 2 mm length was made using a keratome. Then, a triangular pocket was created at the level of medial limbal layers. In the meridian of the pocket position, in 2.5 mm from the limbus, the sclera was perforated with an injection needle 27 G, the needle was led under the IOL's haptic element and through a paracentesis. A strait needle was introduced into it, with a polypropylene 10-0 thread, and both needles were brought outside. In 2.25 mm from the limbus and in 1 mm from the first entrance, the second perforation by an injection needle 27 G was achieved, it was led over the IOL's haptic element, and a second needle was introduced into it, with a polypropylene 10-0 thread, and both needles were brought outside. Therefore, on the haptic element a loop of polypropylene thread was created, which fixed it to the sclera. Both needles were brought intrasclerally in the direction of the limbal pocket, and led out of it. This manipulation was simplified if the needles are bent beforehand, and a slight pressure on the profound pocket's lip was put. The IOL was centered by pulling the ends of threads. The needles were cut off, and the threads were tied one to another by a surgical knot. The threads were cut off leaving short ends, and the knot was buried in the mini-pocket. Same actions were done in the opposite meridian.

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In group II patients an IOL replacement to the "irisclaw" one was performed. A bridle suture was put on the superior rectus muscle. The conjunctiva was separated from the limbus in the upper area. Diathermocoagulation was performed. A sclerocorneal tunnel 6×3 mm was formed. A viscoelastic was introduced into the anterior chamber and under the dislocated IOL. IOL was brought to the anterior chamber, then it was explanted through the sclerocorneal tunnel incision. The "iris-claw" IOL Appalens 100 (Appasamy, India) was turned with its angulation directed downwards taking into account the following retropupillar fixation, and introduced into the

anterior chamber. The haptics were positioned horizontally, brought behind the iris one by one, and enclavation of the iris stroma in the haptic elements was achieved. The tunnel incision was closed by 1 interrupted suture (silk 8-0). The conjunctiva was fixed to the limbus by two interrupted sutures (silk 8-0). The remnants of viscoelastic were aspirated.

Control patient examinations were performed before surgery, in one week, 1, 3 and 6 months postoperatively. At each visit, besides a standard ophthalmologic examination, all patients underwent keratotopography for corneal astigmatism evaluation and optical coherence tomography of the anterior segment to measure the IOL's using the tilt angle Tomey SS1000 CASIA device (Tomey, Japan). This device allows to carry out measurements of keratometric astigmatism, as well as those of anterior and posterior corneal surface astigmatism and of real corneal astigmatism (Fig. 1).

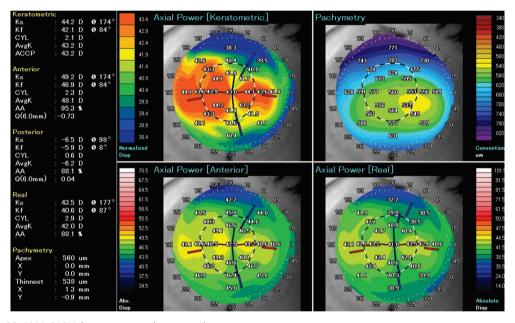


Fig. 1. Tomey SS-1000 CASIA keratotopography protocol

Рис. 1. Протокол кератотопографии, выполненной на приборе Tomey SS-1000 CASIA

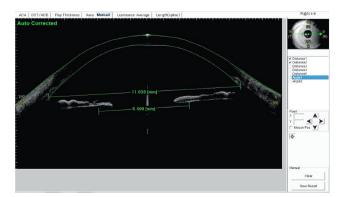


Fig. 2. Base line and Intraocular lens line determination

Рис. 2. Определение базовой линии и линии плоскости интраокулярной линзы

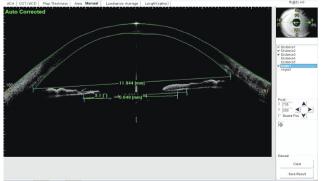


Fig. 3. Intraocular lens tilt determination

Рис. 3. Определение угла наклона интраокулярной линзы

For objective refractometry, we used the autore-fractometer Humphrey 570 (Allergan Humphrey, USA). The intraocular pressure was measured using Icare TA01i tonometer (Icare Finland Oy, Finland).

The tilt angle was measured in the 180° and 90° meridians using the data of the anterior segment optical coherence tomography (AS-OCT). The measurement was performed following the method described by N.P. Pashtaev et al. [13].

