

Early-stage clinical outcomes and rotational stability of TECNIS toric intraocular lens implantation in cataract cases with long axial length

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Abstract

Background: A major focus of toric intraocular lens (IOL) implantation is the rotational stability, especially in the patients with moderate to high myopia. In this study, we aimed to evaluate the clinical outcomes after implantation of TECNIS toric IOL in eyes with long axial length (AL) and identify factors influencing their early-stage stability with preoperative corneal astigmatism. **Methods:** The study population consisted of 64 eyes from 52 cataract patients, and these patients had preoperative corneal astigmatism between 1.0 and 3.7 diopters (D) and underwent phacoemulsification and TECNIS toric IOL implantation. Ophthalmic biological measurements were carried out preoperatively, including AL, anterior chamber depth (ACD), lens thickness (LT), vitreous length (VL), anterior chamber volume (ACV) and sulcus-to-sulcus (STS). The 1- and 3-month clinical outcomes included visual acuity, manifest refraction, keratometry, postoperative toric IOL axis, the area of capsulorhexis, and the overlapped area between IOL optic and anterior capsulorhexis. **Results:** The mean best corrected distance visual acuity (BCDVA) was improved from 0.93 ± 0.35 logarithms of the minimal angle of resolution (logMAR) preoperatively to 0.07 ± 0.10 logMAR postoperatively at 3 months after surgery. The mean residual astigmatism (RAS) was 0.91 ± 0.74 D at 3 months, which was significantly decreased compared with the preoperative corneal astigmatism of 1.71 ± 0.55 D. The mean absolute rotation of TECNIS toric IOL at 1 and 3 months was 7.41 ± 11.32 degree ($^{\circ}$) and $7.48 \pm 11.19^{\circ}$ (0° - 79°), respectively. A positive correlation was found between IOL rotation and the area of capsulorhexis (Pearson's $r=0.297$, $P=0.017$) at 3 months after surgery. No correlation was found between IOL rotation and AL (Pearson's $r=-0.020$, $P=0.876$), ACD (Pearson's $r=-0.123$, $P=0.387$), LT (Pearson's $r=0.083$, $P=0.523$), VL (Pearson's $r=-0.082$, $P=0.546$), ACV (Pearson's $r=-0.094$, $P=0.480$), STS (Pearson's $r=0.019$, $P=0.884$), or the overlapped area between capsulorhexis and optic (Pearson's $r=-0.191$, $P=0.131$). **Conclusions:** The area of capsulorhexis was a risk factor for toric IOL rotation. Implantation of TECNIS toric IOL in cataract cases with long AL was effective and safe.

Background

With the development of micro phacoemulsification in cataract surgery and design of premium IOL, better quality of vision has been achieved postoperatively. Patients with long AL who have undergone cataract surgery and had IOL implantation may be willing to decrease myopia and residual astigmatism (RAS). Therefore, the management of pre-existing corneal astigmatism has become more clinically important [1]. There are several surgical options for correcting preoperative astigmatism, such as femtosecond laser-assisted astigmatic keratotomy[2], limbal or corneal relaxing incisions[3], laser-assisted in situ keratomileusis (LASIK)[4], and implantation of toric IOLs. Implantation of toric IOL has its superiority of accuracy, predictability and economical efficiency compared with other options. A major problem of toric IOL implantation is the rotational stability. Patients with moderate to high myopia accordingly tend to have longer AL and bigger capsular bag than those with emmetropia [5, 6]. It indicates that larger capsular bags may reduce the equatorial friction for a given IOL, and thinner IOL may increase the gap between the optical component and the posterior capsule[7], therefore leading to decreased IOL stability. However, some scholars do not find the correlation between the IOL rotation and AL [8]. The controversy

about the possible correlation between the AL and IOL rotation remains furious. In the present study, we aimed to assess the refractive outcomes and rotational stability of TECNIS toric IOL implantation in cataracts with long AL and identify the potential factors influencing the rotational stability.

