ORIGINAL RESEARCH



# Efficacy of Toric Intraocular Lens Implantation in Patients Older Than 80 Years with Cataracts and Corneal Astigmatism

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### ABSTRACT

*Introduction*: This study analyzed the visual outcome following cataract surgery with toric intraocular lenses (IOLs) in patients older than 80 years with corneal astigmatism.

*Methods*: A total of 159 patients (159 eyes) older than 80 years with corneal astigmatism ( $\geq 0.75$  D) were included. Fifty-three eyes received Acrysof IQ® toric IOLs (SN6AT2–5), while the others received non-toric IOLs: 51 eyes received Acrysof IQ® IOLs (SN60WF) and 55 eyes received A1-UV IOLs. The uncorrected distance visual acuity, corrected distance visual

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Y. Wang · F. Yang · X. Lou · S. Qian · B. Hu · Y. Zhao · P. Chang National Clinical Research Center for Ocular Diseases, Eye Hospital, Wenzhou Medical University, Wenzhou 325027, China acuity, and refraction (spherical equivalent, refractive cylinder) were assessed at 3 months postoperatively. The prediction error of refractive outcome and percentages of eyes within  $\pm$  0.50 D and  $\pm$  1.00 D in the toric IOL group obtained using five toric IOL formulas (Barrett predicted posterior corneal astigmatism (PCA), Barrett measured PCA, Kane, EVO 2.0 and Næser–Savini) were compared.

**Results**: At 3 months postoperatively, the average uncorrected distance visual acuity was better in the toric IOL group than the non-toric IOL group (p < 0.001). The mean residual refractive cylinder was lower in the toric IOL group than the non-toric IOL group (p < 0.001). The Næser–Savini formula achieved the lowest mean absolute error (0.39 D) and had the highest percentages of eyes within an absolute error of 0.50 D and 1.00 D (72% and 98%) compared to the other formulas.

*Conclusion*: The results demonstrate the efficacy of toric IOL implantation in patients older than 80 years with corneal astigmatism and provide strong evidence for cataract surgeons to encourage such patients to choose toric IOLs.

**Keywords:**  $\geq$  80 years old; Cataracts and corneal astigmatism; Toric IOL; Toric formulas

#### **Key Summary Points**

#### Why carry out this study?

Previous studies have demonstrated the effectiveness of toric intraocular lenses (IOLs).

However, due to a number of factors, toric IOL implantation may not be the first choice of treatment for many older adult patients.

#### What was learned from the study?

The outcomes of toric IOLs are better than those of non-toric IOLs in patients  $\geq$  80 years old with cataracts and corneal astigmatism.

Cataract surgeons should consider recommending toric IOLs for patients who are  $\geq 80$  years old with regular corneal astigmatism.

# INTRODUCTION

The Chinese population is currently undergoing societal aging, and the prevalence of cataracts increases markedly with increasing age [1]. In addition, increased age is associated with an increased risk of complications and bad surgical outcomes [2]. Cataracts are the most important forms of reversible visual impairment. It is estimated that significant cataracts are present in about half of all subjects in their seventies and all subjects in their nineties [3]. Reduced vision is associated with decreased ability to perform activities of daily living, decreased social functioning, and reduced life expectancy among older adults [4–7].

Escalating patient expectations and greater recognition of visual quality after cataract extraction have caused a shift from cataract surgery to refractive surgery. Toric intraocular lenses (IOLs) have been designed to replace cataract lenses, reduce postoperative astigmatism, and reduce or eliminate the need for distance-vision spectacles or additional surgery. However, due to traditional views, neglect of the quest for higher visual quality, financial constraints, and so on, toric IOL implantation is not the first choice of treatment for many older adult patients. Some characteristics of patients older than 80 years are that (1) the corneal astigmatism is commonly  $> \sim 1.1$  D [8] and (2) some of the patients are more reluctant to wear glasses due to poor memory [9] and inconvenience [10].

The primary aim of the present study was to analyze the clinical outcomes following cataract surgery with toric IOL implantation in patients older than 80 years and to assess the refractive predictions of modern toric IOL calculation formulas for this specific age group.