The frontal axis was determined by the baseline passing through points corresponding to the scleral spur. Then, the out-to-out distance of the IOL was measured, and the line through its optic center was drawn (Fig. 2). If the visualization of the scleral spur was insufficient for the baseline, we used points corresponding to the pupil margin of the iris.

To determine the IOL's tilt angle in degrees against the plane of scanning, a line was drawn in parallel with

the baseline, from the margin of the lens optic to the crossing with a horizontal line determining the longitudinal axis of the lens. The software automatically measured the angle in degrees (Fig. 3).

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The results were compared in the program SPSS Statistics v20.0. For parametric data, Student's t-test for independent and paired (with Bonferroni correction) samples was used, for non-parametric — Mann-Whitney U test and Fischer's exact test. At p < 0.05, the differences were considered to be statistically significant.

RESULTS

The objective refractometry was difficult before surgery due to the incorrect IOL position. The comparison groups were not different in terms of subjective as well as objective one expressed as a spherical equivalent at all follow-up terms (Table 1).

Table 1. Subjective and objective refraction of patients

Таблица 1. Субъективная и объективная рефракция пациентов групп сравнения

Group	Subjective refraction, D \pm σ	Objective refraction, D \pm σ
•	Before surgery	
Group I	0.61 ± 6.36	-
Group II	0.17 ± 3.89	-
p	0.8814	-
	1 week	
Group I	-1.65 ± 1.89	-1.12 ± 3.56
Group II	-1.1 ± 0.65	-0.81 ± 0.97
p	0.5381	0.8694
	1 month	
Group I	-1.8 ± 2.45	-1.42 ± 3.93
Group II	-1.25 ± 1.358	-1.72 ± 2.29
p	0.6243	0.8941
	3 months	
Group I	-2.3 ± 1.99	-1.55 ± 3.43
Group II	-2.06 ± 1.39	-1.5 ± 1.68
p	0.8281	0.9773
	6 months	
Group I	-2.17 ± 2.23	-1.43 ± 3.26
Group II	-1.33 ± 0.58	-1.21 ± 0.95
p	0.5416	0.8779

Table 2. Maximum and minimum values of subjective and objective refraction of patients

Таблица 2. Максимальные и минимальные значения субъективной и объективной рефракции пациентов групп сравнения

Parameter		Group I	Group II
		3 months	
Subjective spherical equivalent, D	min	-4.75	-4.0
	max	+2.0	-0.75
Objective spherical equivalent, D	min	-4.5	−3.5
	max	+5.62	0−125
		6 months	
Subjective spherical equivalent, D	min	-5.0	-4.0
	max	+2.0	-1.0
Objective spherical equivalent, D	min	-5.0	−3.5
	max	+5.62	−0.375

Table 3. Comparative astigmatism of patients in groups, D $\pm \sigma$

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Таблица 3. Сравнительные показатели астигматизма пациентов в группах, D $\pm \sigma$

Group	Keratometric astigmatism	Astigmatism of the anterior surface of the cornea	Astigmatism of the posterior surface of the cornea	Real astigmatism
		Before surgery		
Group I	1.24 ± 0.1	1.37 ± 1.07	0.26 ± 0.21	1.28 ± 0.9
Group II	1.09 ± 0.93	1.23 ± 1.03	0.5 ± 0.44	1.2 ± 0.9
р	0.7945	0.2023	0.0561	0.8415
		1 week		
Group I	1.07 ± 0.93	1.19 ± 1.02	0.31 ± 0.24	1.2 ± 0.96
Group II	1.52 ± 0.9	1.67 ± 0.1	0.75 ± 0.45	1.5 ± 0.85
р	0.2758	0.2937	0.0178	0.332
		1 month		
Group I	1.31 ± 0.55	1.46 ± 0.6	0.29 ± 0.12	1.41 ± 0.67
Group II	0.97 ± 0.71	1.07 ± 0.76	0.57 ± 0.62	1.22 ± 0.81
р	0.2301	0.2405	0.303	0.5892
		3 months		
Group I	1.03 ± 0.69	1.14 ± 0.74	0.25 ± 0.13	1.03 ± 0.7
Group II	1.57 ± 0.74	1.8 ± 0.79	0.27 ± 0.06	1.73 ± 0.67
р	0.7114	0.1236	0.7718	0.1148
		6 months		
Group I	0.96 ± 0.6	1.08 ± 0.69	0.22 ± 0.1	1.03 ± 0.79
Group II	1.93 ± 1.12	2.17 ± 1.25	0.23 ± 0.06	2.37 ± 0.21
р	0.0293	0.0238	0.4839	0.0108

Note. Embolden are values p < 0.05

However, at long-term after the transscleral suture IOL fixation, there was a significant data scatter evidenced by the increase of standard deviation. The data scatter in the comparison groups at 3 and 6 months after surgery is shown in the Table 2.

