Comparison of clinical effects of two brands of toric intraocular lens

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Abstract

Background This study aimed to compare the clinical effects of two brands of toric intraocular lens used in surgical correction of cataract with corneal astigmatism.

Methods 35 patients (50 eyes) with corneal astigmatism who underwent ophthalmic surgery from April 2019 to July 2019 were retrospectively analyzed. Among them, 25 eyes of 20 patients were implanted with Rayner 623T, while 25 eyes of 15 patients with Alcon AcrySof Toric intraocular lens (IOL). Three months after surgery, the uncorrected distance visual acuity (UCDVA), best corrected distance visual acuity (BCDVA), residual astigmatism, rotational degree of intraocular lens, contrast sensitivity, objective visual quality and the National Eye Institute 25-Item Visual Function Questionnaire (NEI VFQ-25) scale score were compared.

Results The mean postoperative UCDVA (logMAR) and BCDVA (logMAR) in the Rayner group were 0.17 ± 0.20 and 0.08 ± 0.15, respectively (P > 0.05), while those in the Alcon group were 0.21 ± 0.16 and 0.10 ± 0.11, respectively (P > 0.05). The mean residual astigmatism in the Rayner group was (0.69±0.40) while that in the Alcon group was (0.62±0.49), (P >0.05). There was no statistically significant difference between the two groups in IOL rotational stability, contrast sensitivity and objective visual quality (P > 0.05). The NEI VFQ-25 scale score was 85.16±5.91 in the Rayner group while that was 82.08±6.16 in the Alcon group, (P > 0.05).

Conclusions The two brands of toric intraocular lens- Rayner 623T and Alcon AcrySof Toric showed no significant difference in their clinical effects.

Background

Clinical data shows that 40% ~ 45% of patients undergoing cataract surgery have more than 1 diopter (D) of corneal astigmatism [1, 2], which would inevitably affect the visual quality of patients, if not corrected. Since its introduction in 1994, toric intraocular lens (toric IOL) has been widely used with accurate and stable effect of correcting corneal astigmatism [3–6]. Toric IOL is designed with a complex curved surface with a clear axial marker line on the intraocular lens, aiding its accurate implantation for the correction of the corneal astigmatism.

The rotational stability of IOL is a crucial factor that affect the long-term outcomes after toric IOL implantation. The most common cause of toric IOL rotation is the contraction of the lens capsule due to fibrosis, which mainly occurs within 3 months after surgery [7]. Even a slight rotation can lead to a sharp decline in the astigmatism correction ability of Toric IOL, which will lose 3.3% of astigmatism correction ability for each 1° rotation of the toric IOL [8].

At present, many kinds of toric IOLs are widely available clinically, but only limited studies and data are available to compare their clinical effect. In this study, we used two widely used toric IOLs in clinic,

Rayner's 623T (which entered the Chinese market in 2014) and Alcon's AcrySof Toric, and compared the clinical effect three months after implantation in order to provide better options for patients.

Methods

General information

The medical records of 35 cataract patients (50 eyes) with corneal astigmatism who underwent ophthalmic surgery from April 2019 to July 2019 in Peking University Third hospital were retrospectively analyzed. All patients were with preoperative corneal astigmatism with the rule ≥ 1.5D or corneal astigmatism against the rule ≥ 0.75D and underwent cataract phacoemulsification combined with toric IOL implantation. Among them, 25 eyes of 20 cases were implanted with Rayner 623T, while 25 eyes of 15 cases were implanted with Alcon AcrySof Toric IOL. Inclusion criteria: patients diagnosed with age-related cataract, preoperative corneal astigmatism with the rule ≥ 1.5D or corneal astigmatism against the rule ≥ 0.75D. The corneal astigmatism was measured by optical coherence biometrics (IOL master500; Carl Zeiss Meditec, Jena, Germany). Exclusion criteria: patients with irregular corneal astigmatism, corneal leukoplakia, glaucoma, fundus diseases, history of previous intraocular surgery, high myopia, abnormal suspensory ligament and other diseases. This clinical retrospective study has been reviewed by the ethics committee of Peking University Third Hospital.

