ECRONICON OPEN ACCESS

EC OPHTHALMOLOGY
Research article

Results of an Experimental and Clinical Study of a New Hydrophobic Intraocular Lens for the Correction of Aphakia and Corneal Astigmatism

MB Sviridova[1]*, AG Grinev[1,2], OM Zherebtsova[2], EV Kalinina[3], NA Sobyanin[3] and VP Bachurikhin[4]

[1]*Ural State Medical University, Ekaterinburg, Russia*

[2]*Sverdlovsk Region Clinical Hospital №1, Ekaterinburg, Russia*

[3]*F. Gral City Clinical Hospital №2, Perm, Russia*

[4]*Perm State University, Perm, Russia*

***Corresponding Author:** MB Sviridova, Ural State Medical University, Ekaterinburg, Russia.

Received: February 11, 2022; **Published:** April 28, 2022

Abstract

Purpose: Experimental and clinical study of hydrophobic intraocular lenses (IOL) enVista and enVista Toric for the correction of aphakia and corneal astigmatism.

Material and Methods: In the experimental part, enVista and enVista Toric IOLs (manufactured by Baush and Lomb, USA) were studied by electron scanning microscopy. The clinical part of the study included the results of implantation of 100 IOL enVista in patients with cataract and corneal astigmatism up to 1.25 diopters and 20 IOL en Vista Toric in patients with cataract and corneal astigmatism 1.25 diopters or higher.

Results: According to the results of electron microscopy, no "defects" were found on the surface and optical edge of the lenses. The optical edge of the lens has a rectangular shape throughout 360°. The deviation of the shape of the optical edge of the IOL from the ideal square edge area was 71.53 - 164.48 um^2 and 99.05 - 338.61 um^2, respectively, at radii of 40 um and 60 um. High uveal biocompatibility was confirmed by the absence of cellular deposits on the surface of all 120 IOLs. The lens material was not biodegraded, and there was no glistening effect in all cases. The percentage of opacity of the posterior lens capsule due to migration of epithelial cells of the lens was 5.0% in the three-six millimeter zone without indications for laser capsulotomy.

After implantation of the envista Toric IOL, the average value of astigmatism decreased from 1.77 ± 0.38 to 0.42 ± 0.11 diopters ($p < 0.05$). The rotational stability of the IOL position remained within the range of 2.50° ± 0.11° during one year of observation. In both groups, visual acuity significantly improved after surgery ($p < 0.05$), the change in refraction of the target during the year was observed slightly in the direction of myopia, but there were no significant differences.

Conclusions: EnVista and enVista Toric IOL implantation provide high visual acuity in patients with age-related cataracts and cataracts in combination with corneal astigmatism, stable refractive indices.

Keywords: *Hydrophobic Intraocular Lens; Envista; Envista Toric; Electron Scanning Microscopy; Clinical Study*

Introduction

Modern models of intraocular lenses (IOL) should be made of an inert polymer material, not undergo any changes (biodegradation) and turbidity (for example, "glistening") after implantation, have high uveal biocompatibility, and prevent inflammatory cellular reactions on the lens surface. The design of haptic elements should ensure a stable position in the capsule bag during its fibrous compression. IOLs should have a rectangular edge for 360°, which prevents migration of lens cells and reduces the possibility of secondary cataracts in the long-term postoperative period. The back surface of the lens should be in full contact with the capsule according to the principle of "no space – no cells". Implantation of such IOLs should be carried out through a 2.2 mm incision using an injector to prevent induced astigmatism. Fulfillment of all conditions will ensure the invariance of refractive indices [1-10].

One of the quantitative characteristics of the rectangular edge of the IOL is the area of deviation from the ideal rectangular projection of the optical edge of the IOL. Deviation, for example, can occur in the manufacture of hydrophilic lenses when, after hydration of the polymer, the angle of the optical edge changes its ideal rectangular shape [11].

The method of electron scanning microscopy is widely used to study the surface of materials, detect technological "defects", and helps to identify changes resulting from physical and chemical influences. This method enables estimating the shape of the lens surface that will come into contact with the posterior capsule (convex, straight, concave), the optical edge of the IOL (whether there is a rectangular angle along the entire circumference) and calculating the area of deviation from the ideal rectangular projection of the optical edge of the IOL [1,11,12].