Comparing the data of keratometric, real, and anterior corneal astigmatism between the groups, we did not receive any statistically significant differences during the follow-up time up to 3 months. However, in 6 months, there was a statistically significant increase in corneal

astigmatism in group II patients, both in comparison with pre-operative values within the group, and with group I patients. At the same time, the mean values of induced astigmatism in the group II reached following values: the keratometric astigmatism in the group II was +1,13 \pm 0,68 D, that of anterior corneal surface +1,27 \pm 0,81 D, the real one +1,37 \pm 0,67 D. In one week, an increase in posterior corneal surface astigmatism in group II patients was revealed, whereas at other follow-up terms, there was no difference between groups (Table 3).

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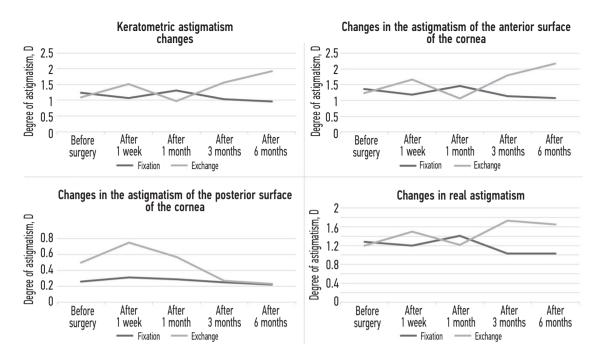


Fig. 4. Changes in corneal astigmatism

Рис. 4. Изменения роговичного астигматизма

Table 4. Intraoperative complications of patients, %

Таблица 4. Интраоперационные осложнения пациентов групп сравнения, %

Complication	Group I	Group II
В	Before surgery	
Hyphema	_	2.5
Hemophthalmos	-	7.5
Intraocular pressure >21 mm Hg	31.5	7.5
	1 week	
Defects in the pigmented epithelium of the iris	-	2.5
Hyphema	_	5.0
Hemophthalmos	-	5.0
Intraocular pressure >21 mm Hg	13.2	5.0
	1 month	
Defects in the pigmented epithelium of the iris	-	2.5
Intraocular pressure >21 mm Hg	13.2	2.5
	3 months	
Defects in the pigmented epithelium of the iris	_	2.5
Intraocular pressure >21 mm Hg	5.3	2.5
	6 months	
Defects in the pigmented epithelium of the iris	_	2.5
Hemophthalmos	-	2.5
Intraocular pressure >21 mm Hg	7.9	_

The dynamics of corneal astigmatism changes in comparison groups is shown in Fig. 4.

Among intraoperative complications, there were hyphema, vitreous hemorrhage, and defects of the pigmented epithelium of the iris in the group II (Table 4).

The comparison groups had no differences in the IOL tilt angle before surgery. In 1 month of postoperative

follow-up and later, there was a decrease in the IOL tilt angle in the group II in comparison with the group I in the 180° meridian (p < 0.05). In the 90° meridian, no statistically significant differences between groups were noted during all the study period (p > 0.05). The dynamics of tilt angle changes in 180° and 90° meridians is shown in Fig. 5.

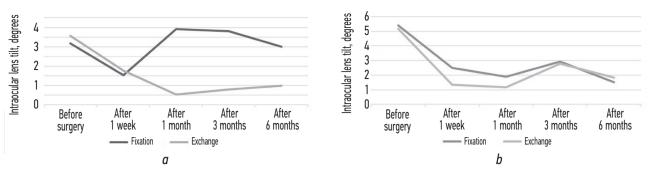


Fig. 5. Changes in Intraocular lens tilt: a — in 180 degrees meridian; b — in 90 degrees meridian **Рис. 5.** Изменение угла наклона интраокулярной линзы: a — в меридиане 180°; b — меридиане 90°