Preoperative examination

All patients underwent preoperative routine cataract examinations, including visual acuity, non-contact intraocular pressure, slit lamp examination, fundus examination, Ophthalmic B-ultrasound, ophthalmic infiltrative A-ultrasound, IOL master and corneal topography (Pentacam; Oculus, Wetzlar, Germany). The ophthalmic parameters used to calculate the IOL degree were mainly from the measurement results of the IOL master. In patients where the refractive medium was highly turbid and the IOL master could not measure the axial length, the infiltrative A-ultrasound was used to measure the optic axis. Pentacam was used to determine the regularity of corneal astigmatism and the size and direction of astigmatism on the posterior surface of the cornea. Two groups of on-line toric IOL calculators (https://www.raytrace.rayner.com) and (https://www.acrysoftoriccalculator.com) were used to obtain the model of toric IOL and the targeted axial position of IOL by inputting relevant data such as the corresponding axial length, corneal curvature on the anterior surface, surgically induced astigmatism and position and size of the incision. It is worth noting that if the astigmatism of the posterior surface of the cornea is special, it is necessary to increase or decrease the diopter of cylindrical power of toric IOL calculated by the calculator according to the situation. The intraoperative digital real-time navigation system (Callisto eye; Carl Zeiss meditec, Jena, Germany) was used to mark the actual incision and the targeted axial position of IOL. All surgeries were performed by the same surgeon and surgically induced astigmatism used the personalized value obtained through preliminary calculation, which was 0.60D in this study. The models of Alcon AcrySof Toric IOL used in this study included SN6AT2 ~ T9 and the diopter of cylindrical power of Rayner 623T IOL ranged from 1.0D to 3.5D.

Surgical procedures

Both groups were treated with cataract phacoemulsification combined with toric IOL implantation. Intraoperative real-time navigation system was used to perform conventional phacoemulsification through the 3.2 mm corneoscleral limbal incision at 12 points and 0.8mm transparent lateral corneal incision at 3 points. Continuous circular capsulorrhexis was performed with a size of about 5.5-6.0mm. IOL was implanted into the capsular bag, immediately after complete absorption of the viscoelastic agent from the capsular bag and the anterior chamber. With the help of the intraoperative navigation system, the IOL was adjusted to the targeted axial position and the incision was made watertight.

Postoperative follow-up

The patients were followed for uncorrected distance visual acuity (UCDVA), best corrected distance visual acuity (BCDVA), residual astigmatism, contrast sensitivity (CS), objective visual quality (including modulation transfer function cut-off (MTF cut-off), Strehl ratio (SR), objective scatter index (OSI), the objective visual acuity under different contrast (VA100 / VA20 / VA9)), rotational degree of IOL and national eye institute 25-item visual function questionnaire (NEI VFQ-25) score 3 months after surgery. The contrast sensitivity tester (CSV-1000; Vector Vision, Ohio, America) was used to test the contrast sensitivity while the dual channel objective visual quality tester (OQAS II; Visiometrics, Barcelona, Spain) was used to check the objective visual quality. Taking Rayner 623T as an example, the measurement method of IOL rotational degree was as follows: after dilating the pupil, a digital camera was used under the slit lamp to take color images of anterior segment under the red light reflection, and the axial markers on the IOL were clearly visible (Figure 1). The image processing software (Photoshop CC 2019 version; adobe, California, USA) was used to mark the axial line (Figure 2 green line) and the horizontal line (Figure 2 blue line) of IOL. The angle of IOL axial marker line (green line) was determined by the angle measuring tool provided by the software, which was compared with the preoperative calculated IOL implantation targeted axial position to confirm the degree of rotation 3 months after surgery.

Statistical methods

Statistical software SPSS 22.0 (version 22.0; IBM SPSS Statistics, Armonk, NY, USA) was used to analyze the data. The measurement data were represented by () and the independent sample t-test was used. $P < 0.05$ was statistically significant.

Results

Preoperative clinical information of patients in the two groups

There were no significant differences in the patient demographic and clinical data including the age, gender, eye type, UCDVA, BCDVA, apparent optometry results, corneal astigmatism, axial length and IOL spherical or cylinder power between the two groups ($P > .05$) as shown in Table 1.