Methods

A total of 64 eyes that underwent phacoemulsification and implantation of TECNIS toric IOL (AMO Groningen BV, 9728 NX Groningen, the Netherlands) were enrolled in this retrospective non-comparative clinical study. AMO TECNIS toric IOL was a single-piece hydrophobic acrylic aspheric lens with a 6-mm optic diameter and an overall diameter of 13 mm. The IOL had a modified C-loop haptic configuration. The diameter for the outermost and innermost marking holes was 6.1 mm and 4.6 mm, respectively. All enrolled patients underwent cataract surgery from May, 2015 to October, 2018 at the Eye Center, the Second Affiliated Hospital of Zhejiang University. Informed consent was provided from every participant preoperatively. For analysis of rotational stability, axis recordings were evaluated approximately 3 months postoperatively. Before surgery, all patients with cataract had a regular total corneal astigmatism (TCA) of ≥ 1.00 D and an AL ≥ 25.0 mm. When the difference of the astigmatism meridian of the anterior and posterior surface was within ± 10 degrees and astigmatism difference was within ± 0.75 D and quality safety (QS) was OK, the total astigmatism shown on Pentacam was used to calculate before surgery. Exclusion criteria included patients with following eye conditions, such as irregular corneal astigmatism, a history of intraocular surgery, pterygium, glaucoma, retinal detachment, uveitis, macular degeneration or retinopathy, lens subluxation, posterior capsule opacification, and abnormal lens morphology. The refractive target was low myopia or emmetropia.

Preoperative examinations

Long AL was defined as an AL of 25 mm or greater. Preoperatively, patients had a routine examination for uncorrected distance visual acuity (UCDVA), BCDVA, intraocular pressure, manifest refraction, slit-lamp examination, biometric measurement and toric IOL calculations. The biometric measurement included AL (IOLMaster, Carl Zeiss, Advanced Technology V.5.5, Germany), TCA (Pentacam; Oculus Optikgeräte GmbH, Wetzlar, Germany), corneal keratometry and anterior chamber volume (ACV) (Pentacam; Oculus Optikgeräte GmbH, Wetzlar, Germany), anterior chamber depth (ACD) (Pentacam; Oculus Optikgeräte GmbH, Wetzlar, Germany) and sulcus-to-sulcus (STS) (Anterior Segment Visante™ OCT, Carl Zeiss, Germany). Immersion A-scan biometry (Quantel Medical CineScan AVISO, France) was used to determine the lens thickness (LT) and vitreous length (VL). The spherical power of IOL was examined using SRK-T formula, and the cylinder power and alignment axis were calculated using an online calculator (<https://www.TecnisToricCalc.com>). Surgically induced astigmatism (SIA) was entered as 0.3 D with a 2.0-mm clear limbal incision, and TCA was taken into account for calculation of the IOL's cylindrical power. The steep meridian of the corneal was used to determine the incision position.

Surgical technique

Each patient underwent the same technique by an experienced surgeon (Dr. Wen Xu). With the patients sitting upright on a slit-lamp microscope, the 0 and 180 D positions of the corneal limbus were precisely marked with a skin marker (Medplus Inc.) before pupil was dilated. Under topical or general anesthesia, toric IOL alignment axis was marked using a Mendez ring and highlighted for recognition. A 2.0-mm clear limbal incision was made on the steep meridian with continuous curvilinear capsulorhexis (CCC), followed by phacoemulsification and cortical aspiration. The toric IOL was inserted into the capsular bag using an injector (DK7786 with One Series Ultra Cartridge Implantation System) and rotated into a position approximately 5° to 10° counter-clock wise from the planned axis. After all the viscoelastic substances were removed from behind and before the IOL, the axis was aligned in a clockwise direction to the intended placement. The incisions were hydrated, and the position of the IOL was properly oriented prior to the end of surgery. No sutures were used to close the wound. The postoperative treatment consisted of prednisolone acetate eye drops (Allergan Pharmaceutical Ireland, Westport, Ireland) and levofloxacin (Cravit, Santen Pharmaceutical) four times a day for 7 days, as well as pranprofen (Pranopulin; Senju Pharmaceutical, Osaka, Japan) and sodium hyaluronate eye drops (URSAPHARM Arzneimittel GmbH, Germany) four times a day for 1 month.