## **METHODS**

#### Patients

This retrospective study was performed at the Eye Hospital of Wenzhou Medical University, Hangzhou, China. All patients underwent phacoemulsification and IOL implantation from 2020 to 2022. The inclusion criteria were age over 80 years and corneal astigmatism (> 0.75 D). The toric IOL group received Acrysof IQ® toric IOLs (SN6ATx, Alcon Inc.), while the non-toric IOL group (comparison group) received Acrysof IQ® IOLs (SN60WF Alcon Inc.) or A1-UV IOLs (Evebright, China). When both eyes of a patient were eligible, the right eye was defined as the number 0 and the left eye as 1. An online random number generator (https://www.iikx.com/tool/radom. html) was then used to determine which eye to include. The exclusion criteria were congenital ocular abnormalities, use of ocular medications that may affect vision, previous retinal disease, glaucoma, previous corneal disease, history of eye trauma, previous cerebrovascular accidents, peri- or postoperative complications, degenerative eye disorders, moderate and severe dry eye disease, and previous refractive surgery.

The Institutional Review Board of Wenzhou Medical University approved the study and waived the requirement for informed consent because of the retrospective nature of the study. Anonymized patient data were used for the analysis, and the study adhered to the principles of the Declaration of Helsinki.

#### **Preoperative Preparation**

Patients with a mild degree [11, 12] of dry eye disease and severe cataracts were enrolled in the study. Dry eye disease of patients with moderate and severe meibomian gland dysfunction (MGD) was ruled out after a series of ocular surface assessments. We firstly collected the history, assessed the eyelid margin under a slit lamp, and evaluated the meibomian gland using meibography via a noncontact meibography system (Kerotography 5 M, Oculus, Wetzlar, Germany). Furthermore, the dry eye questionnaire scale (SPEED) was applied to assess the condition of dry eye disease for each patient.

All other ocular biometry measurements were performed using a Zeiss IOLMaster 500 or 700 (Carl Zeiss, Meditec). A Pentacam (Oculus Optikger EUROAL ATE GmbH) was used to rule out irregular corneal astigmatism and evaluate the curvature of the posterior corneal surface. IOL spherical power was calculated using the Barrett Universal II formula. The cylinder power and target IOL axis were calculated using the Alcon online calculator based on the IOLMaster data (http://www.myalcon-toriccalc.com/). A surgically induced astigmatism of 0.22 D was assumed to fill the calculator.

After topical anesthesia with propantheline (Alcon-Couvreur), each patient was instructed to sit upright, keep their head carefully aligned, and fix their eyesight straight on the distant target with the nonsurgical eye. The light from the slit lamp was adjusted to a sharp line, turned to align with the target axis and the 135° location of the main corneal incision separately, and centered on the corneal apex to ensure that it passed through the middle of the cornea. The target axis position was marked as a sharp line by scratching the corneal epithelium at the limbus with a needle; the main corneal incision was marked in the same way. Thereafter, the scratch marks were stained using a surgical marking pen. The comparison group were examined preoperatively as described above except for the preoperative marking step.

The same experienced surgeon performed all surgeries. Surgery was performed through a 2.2mm clear corneal incision at 135° of the corneal limbus. A 5.0- to 5.5-mm continuous curvilinear capsulorhexis was then made, followed by hydrodissection, phacoemulsification, and posterior capsule polishing. The toric IOL was implanted with a Monarch III delivery system and rotated into a position approximately 10-20° short of the intended axis. Finally, the IOL was aligned to the correct position after removing the residual viscoelastic device. The IOL axis was double-checked after the incision was hydrated and the anterior chamber was reinflated. The comparison group was operated on in the same way except for the axial alignment.

# Postoperative Examination and Calculation

The following visual outcomes were analyzed 3 months after surgery for all patients: postoperative refractive spherical equivalent, refractive cylinder, uncorrected distance visual acuity (UDVA), and corrected distance visual acuity (CDVA). Before any further analysis, all left eye refractive data (pre- and postoperative) were converted; as a result, the new axis of the left eye was equal to 180° minus the original axis [13, 14]. The decimal visual acuity (VA) data were converted to logMAR for statistical analysis and the calculation of the average VA using a standard conversion formula.