Table 1

Demographics and clinical information of patients included in this study

	Rayner 623T	Alcon Acrysof Toric	p value
Eyes (n)	25	25	
Patients (n)	20	15	
Age (y)	74.92 ± 12.94 (25 to 87)	76.52 ± 6.67 (55 to 86)	0.586
Male sex, n (%)	56%	44%	0.406
Right eyes, n (%)	64%	52%	0.400
UCDVA (logMAR)	0.65 ± 0.39 (0.2 to 1.7)	0.62 ± 0.23 (0.2 to 1.0)	0.676
BCDVA (logMAR)	0.51 ± 0.36 (0.2 to 1.7)	0.47 ± 0.15 (0.2 to 0.7)	0.662
Manifest Refraction			
Sphere (D)	0.02 ± 0.63 (−1.25 to 0.50)	0.25 ± 1.14 (−2.25 to 2.75)	0.381
Cylinder (D)	−1.35 ± 0.60 (−3.00 to 0)	−1.57 ± 0.73 (−3.00 to−0.50)	0.252
SE (D)	−0.66 ± 0.69 (−1.75 to 0.75)	−0.54 ± 1.09 (−2.75 to 1.50)	0.645
Corneal astigmatism (D)	2.13 ± 0.57 (0.90 to 3.21)	2.27 ± 0.78 (1.05 to 3.89)	0.492
Axial length (mm)	24.03 ± 0.83 (22.74 to 25.47)	23.92 ± 0.94 (22.09 to 25.64)	0.661
IOL power (D)	20.70 ± 1.92 (16.0 to 23.5)	21.10 ± 2.47 (18.0 to 26.0)	0.525
IOL Cylinder power (D)	2.24 ± 0.66 (1.0 to 3.5)	1.92 ± 1.03 (0.5 to 4.0)	0.198
Mean ± SD (range)			
Y years, LogMAR Logarithm of the minimum angle of resolution, D diopter, UCDVA uncorrected distance visual acuity, BCDVA best corrected distance visual acuity,IOL intraocular lens, SE spherical equivalent refraction			

Table 1. Demographics and clinical information of patients included in this study

Surgical Effects

All patients were operated smoothly without any significant complications and were followed up for 3 months and no patient required a repeated surgical correction to adjust IOL axis due to visual quality or postoperative lens rotation. There was a statistically significant ($P < 0.05$) improvement in the UCDVA and BCDVA of patients in both groups post-surgery compared to pre-surgery. Moreover, the IOL cylinder power of optometry was obviously decreased after surgery compared with that before surgery ($P < 0.05$), which indicated that both brands of Toric IOL could effectively improve patients' vision and correct astigmatism (Table 2). The rotational stability of toric IOL in two groups are as follows: in Rayner group, 80% of the patients rotated below 5° and 20% of the patients (5 eyes) rotated between 5° and 10°, with an average of rotational degree of (3.5 ± 1.6)° while in Alcon group, 76% of the patients rotated below 5° and 24% of the

patients (6 eyes) rotated between 5° and 10°, with an average of rotational degree of (4.0 ± 2.1)° (P > 0.05). There were no statistically significant differences between the two groups in UCDVA, BCDVA, residual astigmatism, IOL rotational stability (Table 2), contrast sensitivity, objective visual quality and VFQ-25 scale score (Table 3) after 3 months of surgery (P > 0.05).

Table 2
Preoperative and postoperative clinical data in the Rayner 623T intraocular lens group and Alcon Acrysof Toric intraocular lens