Postoperative examinations

Postoperatively, patients received examinations at 1 week, 1 month and 3 months. Postoperative 1- and 3-month follow-ups included slit-lamp examination, intraocular pressure, BCDVA, manifest refraction, keratometry and digital anterior segment photography. Pupil was adequately dilated to visualize the toric axis marks and the edge of capsulorhexis with a mixture of phenylephrine and 0.5% tropicamide (Mydrin-P; Santen Pharmaceutical). The patients seated before slit-lamp microscope (TOPCON SL-D701, Japan) with an upright position, and digital anterior segment photographs (Topcon, Tokyo, Japan) were acquired and recorded. A conjunctive blood vessel or pigment was selected as a reference meridian to eliminate the influence of head tilt or eye rotation. The difference of IOL axial direction between target axis and actual alignment, the area of capsulorhexis and the overlapped area between IOL optic and anterior capsulorhexis were calculated using the ruler tool of Rhinoceros 5.0 (Robert McNeel&Assoc, America) for three times. The digital anterior segment photographs taken at 1 and 3 months after surgery were used to calculate the area of capsulorhexis and the overlapped area between IOL optic and anterior capsulorhexis. The mean value was selected for statistical analysis.

Statistical analysis

All statistical analyses were performed using SPSS Statistics 17.0 (SPSS, Chicago, Illinois, USA). Continuous variables were expressed as the mean and standard deviation (SD). The correlations between continuous variables were assessed using Pearson's correlation analysis. Multiple linear regression analysis was then performed to assess the independent effects of the various factors that might be associated with toric IOL rotation. A probability value of less than 0.05 was considered statistically significant.

Results

Preoperative characteristics

A total of 64 eyes from 52 patients, including 35 right and 29 left eyes, were enrolled in the present study. The mean age of patients at the time of surgery was 59.17 ± 17.14 years, ranging from 17 to 83 years. The mean preoperative BCDVA was 0.93 ± 0.35 logMAR. Table 1 shows the statistical characteristics of patients before the cataract surgery. Table 2 lists the TECNIS toric IOL models.

Postoperative visual acuity and refraction

BCDVA was significantly improved from 0.93 ± 0.35 logMAR to 0.07 ± 0.10 logMAR after surgery. The RAS was decreased from 1.71 ± 0.55 D to 0.91 ± 0.74 D at 3 months after surgery. Table 3 shows RAS at 3 months after implantation of toric IOL. The mean area of capsulorhexis was 21.04 ± 3.30 mm². The absolute rotation was within 5° in 54.68% (35/64) of eyes, within 10° in 87.50% (56/64) of eyes and within 15° in 93.75% (60/64) of eyes 3 months postoperatively. There were four eyes which were rotated more than 15°, and the greatest rotation reached 79°. Table 4 shows the IOL misalignment after toric IOL implantation.

Factors associated with toric IOL rotation

The mean area of capsulorhexis was 21.04 ± 3.30 mm², ranging from 14.45 to 31.16 mm². Toric IOL rotation was positively correlated with the area of postoperative capsulorhexis. The regression equation was $y = 1.004x - 13.648$ (Figure 1). A correlation was not found between IOL rotation and AL, ACD, LT, VL, ACV, STS, the spherical power of the implanted IOLs, or the overlapped area between capsulorhexis and optic. According to the regression equation, when the toric IOL rotation was 5°, the area of capsulorhexis was 18.57 mm², indicating a CCC of approximately 4.86 mm in diameter. When the rotation was within 10°, the area of capsulorhexis was 23.55 mm², indicating a 5.48mm CCC. When the area of capsulorhexis was over the limit, as the diameter of CCC was over 6.02 mm, the mean toric IOL rotation was increased to 15°. Table 5 shows the correlation analysis of toric IOL rotation as the dependent variable.