The power data are represented by the mean sphere M and two crossed cylinders  $J_0$  and  $J_{45}$  [15]. The magnitude of the astigmatic power vector (APV) represents the magnitude of the astigmatic error. The conversion process is as follows:

$$M = S + C/2, J_0 = -C/2\cos(2\alpha), J_{45}$$
  
= -C/2sin(2\alpha), APV =  $\sqrt{J_0^2} + J_{45}^2$ 

Here, *S* is the spherocylindrical sphere power, *C* is the signed cylinder power, and  $\alpha$  is

	Toric $(n = 53)$	IQ (n = 51)	A1-UV $(n = 55)$	P value
Age (y)	$83.98 \pm 2.98$	$84.08 \pm 3.11$	83.62 ± 2.99	0.724 <sup>b</sup>
	83.00 (82.00;86.00)	83.00 (82.00;86.00)	83.00 (81.00;85.00)	
Sex (M/F)	30/23	22/29	26/29	0.369 <sup>c</sup>
Eye (R/L)	30/23	25/26	30/25	0.511 <sup>c</sup>
IOL spherical power (D)	$21.08 \pm 2.40$	$20.98 \pm 3.57$	$21.09\pm2.89$	0.892 <sup>b</sup>
	21.50 (20.00;22.50)	22.00 (18.75;23.00)	21.00 (20.00;23.00)	
Axial length (mm)	$23.72 \pm 1.13$	$23.66 \pm 1.39$	$23.47 \pm 1.01$	0.631 <sup>b</sup>
	23.42 (22.95;24.12)	23.29 (22.74;24.53)	23.33 (22.78;24.01)	
Average $K(D)$	$44.04 \pm 1.16$	$44.21 \pm 1.77$	$44.25 \pm 1.64$	0.766 <sup>d</sup>
ACD (mm)	$2.92\pm0.38$	$2.90 \pm 0.47$	$2.89\pm0.42$	0.094 <sup>d</sup>
Corneal astigmatism (D)	$1.24\pm0.29$	$1.17\pm0.45$	$1.27\pm0.55$	0.068 <sup>b</sup>
	1.23 (1.03;1.39)	0.97 (0.88;1.29)	1.11 (0.88;1.40)	
IOL type	T2 (2)	SN60WF(51)	A1-UV(55)	
	T3 (10)			
	T4 (33)			
	T5 (8)			

Table 1 Patient demographics and clinical features<sup>a</sup>

*IOL* intraocular lens, *D* diopters, *ACD* anterior chamber depth

<sup>a</sup>The Shapiro–Wilk test was used to test the normality or non-normality of the data distribution

<sup>b</sup>Using the Kruskal–Wallis test, the median and interquartile range  $(P_1;P_3)$  were added to provide a statistical description <sup>c</sup>Chi-squared test

<sup>d</sup>One-way ANOVA test

the cylinder axis. The above data results were used for statistical analysis.

Five toric IOL formulas [Barrett predicted posterior corneal astigmatism (PCA), Barrett measured PCA, Kane, EVO 2.0, and Næser-Savini] were employed using each patient's preoperative ocular biometry measurement data (real world analysis [16]), which were entered into the respective calculators (Barrett [predicted or measured PCA]: https://ascrs.org/ tools/barrett-toric-calculator; Kane: https:// www.iolformula.com/agreement/; EVO 2.0: https://www.evoiolcalculator.com/toric.aspx; Næser–Savini: https://www.sedesoi.com/toric-2021/). We used the vector analysis [17]. The actual postoperative refractive astigmatism was

calculated by vertexing the postoperative

manifest refractive astigmatism to the corneal plane. The prediction error (PE) was calculated as the vector difference between the actual and predicted postoperative refractive astigmatism. The median absolute error (MedAE), mean absolute error (MAE), vector calculated centroid error [mean centroid (diopters @ degree-s)  $\pm$  SD], and percentages of eyes with a postoperative absolute error (AE) within 0.50 D and 1.00 D were calculated.

#### **Statistical Analysis**

The sample size was calculated according to the main indicators [mean UDVA (logMAR); postoperative mean refractive cylinder (D); APV (D)], and the results showed that the total



Fig. 1 Flow chart of patient selection

number of samples needed was more than 90 (each group was 30). Graphs for intraocular lens-based refractive surgery were drawn according to the standard requirement [18]. Statistical analysis was performed using SPSS 26.0 (SPSS Inc., Chicago, IL, USA). The chisquared test was used to compare both the gender composition and the right to left eye ratio among the three groups. The normality of the distributions was evaluated using the Shapiro-Wilk test. For comparative statistics, if the data were normally distributed, a one-way ANOVA test was selected; otherwise, the Kruskal-Wallis test was used. Values were expressed as the mean  $\pm$  standard deviation. If the Kruskal-Wallis test was used, the median and interquartile range  $(P_1;P_3)$  were also presented to provide a statistical description. The Hotelling test was used to perform multivariate statistical analysis of the centroid errors [16]. Statistical significance was set at p < 0.05.