Parameters	**Rayner 623T**			**Alcon Acrysof Toric**			**P* value**
	Preop	Postop	p value	Preop	Postop	p value	
UCDVA (logMAR)	0.65 ± 0.39 (0.2 to 1.7)	0.17 ± 0.20 (0.0 to 0.9)	0.000	0.62 ± 0.23 (0.2 to 1.0)	0.21 ± 0.16 (0.0 to 0.6)	0.000	0.490
BCDVA (logMAR)	0.51 ± 0.36 (0.2 to 1.7)	0.08 ± 0.15 (0.0 to 0.5)	0.000	0.47 ± 0.15 (0.2 to 0.7)	0.10 ± 0.11 (0.0 to 0.4)	0.000	0.433
Manifest Refraction							
Sphere (D)	0.0 ± 0.63 (−1.25 to 0.50)	0.20 ± 0.27 (−0.25 to 0.75)	0.195	0.25 ± 1.14 (−2.25 to 2.75)	0.22 ± 0.42 (−0.50 to 0.75)	0.903	0.843
Cylinder (D)	−1.3 ± 0.60 (−3.00 to 0)	−0.69 ± 0.40 (−1.50 to 0)	0.000	−1.57 ± 0.73 (−3.00 to−0.50)	−0.62 ± 0.49 (−2.00 to 0)	0.000	0.582
SE (D)	−0.6 ± 0.69 (−1.75 to 0.75)	−0.14 ± 0.32 (−0.75 to 0.75)	0.002	−0.54 ± 1.09 (−2.75 to 1.50)	−0.09 ± 0.36 (−0.75 to 0.75)	0.062	0.570
Rotation (°)		3.46 ± 1.59 (1.0 to 7.5)			4.00 ± 2.08 (0 to 9.1)		0.304
group at 3-month postoperatively							
Mean ± SD (range)							
SD standard deviation, UCDVA uncorrected distance visual acuity, LogMAR Logarithm of the minimum angle of resolution, BCDVA best corrected distance visual acuity, D diopter, SE spherical equivalent refraction							
*P values between the two groups postoperatively, P < 0.05							

Table 3

Visual Quality Analysis at 3-Month Postoperatively

Parameters	Rayner 623T	Alcon Acrysof Toric	p value
CS (dyl/deg)			
3 c/d	28.92 ± 13.77 (0 to 43)	26.44 ± 11.50 (0 to 43)	0.493
6 c/d	39.08 ± 21.53 (0 to 99)	30.48 ± 28.18 (0 to 99)	0.231
12 c/d	9.88 ± 8.55 (0 to 35)	8.84 ± 9.38 (0 to 35)	0.684
18 c/d	3.96 ± 4.08 (0 to 13)	2.10 ± 3.33 (0 to 13)	0.084
MTF cut off (c/deg)	26.66 ± 8.47 (8.57 to 42.07)	24.62 ± 13.71 (5.84 to 46.88)	0.530
SR	0.16 ± 0.06 (0.07 to 0.25)	0.14 ± 0.11 (0.05 to 0.6)	0.478
OSI	1.76 ± 0.86 (0.5 to 4.5)	2.40 ± 1.37 (0.7 to 6.1)	0.057
VA100	0.91 ± 0.29 (0.3 to 1.4)	0.80 ± 0.43 (0.2 to 1.9)	0.308
VA20	0.58 ± 0.19 (0.2 to 0.95)	0.53 ± 0.37 (0.1 to 1.8)	0.534
VA9	0.34 ± 0.12 (0.1 to 0.6)	0.34 ± 0.29 (0.1 to 1.5)	0.975
NEI VFQ-25 score	85.16 ± 5.91 (74 to 94)	82.08 ± 6.16 (72 to 95)	0.077
Mean ± SD (range)			
CS contrast sensitivity,MTF modulation transfer function,SR Strehl ratio,OSI objective scatter index,NEI VFQ-25 national eye institute 25-item visual function questionnaire			

Table 2. Preoperative and postoperative clinical data in the Rayner 623T intraocular lens group and Alcon Acrysof Toric intraocular lens group.

Table 3. Visual Quality Analysis at 3-Months Postoperatively

Discussion

Several traditional and surgical clinical therapies are implemented for correction of corneal astigmatism. Many kinds of IOLs are available which are designed with multiple characteristics for the improvement of the clinical outcomes including visual acuity, correction of astigmatism, and rotational stability. Toric IOLs are increasingly used to correct corneal astigmatism at the time of cataract surgery and have greatly improved post-operative visual performance. In addition to the implantation of toric IOLs, transparent corneal incision release is more commonly used. However, due to the requirements for the position of the surgical incision, the limitation of the astigmatism correction, and the poor predictability of the postoperative effect [9], surgeons prefer to choose a method that can treat corneal astigmatism while performing routine cataract surgery procedures. With growing interests in reducing undesirable residual

astigmatism, a well-designed toric IOLs greatly improves the postoperative visual quality and surgical satisfaction of patients [10], and are considered as the best way for the treatment of cataract with corneal astigmatism.