Discussion

Astigmatism and myopia are the most common refractive errors of patients with cataract. Toshiyuki Miyake et al. have studied the distribution of corneal astigmatism in 12,428 eyes after cataract surgery and reported that 36.3% of eyes have more than 1.0 D of corneal astigmatism, 8.0% have more than 2.0 D, and 2.4% have more than 3.0 D[9]. Postoperative misalignment is a significant problem in toric IOL implantation. The healing process of capsular bag takes place progressively after removal of the crystalline lens[8], and such process is normally complete within 1 month after surgery[10]. During the first 3 months after surgery, early toric IOL rotation can be attributed to an IOL surface with a low coefficient of friction[11], the design of the IOL[12], an overall length of the IOL that is too small for the capsular bag[13] and instability of the anterior chamber[14]. Some scholars have believed that rotational instability may be

associated with low-powered IOLs, which have a thinner optic and can decrease the IOL stability [9]. The capsular bag collapses and fibroses around the IOL, tightening and shortening the horizontal diameter of the bag and eventually leading to the increased tension and pressure between the capsule and the IOL[15]. Myopic eyes require special attention because of the risk for early rotation of the toric IOL. Toric IOL rotation will occur less often if the anterior and posterior capsules are fused. Yasushi Inoue et al. have reported that the greatest misalignment occurs as the IOL rotation within 1 h after surgery, suggesting that it is important to keep the patient to rest after surgery[16]. We didn't find a correlation between rotation and spherical power of IOL. We established that Toric IOL rotation was positively correlated with the area of capsulorhexis. These findings indicated that an appropriately sized CCC and the centre of CCC were essential to prevent IOL rotation, especially at early stage after surgery. Moreover, we didn't find a correlation between IOL rotation and AL, LT, VL, ACD, STS, the spherical power of the implanted IOL, or the overlapped area between capsulorhexis and optic.

In all five cases with significant rotation ($\geq 15^\circ$) in our study, the AL ranged from 26.20 mm to 27.57 mm, and the corneal astigmatism ranged from 1.3 D to 2.8 D. The axis alignment of these five cases was 87° , 158° , 88° , 92° and 81° intraoperatively and rotated 15° , 16° , 33° , 40° and 79° at 3 months after surgery, respectively.

There were two cases highly indicated that the size of capsulorhexis played an important role in risk factors of rotational stability. In case 1 (Figure 2), the rotation of IOL 3 months postoperatively was 5° , and the area of capsulorhexis was 14.84 mm^2 . The edge of IOL was tightly surrounded, demonstrating better rotational stability. In case 2 (Figure 3), the area of capsulorhexis was 31.16 mm^2 , and it rotated 79° at 3 months after surgery. The capsulorhexis size was too large to fix the toric IOL, and the edge of IOL was free. In these two cases, the rotation degree in the first case was smaller compared with the second case, since the area of capsularhexis of the former was smaller than the latter, although the AL of the former was larger than the latter. Table 6 shows the parameters of the two cases.

An earlier study has found a positive correlation between early rotation of the toric IOL and AL, which is positively correlated with the diameter of the capsular bag [17–19]. Since the diameter of capsular bag cannot be measured directly, we measured STS using Anterior Segment Visante™ OCT, which is a non-contact optical signal acquisition. We didn't find a correlation between AL and STS (Pearson's $r = -0.005$, $P = 0.971$), suggesting that AL was not positively correlated with the diameter of the capsular bag.

There are some limitations in our study. The digital anterior segment photographs were used to calculate the area of capsulorhexis as well as the overlapped area between capsulorhexis and optic. In order to minimize the influence of inaccurate calculation, we repeated the measurement for three times. The toric IOL alignment axis marker was at 10° intervals, and manual marking was used. VERION system has the advantage of intraoperative digital guidance of the toric IOL alignment even for 1° [20]. It has been reported that the underlying capsular shrinking probably occurs at 6 months or 1 year after cataract surgery, with the majority in the first 3 months[21]. In order to balance these two factors associated with the follow-up time, the influence to the position of IOL caused by capsular contraction and the stability of

the corneal SIA, we evaluated the early-stage outcomes until 3 months after the surgery in this study. Inevitably, some cases might already suffer from a very early-stage fibrosis and contraction of the capsular bag at this time.