## RESULTS

#### **Patient Demographics**

The demographics and clinical features of the 159 patients (159 eyes) are shown in Table 1. When both eyes of a patient were eligible, one eye was selected at random for analysis. Among them, 53 eyes received toric IOLs, 51 eyes

Parameter	Toric $(n = 53)$	IQ $(n = 51)$	A1-UV $(n = 55)$	P value <sup>b</sup>
Refractive spherical equivalent	$-0.42 \pm 0.68$	$-0.70 \pm 0.93$	$-0.49 \pm 0.71$	0.170
(D)	- 0.25 ( - 0.50;0.00)	- 0.50 ( - 0.88; - 0.07)	- 0.38 ( - 0.75; - 0.13)	
Refractive cylinder (D)	$0.58\pm0.36$	$1.10\pm0.53$	$1.35\pm0.90$	< 0.001
	0.50 (0.50;0.75)	1.00 (0.75;1.50)	1.25 (0.75;1.75)	
APV	$0.29\pm0.18$	$0.55\pm0.26$	$0.68 \pm 0.45$	< 0.001
	0.25 (0.25;0.38)	0.50 (0.38;0.75)	0.63 (0.38;0.88)	
Mean CDVA (logMAR)	$0.10\pm0.09$	$0.15 \pm 0.11$	$0.15\pm0.12$	0.059
	0.10 (0.00;0.15)	0.10 (0.10;0.22)	0.10 (0.10;0.22)	
Mean UDVA (logMAR)	$0.15\pm0.10$	$0.29\pm0.16$	$0.29\pm0.17$	< 0.001
	0.10 (0.10;0.22)	0.30 (0.16;0.40)	0.30 (0.22;0.40)	

 Table 2 Outcomes at 3 months postoperatively<sup>a</sup>

*D* diopters, *APV* astigmatic power vector, *CDVA* corrected distance visual acuity, *UDVA* uncorrected distance visual acuity <sup>a</sup> The Shapiro–Wilk test was used to test the normality or non-normality of the data distribution

<sup>b</sup>Using the Kruskal–Wallis test, the median and interquartile range  $(P_1;P_3)$  were added to provide a statistical description



**Fig. 2** Plot of  $J_0$  versus  $J_{45}$  for the postoperative refractions in both the toric and the non-toric groups

received IQ IOLs, and 55 eyes received A1-UV IOLs. Figure 1 summarizes the patient selection process. The average age in the toric IOL, IQ IOL, and A1-UV IOL groups was  $83.98 \pm 2.98$  years,  $84.08 \pm 3.11$  years, and  $83.62 \pm 2.99$  years, respectively. The IOL spherical power, anterior chamber depth (ACD), axial length (AL), average keratometry, and corneal astigmatism did not significantly differ between the three groups. The numbers and types of IOLs inserted are shown in Table 1.

# Postoperative Refraction and Visual Acuity

Table 2 shows the refraction and VA outcomes. The mean residual refractive cylinder was  $0.58 \pm 0.36$  D in the toric IOL group,  $1.10 \pm 0.53$  D in the IQ IOL group (*p* < 0.001), and  $1.35 \pm 0.90$  D in the A1-UV IOL group (p < 0.001). The APV was  $0.29 \pm 0.18$  D in the toric IOL group,  $0.55 \pm 0.26$  D in the IQ IOL group (p < 0.001), and 0.68  $\pm$  0.45 D in the A1-UV IOL group (p < 0.001). The toric IOL group showed a significantly better mean UDVA  $(0.15 \pm 0.10 \text{ logMAR}; p < 0.001)$  compared with the non-toric group. No significant difference in the CDVA was found between the toric IOL group and the comparison groups. Figure 2 shows a plot of  $J_0$  versus  $J_{45}$  for the postoperative refractions in both the toric and the non-toric groups.