Purpose

To conduct an experimental and clinical study of new hydrophobic intraocular lenses for the correction of aphakia and corneal astigmatism.

Research objectives

1. To study the shape of the surface and the optical edge of the enVista and enVista Toric intraocular lenses (Baush and Lomb, USA) by microphotography and computer analysis, to calculate the area of the smallest deviation from the ideal rectangular projection of the optical edge of the IOL, to identify possible technological "defects" of the surface. 2. To conduct a clinical study of enVista and enVista Toric intraocular lenses with an assessment of uveal biocompatibility, the percentage of opacities of the posterior lens capsule, rotational stability of toric IOLs, deviations from target refraction in the long term.

Material and Methods

The experimental part of the study

EnVista and enVista Toric IOLs were studied by electron scanning microscopy on the S-3400N microscope (Hitachi, Japan) according to the standard procedure described earlier in the literature [11]. The surface of the lens and the shape of the angle of the optical edge of the IOL were evaluated from the obtained images, which were stored electronically with a JPEG file resolution, then imported into the AutoCAD LT 2000 (Autodesk) program for research. Figures 1 and 2 show the obtained images at 13-100 times magnification: the front (Figure 1a, 1c), rear (Figure 1b, 1c) and side (Figure 2a-d) surfaces. No "defects" of the lens surface were detected.

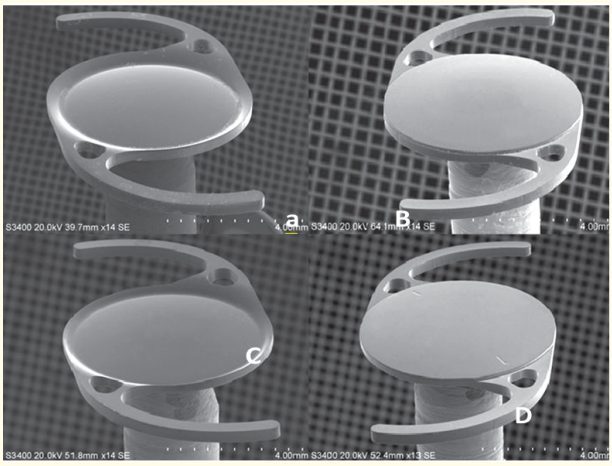

Figure 1: *EnVista design: a) front surface; B) back surface; enVista Toric design: C) front surface; D) back surface.*

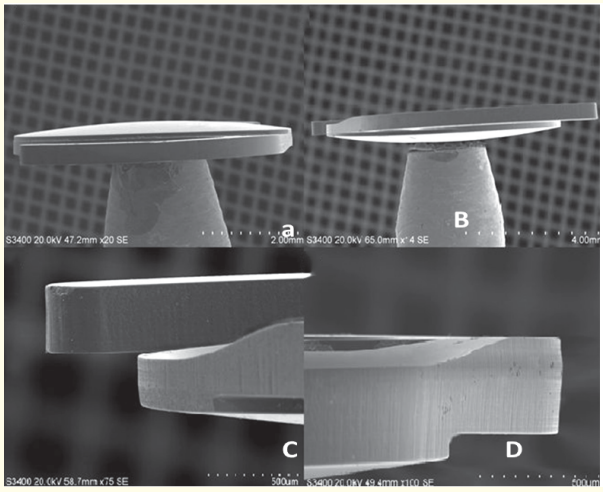

Figure 2: *a) IOL enVista design, side view, back surface up); B) IOL enVista design, side view, back surface down; C) IOL enVista design, optics and haptics side surface; D) IOL enVista design, side view, optical angle.*

The AutoCAD program is used to analyze and evaluate the deviation of the shape of the optical edge of the IOL from the ideal square edge area. In the scaled image, the researchers displayed the angle of the optical edge at 300x magnification (Figure 3a, 3b), and constructed tangents of the edges of the rear and side surfaces of the optical angle of the lens before their intersection (Figure 3c, d). From the point of intersection of the tangents, a circle sector with radii of 40 microns and 60 microns was marked. The intersections of the axes with the circle were correlated to the picture so that the intersections were tangent to the edges of the section of its rear and side surfaces of the lens. After that, the contour of the lens section was traced in the sector of the circle. The area of the resulting figure between the

tangents and the contour of the optical edge was calculated at radii of 40 microns and 60 microns, respectively (the area of the smallest deviation from the ideal rectangular projection).