Accurate preoperative biometry is the basis of the calculation of toric IOL cylinder power and targeted axial position. The measurements for axial lengths are limited, but there are many methods available for the measurement of corneal curvature. Kim [11] *et al*. have found that there was no statistical difference in the corneal curvature measured by the keratometer, IOL master and Pentacam corneal topography, and there was no statistical difference in the calculated IOL cylinder power and the targeted axial position by the toric IOL calculation formula. Therefore, in this study we used the currently recognized gold standard - IOL master to measure the corneal curvature.

Anterior corneal astigmatism (ACA) shows great variability among people compared to the posterior corneal astigmatism (PCA) which tend to be more unique with sight differences. 85.0% ~ 96.1% of PCA in the population is -0.01D ~ -1.10D astigmatism against the rule, with the mean value of about − 0.3D [12]. PCA is of great significance in the calculation of toric IOL degree. If PCA is ignored, when ACA is with the rule, the whole corneal astigmatism will be over-estimated to 0.22D on an average, while ACA is against the rule, the whole corneal astigmatism will be underestimated to 0.22D on average [12]. If PCA is larger, the effect on whole corneal astigmatism will be greater. The two toric IOL online calculators used in this study only input the ACA value, without considering the actual PCA value. As feasible in most cases, the PCA was − 0.5D astigmatism against the rule by default, but when the PCA is special (the value is too large or too small, or the direction is astigmatism with the rule), the calculation error will be larger. Therefore, in addition to judging the regularity of corneal astigmatism, we also directly measured PCA by Pentacam corneal topography. If PCA is special, we need to be more careful in the calculation of toric IOL cylinder power and the toric IOL cylinder power needs to be increased or decreased according to the vector analysis results.

The postoperative UCDVA is the most direct and important index used to evaluate the success of cataract surgery, and in our study the postoperative UCDVA in Rayner group was 0.17 ± 0.20. The postoperative residual astigmatism is the objective index indicated to evaluate the astigmatism correction effect of toric IOL and the average residual astigmatism in Rayner group was (0.69 ± 0.40) D. Through the literature reviews, a four-year clinical study from the Pasteur medical center showed [13] that the postoperative UCDVA after the implantation of Rayner toric IOL in 84 cases was 0.3, and the residual astigmatism was 0.8D, which was consistent with results of this study.

The rotational degree of IOL reflects the stability of toric IOL in the capsule. In order to achieve a good postoperative effect, the axial rotation of toric IOL should be controlled within 5° [14]. In this study, 80% of patients in the Rayner group rotated below 5° and 20% of patients (5 eyes) rotated between 5° and 10°, with an average rotational degree of (3.5 ± 1.6)°. 76% of patients in the Alcon group rotated below 5° and 24% of patients (6 eyes) rotated between 5° and 10°, with an average rotational degree of (4.0 ± 2.1)°. By reviewing the literature, a study by Molham *et al*. showed [15] that the average postoperative rotational

degree of Rayner 623T was 3.44°, and the range of rotational degree was 0 ~ 12°. In another study, Mendicute *et al*. found that Alcon Acrysof Toric had better rotational stability, and the rotational degree was all below 12° [16], which was consistent with results of this study. Both brands of toric IOLs adopted a one-piece design to increase the rotational stability of IOL. Correspondingly, the three-piece toric IOL has poor rotational stability, with about 41% of the postoperative rotational degree greater than 10° [17], and therefore not recommended to use and gradually withdrawn from the market. In addition to the one-piece design, the excellent rotational stability of Rayner 623T is due to its unique anti-vaulting haptic (AVH) loop design. The total length of IOL is 12.5 mm and when the diameter of the capsule is ≥ 12.5 mm, the loop is fully extended. When the diameter of the capsule shrinks to 10.5 mm after surgery, the outer loop begins to resist the pressure generated by the capsule contraction. As the diameter of the capsule reaches 10 mm, the outer loop begins to contact with the inner loop, generating an additional progressive support force, and when the diameter of the capsule reaches 9.5 mm, the outer loop is in full contact with the inner loop, and the contact between the top of the loop and the optical part produces a strong supporting force to resist the impact of the capsule contraction on IOL.