Figure 3 shows standard graphs for reporting the refractive outcomes for IOL-based procedures in a cataract population. A Snellen VA of 20/40 or better was achieved by 98% (n = 52) of the patients in the toric IOL group (Fig. 3A). Overall, 49% (n = 26) of the eyes with toric IOLs





Fig. 3 Standard graphs for reporting refractive outcomes of intraocular lens-based procedures in a cataract population. A Uncorrected distance visual acuity. B Uncorrected distance visual acuity versus corrected distance visual

reporting refractive outcomes cedures in a cataract populae visual acuity. **B** Uncorrected us corrected distance visual corrected distance visual

had a UDVA that was the same as the CDVA (Fig. 3B). A spherical equivalent refraction of – 0.5 to – 0.14 was achieved in 42% (n = 19), 31% (n = 16), and 31% (n = 17) of the toric IOL, IQ IOL, and A1-UV IOL groups, respectively (Fig. 3C). A postoperative refractive cylinder of less than 1.00 D was achieved in 94% (n = 51), 57% (n = 29), and 44% (n = 24) of the eyes in the toric IOL, IQ IOL, and A1-UV IOL groups, respectively (Fig. 3D).

#### Accuracies of the Five Toric IOL Formulas

Table 3 shows the refractive astigmatism error results for the five toric IOL formulas. The Næser–Savini formula achieved the lowest MAE (0.39 D), though no statistically significant difference was found between the five formulas (p = 0.435). Using the vector algorithm, the centroid of the PE varied significantly from 0 for

the Kane formula (p < 0.001) and was not statistically significantly different from 0 for the other formulas (p > 0.05). Figure 4 shows the

double-angle plots of the PE for each toric IOL

#### DISCUSSION

formula.

The present study demonstrated that toric IOL implantation gave better visual outcomes than non-toric lens implantation in patients older than 80 years with corneal astigmatism ( $\geq 0.75D$ ). The availability of medical insurance and the additional cost of a toric IOL may be a burden for some frugal or low-income patients, especially in the older adult population in China. However, a VA improvement in very old patients translates into improved quality of life and postural stability and a reduction in fall-

Formula	Med AE MAE ± SD Mean centroid (diopters @ degrees) ± SD		Postoperative refractive astigmatism prediction error (%)		
				± 0.50D	± 1.00D
Barrett (predicted PCA)	0.32	$0.41\pm0.28$	$0.01@136^{\circ} \pm 0.49$	72	96
Barrett (measured PCA)	0.33	$0.40\pm0.29$	$0.02@157^{\circ} \pm 0.49$	72	92
Kane	0.37	$0.43\pm0.32$	$0.22@177^{\circ} \pm 0.48$	62	92
EVO 2.0	0.35	$0.41\pm0.28$	$0.02@125^{\circ} \pm 0.49$	66	96
Næser–Savini	0.33	$0.39\pm0.27$	$0.03@175^{\circ} \pm 0.47$	72	98

**Table 3** Refractive astigmatism error results of the five toric IOL formulas (n = 53)

EVO Emmetropia Verifying Optical, MAE mean absolute error, Med AE median absolute error, SD standard deviation



Fig. 4 Double-angle plots of the prediction error for the four toric intraocular lens formulas. A Barrett (predicted PCA), B Barrett (measured PCA) C Kane, D EVO 2.0, E Næser–Savini

related fractures, which would benefit patients, families, society, and the nation.

The comparison group in the present study included both IQ and A1-UV IOLs rather than solely IQ IOLs because the A1-UV IOL has become increasingly popular due to its good clinical outcomes and suitable price in China. A previous study [19] showed that a comparison between the A1-UV IOL and SN60WF IOL can minimize the potential impact of material as these lenses use the same hydrophobic acrylic materials and have similar profiles. Therefore, for some aspects, the A1-UV IOL can be used as a control IOL in clinical studies.