Our data showed that the implantation of TECNIS IOL in eyes with long AL was effective, and some factors affected their early-stage stability after surgery with preoperative corneal astigmatism. However, the long-term influence from the capsular bag contraction and posterior capsular opacity should be considered.

Conclusions

Our study shows that the area of capsulorhexis was a risk factor for toric IOL rotation in eyes with long AL. The area of capsulorhexis within 18.57 mm^2 or the diameter of capsulorhexis within 4.86mm has an important significance on improving rotational stability. We did not find the correlation between IOL rotation and AL, ACD, LT, VL, ACV, STS, the spherical power of the implanted IOLs, or the overlapped area between capsulorhexis and optic. Implantation of TECNIS toric IOL in cataract cases with long AL was effective and safe.

Abbreviations

IOL: intraocular lens; AL: axial length; D: diopter; ACD: anterior chamber depth; LT: lens thickness; VL: vitreous length; ACV: anterior chamber volume; STS: sulcus-to-sulcus; BCDVA: best corrected distance visual acuity; logMAR: logarithms of the minimal angle of resolution; RAS: residual astigmatism; °: degree; LASIK: laser-assisted in situ keratomileusis; TCA: total corneal astigmatism; QS: quality safety; UCDVA: uncorrected distance visual acuity; OCT: optical coherence tomography; SIA: Surgically induced astigmatism; CCC: continuous curvilinear capsulorhexis; SD: standard deviation

Declarations

Ethics approval and consent to participate

This research article was approved by the ethics committee of the second Affiliated Hospital, Zhejiang University School of Medicine, and the research followed the tenets of the Declaration of Helsinki. Written consent was obtained from all patients.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or 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

All authors conceived of and designed the study. All authors were involved in the data analysis. HSH did the patients follow-up, collected data and drafted the article. WXD and MYJ reviewed the literature. CX and YXW revised the manuscript. XW did the surgery and drafted the article. All authors reviewed the manuscript and approved the final manuscript.