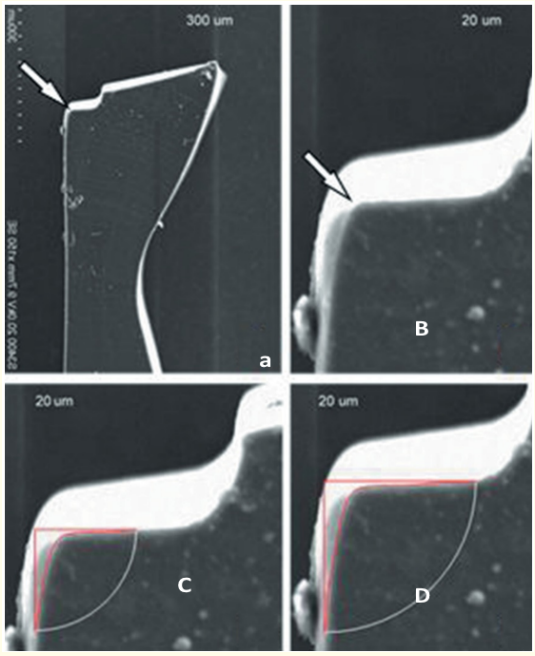

Figure 3: *a, B) The arrows indicate the angle of the optical edge being studied; C, D) Investigation of the deviation of the shape of the optical edge of the IOL from the ideal square edge area with a radius of 40 um and 60 um.*

The clinical part of the study

The study included 120 eyes of 113 patients after cataract phacoemulsification: 93 patients (100 eyes) – group 1, with implantation of the enVista lens; 20 patients (20 eyes) - group 2, with implantation of the enVista Toric lens. Before the operation, all patients underwent ophthalmological examination, which included visometry, refractometry, keratometry, tonometry, biomicroscopy, ophthalmoscopy, perimetry, ultrasound (AV scan), calculation of the spherical component of the IOL according to the formula SRK-T. The exclusion criteria from the study were: pronounced weakness of the ligamentous apparatus of the lens, narrow rigid pupil, macular diseases, abnormal corneal astigmatism, glaucoma, retinal detachment in the anamnesis, diabetes.

In the first group, the average age of patients was 62.2 ± 13.06 years (men 39, women 54). In the second group, the average age was 59.45 ± 7.81 years (12 men, 8 women). The initial visual acuity with correction in patients of both groups varied from 0.01 to 0.5. In the first group, the average visual acuity (M ± m) was 0.20 ± 0.15, in the second 0.23 ± 0.11. Corneal astigmatism in the first group did not exceed 1.25 diopters (D) and averaged 0.80 ± 0.36 D. Patients of the second group had initial congenital corneal astigmatism from 1.25 to 2.5 D, on average 1.77 ± 0.38 D.

Patients with toric IOLs were marked with a horizontal meridian before surgery, and the IOL axis was marked on the operating table. The calculation of the cylindrical component of the IOL was carried out using a program developed by the manufacturer (https://envista.toriccalculator.com). IOLs were implanted with a cylindrical component +1.25 D - 10 lenses, +2.0 D - 7 lenses, +2.75 D - 3 lenses, which corresponded to the correction of corneal astigmatism of 0.9 D, 1.4 and 1.93 D. It should be noted that with enVista Toric lenses it is possible to correct the initial astigmatism in the range from 0.9 to 4.03 D.

All 120 operations were performed under local anesthesia by the standard method of phacoemulsification on a Stellaris device (Baush and Lomb, USA), lenses were implanted using a Comport injector (South Korea) through 2.2 mm incisions.

In the postoperative period, visual acuity was determined with and without correction, other studies listed below, the follow-up period was 1 - 3 days, 1 month, 1 year after surgery.