The National Eye Institute 25-Item Visual Function Questionnaire (NEI VFQ-25) can quickly and accurately determine the quality of life related to visual function of patients through more than 20 questions, and thus is widely used in clinical and scientific research of ophthalmology. The scores of Rayner group and Alcon group were both higher and showed no statistical difference, reflecting the good postoperative visual related quality of life in the two groups. In addition, there was no statistically significant difference in contrast sensitivity or objective visual quality at each spatial frequency between the two groups 3 months post-surgery ($P > 0.05$). We have seen that both toric IOLs are equally beneficial and precise to correct residual astigmatism after cataract surgery, and was have ascertained with good rotational stability, postoperative visual function, and high visual quality of life for patients. As far as we know, this is the first time NEI VFQ-25, contrast sensitivity and objective visual quality have been simultaneously introduced into studies to investigate the clinical effect of toric IOL, providing more dimensional evidence to support the evaluation of postoperative visual quality and quality of life of patients.

There are still some shortcomings in this study: All patients have underwent a detailed and necessary preoperative ophthalmic examination as possible, but due to the limited availability of examination equipment, it was not possible to measure and compare the size of lens capsule in the two groups before the surgery. Since the size of the capsule can affect the rotational stability of toric IOL, in the future studies, the measurements of capsule size can be carried out to improve the preoperative measurements; In the measurement of rotational degree of IOL, it is always ideal to compare the IOL axial position immediately after surgery and 3 months post-surgery, but the IOL cannot be placed on the targeted axial position calculated before surgery due to a variety of subjective and objective reasons. Because we used the intraoperative navigation system, the intraoperative axial position anchoring was very accurate, and at the end of the surgery, the operator repeatedly confirmed that the IOL marker line has been placed in the targeted axial position. Therefore, from the perspective of patients maximum benefit, photographs of anterior segment under slit lamp at sitting position at the end of the surgery were not taken, as we were worried that above operations may cause discomfort, and even increase the risk of postoperative

infection in patients. Under conditions of good sterility and patient's cooperation, photographs of anterior segment under slit lamp at sitting position at the end of the surgery can be taken to calculate the rotation axis of the IOL more accurately and scientifically.

Conclusion

In conclusion, both Rayner 623T and Alcon Acrysof Toric are equally beneficial to accurately correct the corneal astigmatism of cataract patients, and the postoperative visual quality, visual related quality of life score and intracapsular rotational stability of the two groups were high and comparable. The Rayner 623T toric IOL provides more options for cataract patients with corneal astigmatism.

Abbreviations

IOL: Intraocular lens; UCDVA: Uncorrected distance visual acuity; BCDVA: Best corrected distance visual acuity; NEI VFQ-25: National Eye Institute 25-Item Visual Function Questionnaire; CS: Contrast sensitivity; MTF cut-off: Modulation transfer function cut-off; SR: Strehl ratio; OSI: Objective scatter index; ACA: Anterior corneal astigmatism ; PCA: Posterior corneal astigmatism; AVH: Anti-vaulting haptic; LogMAR: Logarithm of the minimum angle of resolution; SE: Spherical equivalent refraction; SD: Standard deviation

Declarations

Ethics approval and consent to participate

The study followed the tenets of the Declaration of Helsinki and was approved by the Peking University Third Hospital Medical Science Research Ethics Committee. All patients provided written informed consent.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

XYC contributed to the ideas and design of study. YNL and QRW performed the experiment and collected data. HYC helped in the statistical analysis. YNL drafted the manuscript. QRW and XYC reviewed and revised the manuscript. YNL and QRW contributed equally to this article, they are co-first authors of the article. All authors read and approved the final manuscript.