In patients with a cataract alone, significant improvements in UDVA are often reported when using toric IOLs compared with non-toric IOLs [20, 21]. Dan et al. [18] noted that the preoperative CDVA does not help when assessing the refractive outcomes in a population of patients with cataracts because removing the lens typically achieves a significant improvement in VA, independent of the refractive correction. Thus, the UDVA is reported as the best measurement of the VA. In the present study, compared with non-toric IOLs, the use of toric IOLs significantly improved the UDVA. These results are consistent with previous reports [20, 21]. Although there were differences in preoperative corneal astigmatism between the three groups, the mean residual refractive cylinder of the toric IOL group was significantly less than that of the comparison group postoperatively. Minimizing refractive astigmatism after cataract surgery can significantly improve a patient's vision [22]. The present study found a significant improvement in postoperative refractive astigmatism and UDVA after toric IOL implantation compared with non-toric IOL implantation in patients older than 80 years with corneal astigmatism. This, in turn, increases the chances of postoperative spectacle independence and decreases the possibility of complications caused by additional correcting astigmatism surgery. Therefore, age should not be a limiting factor in the quest for better visual quality.

Elderly patients are of concern because their eyes change as they get older. Some studies have shown that older age is associated with structural changes to collagen that impact scleral fiber alignment, matrix stiffness [23], and the stretching qualities of the anterior capsule and lens zonule. This changes the elastic properties over time [24, 25]. Moreover, age has been shown to affect the morphology of Schlemm's canal and the trabecular meshwork [26]. ACD changes have also been reported in the older adult population [27]: the AL is significantly shortened and the ACD becomes shallower with increasing age. Increased age is associated with a flatter corneal curvature, although the correlation is weak. Accordingly, the AL, ACD, and corneal curvature at baseline may contribute to the degree of prediction error, possibly through age-related changes in these parameters [28]. In addition, dry eye, mental status, and systemic comorbidities may hamper the ability of older adults to cooperate with meticulous manifest refraction or fixation to achieve technically decent biometry, which affects the refractive outcome and accuracy of IOL calculation formulas [29].

No studies have attempted to assess the refractive predictions of modern toric IOL calculation formulas in the population older than 80 years. Therefore, the present study aimed to compare the accuracies of toric IOL formulas (Barrett [predicted and measured PCA], Kane, EVO 2.0, and Næser-Savini) in patients older than 80 years. The Barrett toric IOL formula uses the Barrett Universal 2 formula to calculate the effective lens position (ELP), and uses a PCA prediction algorithm or actual measurements to predict the actual postoperative refractive astigmatism. The Kane toric IOL formula uses the Kane formula to calculate the ELP before using an advanced algorithm incorporating regression, theoretical optics, and artificial intelligence techniques to calculate the total corneal astigmatism [30, 31]. The EVO 2.0 toric IOL formula uses the EVO 2.0 formula to calculate the ELP, and uses a theoretical posterior corneal astigmatism prediction to calculate the total corneal power. The Næser-Savini formula uses equations to modify the measured anterior corneal astigmatism to better represent the overall corneal astigmatism [32]. In the current study, there was no statistically significant difference among the five formulas. Therefore, we

consider that the five formulas were consistent in their effectivenesses for the present sample. It is also possible that the present sample size was too small to detect the most accurate formula. A study with a larger sample size is required to compare the accuracies of toric IOL formulas.

The present study had several limitations. First, the sample size of patients older than 80 years with toric IOL implantation was comparatively small. Second, VA was the only objective measure of vision used. Moreover, the relatively short follow-up for VA limits the estimation of long-term results. Measuring contrast sensitivity may add helpful information.

## CONCLUSION

In conclusion, visual outcomes were better in patients 80 years and older with corneal astigmatism who underwent implantation of toric IOLs than in those implanted with non-toric IOLs. The accuracies of five toric formulas were excellent and consistent in the patients. In future clinical applications, cataract surgeons should consider recommending toric IOLs for patients 80 years and older with corneal astigmatism.

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*Author Contributions.* Pingjun Chang and Yalan Wang conceived and designed the presented study. Xicong Lou, Shuyi Qian, Bin Hu, and Fuman Yang performed the data collection. Yalan Wang performed the analysis and wrote the manuscript. Yune Zhao provided a critical review of the manuscript.

*Disclosures.* Yalan Wang, Fuman Yang, Xicong Lou, Shuyi Qian, Bin Hu, Yune Zhao, and Pingjun Chang have nothing to disclose.

Compliance with Ethics Guidelines. Approval was obtained from the Institutional Review Board of the Eye Hospital of Wenzhou University Medical (number: 2021-036-K-29-01). The requirement for informed consent was waived because of the retrospective nature of the study. Anonymized patient data were used for the analysis, and the study adhered to the principles of the Declaration of Helsinki.

*Data Availability.* The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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