Uveal biocompatibility was assessed by counting cellular deposits on the anterior surface of the IOL. The presence of cellular deposits was regarded with a plus sign, their absence with a minus sign.

Opacities of the posterior capsule of a regenerative nature were assessed according to their presence under the IOL in the three-millimeter zone (with a narrow pupil) and behind the three-millimeter zone with drug-induced mydriasis. The presence of epithelial lens cells in the optical zone was marked by a two plus sign, in the three- to six-millimeter zone by a plus sign, the absence of cells by a minus sign. Assessment of opacities in the central zone and in the three- to six-millimeter zone under the IOL optics is the most common method of investigation [6,9].

Deviation from the refraction of the target in the long-term period was assessed in all patients by changes in corneal refraction (astigmatism), the spherical component of clinical refraction of the eye and the spherical equivalent.

To assess the rotational stability of toric IOLs, the technique described earlier was used [13]. Photographing of the anterior segment of the eye on a photo-slit lamp was carried out when the maximum mydriasis was reached and the light beam of the slit lamp was compared with the position of the axis of the IOL cylinder. A 360^0 scale was superimposed on the digitally obtained image, with the help of which the position of the axis of the IOL cylinder was determined.

Statistical analysis was performed in Excel (Microsoft Office 2010) and Statistica Trial, Version 13.3. The average value and standard deviation were calculated. When comparing quantitative data, the Student *t*-test was used for dependent samples with a normal distribution, the critical level of acceptance of the null hypothesis was taken as $p < 0,05$.

Results and Discussion

The experimental study of the surface shape and optical edge of the enVista and enVista Toric intraocular lenses by scanning electron microscopy did not reveal any defects. The front surface of the lenses is concave, the back surface of the lenses is convex. The optical edge of the lens on the back surface has a rectangular edge of the optics for 360°. Therefore, the lenses should be implanted into the capsule bag according to the design. There are two marks on the back surface of toric IOLs for lens reposition and corneal astigmatism correction. Calculations of the deviation of the shape of the optical edge of the IOL from the ideal area of the square edge were made in the intervals 71.53 - 164.48 um^2 and 99.05 - 338.61 um, respectively, at radii of 40 um and 60 um (Figure 4). Compared with the results of a similar study in which other IOL models were studied, the optical edge of the enVista platform lenses has the smallest deviation area from the ideal square edge area [11].

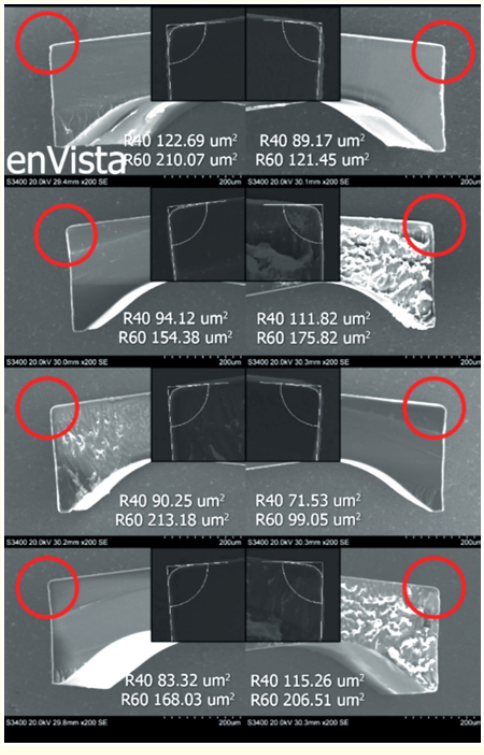

Figure 4: *Calculations of the deviation of the shape of the optical edge of the IOL from the ideal square edge area in various points.*

The results of the clinical trial were as follows. All operations were performed without complications, the postoperative period in all cases was regarded as areactive.

The dynamics of changes in visual acuity and refractive indices after surgery in patients of the first group are presented in table 1.