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Figures

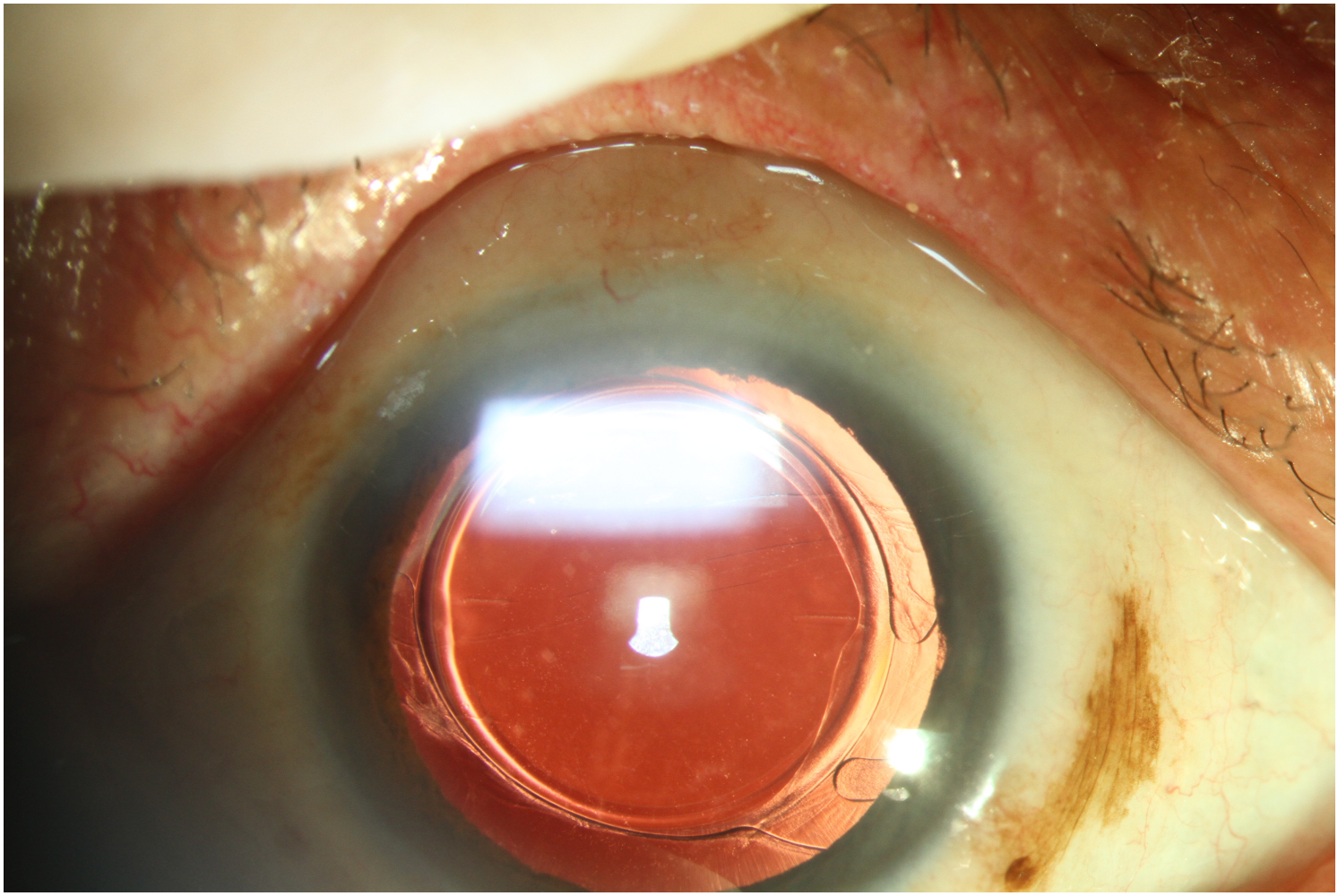

Figure 1

The color image of anterior segment under slit lamp 3 months after surgery: IOL axial marker was clearly visible (the marker line was at approximate horizontal position)