DISCUSSION

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In the article by E.Y. Choi et al. [14], the absence of refractive spherical equivalent changes during the 24 months follow-up period was demonstrated in patients, in whom the exchange to the "iris-claw" IOL with retropupillar fixation was performed. There were also no changes of refractive spherical equivalent revealed at 12 months after the transscleral suture IOL fixation. at the same time, a high value of the standard deviation was noted [15]. However, O. Kristianslund et al. [16] found that the target refraction was reached in smaller number of patients after the transscleral suture IOL fixation, than in those after the exchange to the "iris-claw" IOL. The myopic shift of refraction in 6 months after surgery in patients, in whom IOL repositioning was performed, is described in the article by M. Dalby et al. [17]. At the same time, it is important to note that from the 6^{th} through the 24^{th} months of follow-up, the spherical equivalent stayed stable both after IOL exchange and IOL repositioning. Based on our study results, it is possible to suggest that the manifest refraction at long-term after the transscleral suture fixation of the "IOL-capsular bag" complex, was much less predictable in comparison with the exchange to the "iris-claw" IOL.

The literature data on corneal astigmatism changes after surgical treatment of the "IOL-capsular bag" complex dislocation are contradictory. In the article by O. Kristianslund et al. [16], after 6 months of follow-up, according to the results of vector analysis, in patients after an IOL exchange, there was a higher tendency for the surgically induced astigmatism development than in patients after a transscleral suture IOL fixation. At the same time, in another study by O. Kristianslund et al. [18], comparing the corneal astigmatism 6 months after surgery, they did not find any differences between two groups, one after the "IOL-capsular bag" complex repositioning, and another after IOL exchange [18].

E.Y. Choi et al. [14] did not establish any corneal astigmatism changes during all the follow-up period (excluding 1 month after surgery, when a statistically significant increase in spherical equivalent was noted)

in patients, in whom because of the "IOL-capsular bag" complex dislocation, an exchange to an "iris-claw" IOL with retropupillar fixation was done. An increase in corneal astigmatism was revealed only at the end of 24 months follow-up. According to the data obtained by A. Kemer et al. [15], in patients after a transscleral suture IOL fixation, there were no corneal astigmatism changes during 12 months of follow-up.

The conducted analysis of literature and of own data give the possibility to suggest that the IOL exchange to an "iris-claw" IOL predictably leads to more significant surgically induced astigmatism, which becomes evident at long-term after surgical treatment. Probably, this is related to a biodegradation of the interrupted silk 8–0 suture put on the center of the tunnel incision.

In our study, we did not reveal any differences between groups concerning the IOL's tilt angle. Because of the absence of a single common technique of the IOL's tilt angle evaluation, the comparison of our results with the data obtained by other authors is difficult. It is important to note that the IOL's tilt angle does not cause any influence or causes a significantly smaller influence on the quality of vision in contrast to the IOL's decentration [19].

In the group II, the prevalence of intraoperative complications was higher than in the group I. Intraocular hemorrhages and iris pigmented epithelium defects are anticipated in IOL exchange, because the excision of the whole "IOL-capsular bag" complex increases the risk of iris damage. During all the follow-up period, no post-operative complications were noted in patients of both groups.

Therefore, the data we obtained and the survey of modern literature allow to draw a conclusion that after a transscleral suture IOL fixation, the probability of surgically induced astigmatism development is lower than after IOL exchange to an "iris-claw" IOL with retopupillary fixation, provided that these changes have a tendency to manifest at long-term after surgery. At the same time, both methods give the possibility to obtain a good refraction result, but it is obvious that in the IOL exchange

the resulting refraction would be more predictable. The method of transscleral suture IOL fixation does not lead to clinically significant IOL tilt, as well as is related to lower risk of intra- and post-operative complications.

ADDITIONAL INFORMATION

Authors' contribution. Thereby, all authors made a substantial contribution to the conception of the study, acquisition, analysis, interpretation of data for the work, drafting and revising the article, final approval of the version to be published and agree to be accountable for all aspects of the study. Personal contribution of each

author: V.V. Potemkin — research concept and design, conducting research and operations, collecting material, analyzing data and literature, writing the text of the article; S.Yu. Astakhov — research design, scientific editing; T.S. Varganova — conducting research, data analysis; S. Van — collecting material, analyzing data and literature; L.K. Anikina — analysis of data and literature, writing the text of the article; Sh.E. Babaeva — analysis of data and literature, writing the text of the article.

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