Research **Research**	**Before the operation** **Preoperative**	**At discharge** **At discharge**	**1 month** **1 month**	**1 year** **1 year**
Visual acuity, (M±6) Visual acuity, (M±6)	0,20 ± 0,15*	0,54 ± 0,26	0,76 ± 0,19	0,78 ± 0,15*
Astigmatism, D, (M±6) Astigmatism, D, (M±6)	0,80 ± 0,36**	0,94 ± 0,62	0,93 ± 0,57	0,92 ± 0,51**
Target refraction, (M±6) Target refraction, (M±6)	Calculation for emmetropia Calculation for emmetropy	-0,28 ± 0,31**	-0,34 ± 0,28	-0,36 ± 0,33**

Table 1: *Refractive indices in the enVista group.*

Note: *Comparison between groups is Student t-test for dependent samples with normal distribution (*p < 0.05, **p > 0.05).*

Visual acuity improved after surgery in all patients, which had a statistically significant difference ($p < 0.05$) from the baseline at all stages of the study. The average values of corneal astigmatism increased slightly in the postoperative period, but these changes were not statistically significant ($p >> 0.05$). Refractive indices stabilized by the first month after surgery and remained virtually unchanged during the subsequent period. In some patients, there was a slight shift towards myopic refraction, in general, the change in refraction of the target also had no significant differences ($p > 0.05$).

The dynamics of changes in visual acuity and refractive indices after surgery in patients of the first group are presented in table 1.

Visual acuity after surgery improved in all patients, which had a statistically significant difference ($p < 0.05$), visual acuity without correction in 90% of cases exceeded 0.6 a year after surgery, the average value of astigmatism decreased from 1.77 ± 0.38 to 0.42 ± 0.11 D, which had a statistically significant difference ($p < 0.05$). During the year, the change in refraction of the target occurred in the direction of myopic refraction, but had no significant differences ($p > 0.05$) (Table 2).

Research **Research**	**Before the operation** **Preoperative**	**At discharge** **At discharge**	**1 month** **1 month**	**1 year** **1 year**
Visual acuity, (M±6) Visual acuity, (M±6)	0,23 ± 0,11*	0,58 ± 0,3	0,72 ± 0,15	0,75 ± 0,13*
Astigmatism, D (M±6) Astigmatism, D, (M±6)	1,77±0,38*	0,34 ± 0,28	0,39 ± 0,22	0,42 ± 0,11*
Target refraction, (M±6) Target refraction, (M±6)	Calculation for emmetropia Calculation for emmetropy	-0,16 ± 0,35**	-0,20 ± 0,32	-0,24 ± 0,30**
Rotational stability, (M±6) Rotational stability, (M±6)	Calculation of the IOL position Position of IOL calculation	0,75 ± 0,78°	1,15 ± 1,23°	2,5 ± 0,11°

Table 2: *Refractive indices in the enVista Toric group.*

Note: *Comparison between groups is Student t-test for dependent samples with normal distribution (*p < 0.05, **p > 0.05).*

The rotational stability of the IOL position was monitored throughout the year. The final rotation of the enVista Toric during 1 year of observation remained within 2.5 ± 0.11°.

One year after the operation, no elements of biodegradation of the material (microvacuoles, opacities) were recorded in both groups, which is confirmed by other previously conducted studies [14]. Out of 120 cases, no epithelial lens cells in the three-millimeter zone were observed in any patient, in the three-six-millimeter zone, cell germination was noted in 6 eyes, which was 5.0% of the total number without reducing visual acuity. There were no indications for laser capsulotomy in any case.

The optical and haptic parts of the enVista and enVista Toric lenses are hydrophobic acrylic, the surface hardness of the material of which is 11.0 Mpa, which provides resistance to mechanical damage. Such "hardness" of the IOL material requires a rather slow advance of the lens through the injector during implantation. No surgeon had any difficulties with implantation of IOL through a 2.2 mm incision. The slow straightening of the lens made it easy to position it in the capsule bag and remove viscoelastic from the capsule bag without hindrance.

Both models have the same platform, a modified C-shaped closed-loop-style lens with a contact area of the support elements with a capsule bag. The rigidity of this design ensures a stable position in the capsule bag and resistance to rotational displacement. After implantation of these lenses, a characteristic fold is formed on the posterior capsule between the haptic elements, which straightens out on average after a month.