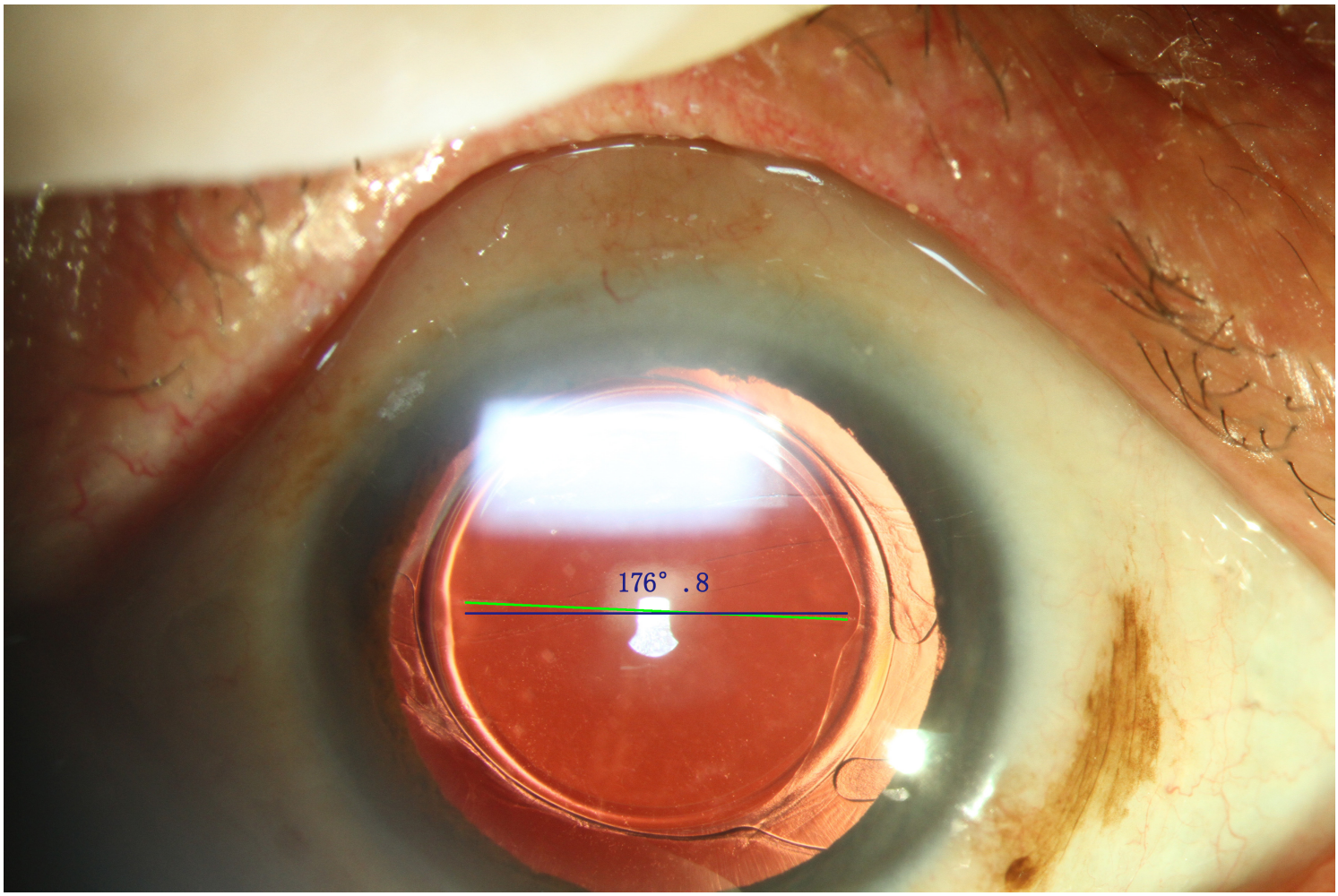

Figure 2

Measurement of IOL axis 3 months after surgery by the software (the green line is the IOL axis shown by the IOL marker line, the blue line is the horizontal line, and the software automatically generates the angles of the two)