

Optical quality of toric intraocular lens implantation in cataract surgery

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Abstract

• **AIM:** To analyze the optical quality after implantation of toric intraocular lens with optical quality analysis system.

• **METHODS:** Fifty-two eyes of forty-four patients with regular corneal astigmatism of at least 1.00 D underwent implantation of AcrySof toric intraocular lens, including T3 group 19 eyes, T4 group 18 eyes, T5 group 10 eyes, T6 group 5 eyes. Main outcomes evaluated at 3mo of follow-up, included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), residual refractive cylinder and intraocular lens (IOL) axis rotation. Objective optical quality were measured using optical quality analysis system (OQAS II®, Vismetrics, Spain), included the cutoff frequency of modulation transfer function (MTFcutoff), objective scattering index (OSI), Strehl ratio, optical quality analysis system value (OV) 100%, OV 20% and OV 9% [the optical quality analysis system (OQAS) values at contrasts of 100%, 20%, and 9%].

• **RESULTS:** At 3mo postoperative, the mean UDVA and CDVA was 0.18 ± 0.11 and 0.07 ± 0.08 logMAR; the mean residual refractive cylinder was 0.50 ± 0.29 D; the mean toric IOL axis rotation was 3.62 ± 1.76 degrees, the mean MTFcutoff, OSI, Strehl ratio, OV 100%, OV 20% and OV 9% were 22.862 ± 5.584 , 1.80 ± 0.84 , 0.155 ± 0.038 , 0.76 ± 0.18 , 0.77 ± 0.19 and 0.78 ± 0.21 . The values of UDVA, CDVA, IOL axis rotation, MTFcutoff, OSI, Strehl ratio, OV100%, OV20% and OV9% depending on the power of the cylinder of the implantation were not significantly different ($P > 0.05$), except the residual refractive cylinder ($P < 0.05$).

• **CONCLUSION:** The optical quality analysis system was useful for characterizing the optical quality of AcrySof toric IOL implantation. Implantation of an AcrySof toric

IOL is an effective and safe method to correct corneal astigmatism during cataract surgery.

• **KEYWORDS:** optical quality analysis system; toric intraocular lens; astigmatism

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INTRODUCTION

It has been estimated that 15% to 29% of cataract patients have more than 1.50 diopters (D) of preexisting astigmatism and that 3% to 15% of eyes have astigmatism greater than 2.00 D^[1,2]. Wolffsohn *et al*^[3] showed that uncorrected astigmatism caused an average loss of visual acuity of 1.5 lines per diopter at high contrast and a similar effect at 50% and 10% contrast. Therefore, even a relative low amount of uncorrected astigmatism would significantly reduce visual acuity, which will further reduce the ability to perform low-contrast tasks.

Astigmatism can be corrected during cataract surgery in a number of ways, including placement of the phacoemulsification incision on the steepest meridian of the cornea, use of limbal relaxing incisions, use of opposite clear corneal incisions, and implantation of a toric intraocular lens (IOL)^[4,5]. After cataract surgery, laser refractive surgery can be used to correct residual refractive errors, including cylinder errors^[6]. However, aside from the disadvantage of an additional surgery, these procedures are associated with complications, such as limited predictability, exacerbation of dry-eye symptoms, corneal epithelial defects and delayed wound healing^[7]. Recent studies suggested that correcting corneal astigmatism appears to be more reliable if implanting toric IOL at the time of cataract surgery rather than cases of spherical IOL implantation with associated corneal relaxing incisions^[5].

The idea of implanting a toric IOL was initiated in 1994 by Shimizu *et al*^[8], however, a hydrophobic acrylic toric IOL with a single-piece design (AcrySof toric SN60T, Alcon Laboratories, Inc.) recently became available worldwide. The AcrySof toric IOL effectively decreased preexisting corneal astigmatism and provides excellent uncorrected distance visual acuity (UDVA)^[9,10].