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Tables

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Figures

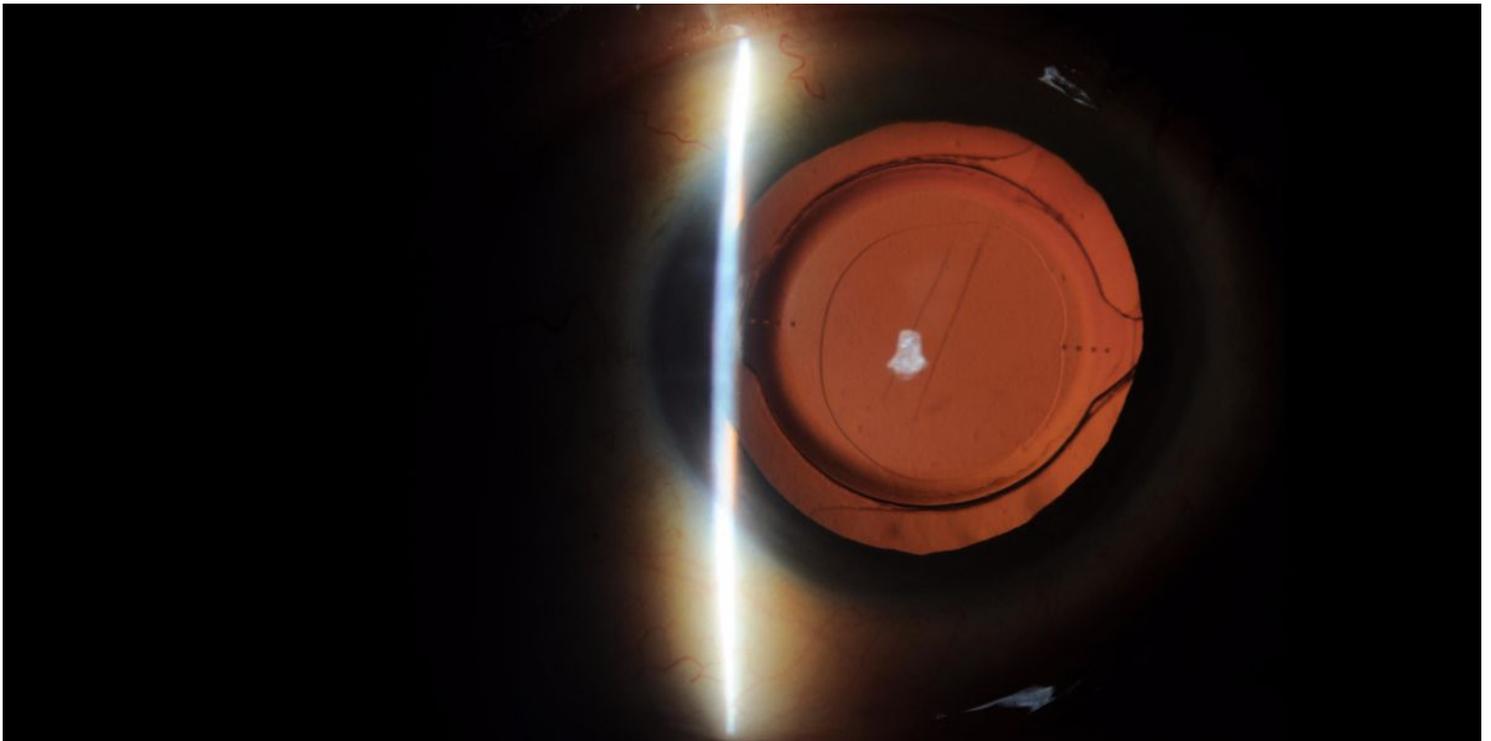


Figure 1

Toric IOL rotation was positively correlated with the area of capsulorhexis

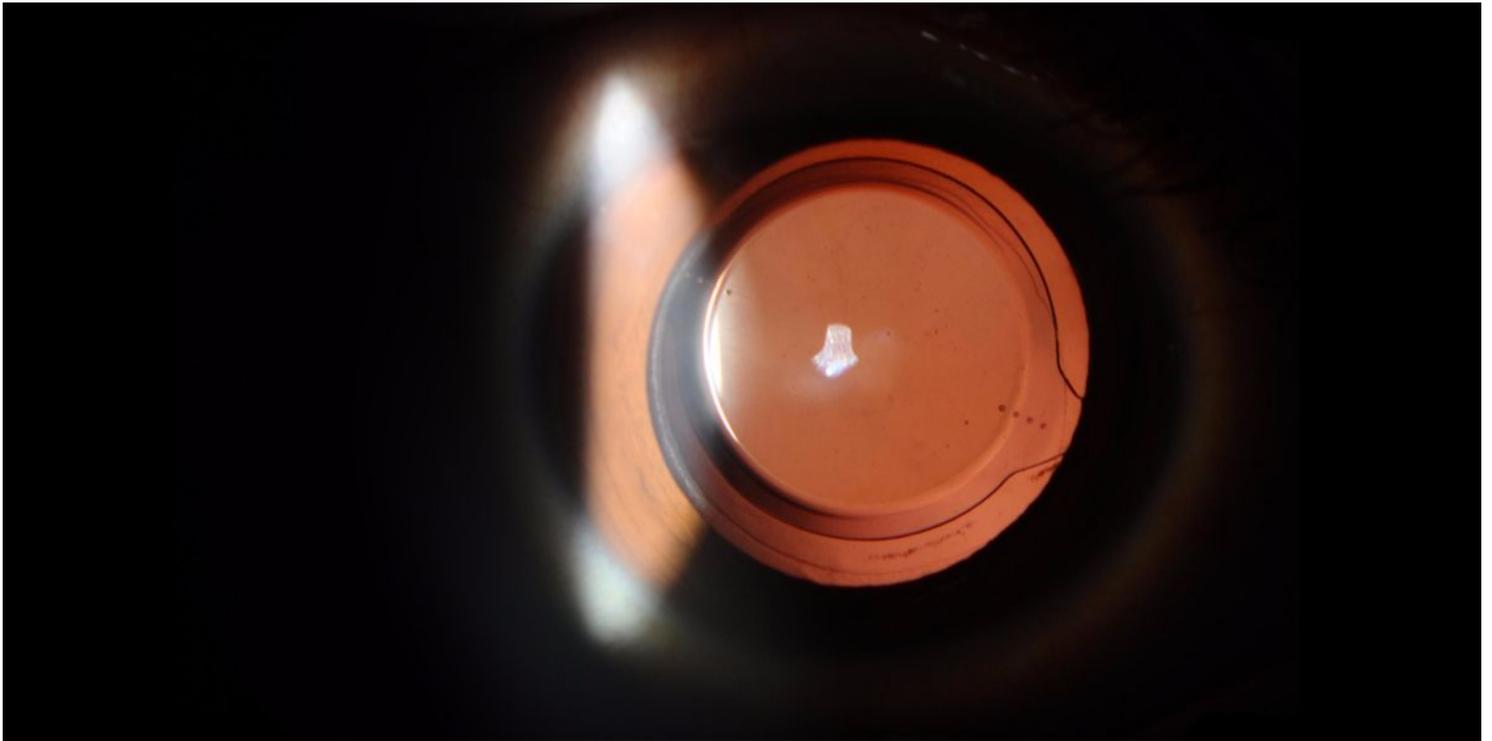


Figure 2