The features of the material in a liquid medium give hydrophobic acrylic hydrophilic properties, or rather their combination: on the one hand, high uveal biocompatibility without deposition of cellular deposits on the surface of the IOL, on the other hand, tropicity to the capsule bag with decreased fibrosis of the posterior capsule. The square shape of the optical edge over 360° of the lens serves as a good barrier to the migration of epithelial cells of the lens.

Conclusions

1. An experimental and clinical study of new hydrophobic intraocular lenses for the correction of aphakia and corneal astigmatism was conducted.

2. The method of electron scanning microscopy of intraocular lenses enVista MX60 and enVista Toric did not reveal any "defects" of the surface, the optical edge of the lens has a rectangular edge of optics for 360°. The deviation of the shape of the optical edge of the IOL from the ideal square edge area was within the intervals 71.51-164.48 um^2 and 99.05-338.61 um^2, respectively, at radii of 40 um and 60 um.

3. The material and design of the enVista MX60 and enVista Toric intraocular lenses provides high uveal biocompatibility, a low level of opacities of the posterior lens capsule, rotational stability of toric IOLs, stable refractive indices.

Bibliography

1. Malyugin BE., *et al*. "Optimization of femtosecond laser transection of a hydrophobic intraocular lens and long-term results in a clinical study (first experience)". *Ophthalmosurgery* 4 (2018): 18-24.

2. Shukhaev SV., *et al*. "Comparative evaluation of target refraction in three monofocal flexible intraocular lenses". *Ophthalmosurgery* 1 (2018): 53-58.

3. Holladay JT and Pettit G. "Improving toric intraocular lens calculation using total surgically induced astigmatism for a 2.5 mm temporal incision". *The Journal of Cataract and Refractive Surgery* 45.3 (2019): 272-283.

4. Chang A and Kugelberg M. "Glistenings 9 years after phacoemulsification in hydrophobic and hydrophilic acrylic intraocular lenses". *The Journal of Cataract and Refractive Surgery* 41.6 (2015): 1199-1204.

5. Miyata A., *et al*. "Clinical and Experimental Observation of Glistening in Acrylic Intraocular Lenses". *Japanese Journal of Ophthalmology* 45.6 (2001): 564-569.

6. Shkolyarenko NYu. "Modification of the posterior capsule of the lens after implantation of flexible acrylic hydrophobic intraocular lenses". *Dissert. ...Candidate of Medical Sciences. M* (2007).

7. Poznyak SN and Poznyak NI. "Clouding of the posterior lens capsule after implantation of hydrophilic and hydrophobic intraocular lenses in patients with refractive errors". *Medical Journal* 1.15 (2006): 79-81.

8. Tereshchenko YuA., *et al*. "Clarification of interrelations between implanted intraocular lenses of various materials and options of opacity formation in the posterior capsule after phacoemulsification of senile cataract". *Ophthalmosurgery* 4 (2014): 30-34.

9. Yusef YuN., *et al*. "Changes in the posterior lenticular capsule during implantation of hydrophobic acrylic intraocular lenses of different construction". *The Russian Annals of Ophthalmology* 6 (2007): 51-54.

10. Sorokoletov G.V., *et al*. "Influence of intraocular lens material and eye axial length on posterior capsule opacification dynamic rate and frequency". *Ophthalmology* 4 (2016): 247-251.

11. Werner L., *et al*. "Evaluating and defining the sharpness of intraocular lenses: Microedge structure of commercially availble square-edged hydrophilic intraocular lenses". *Journal of Cataract and Refractive Surgery* 35.3 (2009): 556-566.

12. Hart JC Jr., *et al*. "Electron microscopy of silicone irrigation/aspiration tips involved in posterior capsule rupture". *Journal of Cataract and Refractive Surgery* 44.12 (2018): 1517-1520.

13. Egorova AV and Vasiliev AV. "Comparative analysis of rotational stability of various types of acrylic models of toric IOLs". New technologies for the diagnosis and treatment of diseases of the visual organ in the Far Eastern region (2013): 154.

14. Packer M. "EnVista hydrophobic acrylic intraocular lens: glistening free". *Expert Review of Ophthalmology* 10.5 (2015): 415-420.

Volume 13 Issue 5 May 2022