AL=26.96mm, the area of capsulorhexis=31.16mm², the rotation of IOL 1 and 3 months postoperatively was both 79°

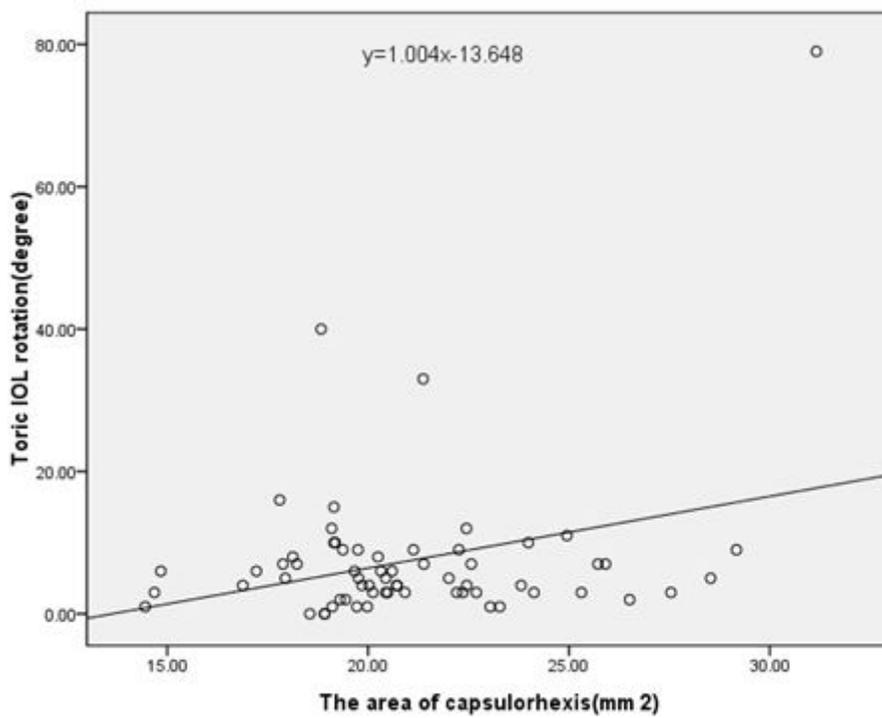


Figure 3

AL=29.91mm, the area of capsulorhexis=14.84mm², the rotation of IOL 1 and 3 months postoperatively was 5° and 6°, respectively

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