In this study, we objectively evaluated the effect of AcrySof toric IOL correcting astigmatism with a commercially available double-pass system (optical quality analysis system, OQAS II®, Visiometrics, Spain) that was commonly used to assess visual quality in real eyes and simulate *in vivo* conditions. This technique was proposed half a century ago as a means of estimating retinal image quality [11]. Over time, the method incorporated technical advancements [12] and was shown to provide accurate estimates of the eye's image quality. It has been widely used to evaluate retinal image quality in situations in which the optical quality in the human eye might be known, such as in the normal population as a function of age, in contact lens wearers, in laser *in situ* keratomileusis patients, and in patients with monofocal, or multifocal IOLs^[13-16].

SUBJECTS AND METHODS

Subjects This prospective clinical study was performed at Tianjin Medical University Eye Hospital and enrolled eyes having phacoemulsification with implantation of an AcrySof toric IOL from August 2012 to November 2012. Patient inclusion criteria were visually significant cataract, regular corneal astigmatism of at least 1.00 D (measured by keratometry). Exclusion criteria were pathology of the cornea, vitreous, macula, or optic nerve; extensive irregular corneal astigmatism determined using corneal topography; planned extracapsular cataract extraction; a history of ocular surgery or inflammation; patient refusal; and anticipated difficulties with the examinations, analyses, or follow-ups. The research adhered to the tenets of the Declaration of Helsinki and all patients provided informed consent regarding this study, and the protocol was approved by the Ethics Committee of Tianjin Medical University Eye Hospital.

Methods Preoperatively, all patients had an extensive ophthalmic examination consisting of uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), subjective refraction, keratometry, slitlamp examination, fundoscopy, and biometry (Lenstar LS900®, Haag-Streit AG, Koeniz, Switzerland).

Intraocular lens The AcrySof toric series of IOLs (Alcon Laboratories, Fort Worth, TX, USA) is made of hydrophobic acrylate and shares the same biconvex single-piece design as the AcrySof SA60AT monofocal IOL(Alcon Laboratories). It has open-loop modified L-haptics with no angulation; the haptics are of the same acrylic material as the optic. The posterior surface of the optic has the toric component as well as 3 peripheral dots that indicate the cylindrical axis of the lens and thus enable its correct alignment with the steepest axis of corneal astigmatism during surgery. The AcrySof toric IOL is available in seven types: SA60T3, SA60T4, SA60T5, SA60T6, SA60T7, SA60T8 and SA60T9 with cylinder powers at the IOL plane (corneal plane) of 1.50 D (1.03 D), 2.25 D (1.55 D), 3.0 D (2.06 D), 3.75 D (2.57 D),

4.50 D (3.08 D), 5.25 D (3.60 D) and 6.0 D (4.11 D), respectively. The type of toric IOL implantation, intraocular lens cylinder power and alignment axis were calculated using a program available from the IOL manufacturer (www.acrysoftoriccalculator.com), considering the Lenstar LS900® biometric and keratometric data as well as the surgically induced astigmatism (SIA) by clear corneal incision of 0.30 D. The target refraction was near to emmetropia (within -0.50 D) in all cases.

Surgical technique For preoperative corneal marking, the eye was anesthetized with a single drop of oxybuprocaine. With the patient sitting upright and with the head carefully aligned, the patient was asked to fixate straight ahead on a distant target with the nonsurgical eye. The corneal limbus was marked at the 0-degree and 180-degree positions using a corneal marker with an air-bubble to ensure accurate horizontal positioning of the marker on the limbus.

The same surgeon performed all surgeries using topical anesthesia, microcoaxial phacoemulsification, and a standardized technique. A 2.2 mm clear corneal incision was located at 120 degree of the corneal limbus.

Optical quality parameters The head of the subject was positioned on the chin rest and fixated on the center of a figure. The operator manually aligned the subject's pupil center with the optical axis of the device. The spherical refractive error was automatically measured and corrected by the double-pass system by means of a motorized optometer within a range of -8.00 to +6.00 D. External cylindrical lenses were required for astigmatism more than 0.50 D. After resting for 5min subjects were asked to blink before the measurement. For objective scattering index (OSI), the device took 6 measurements and 6 images were recorded for lasting 5s. After repeating former procedure, 6 images were recorded simultaneously for MTFcutoff, Strehl ratio, OV100%, OV20% and OV9%. It then calculated the mean of the measurements to provide the final results for each parameter. Room illumination was kept low during testing.

The double-pass technique has been widely used in the past to evaluate the optical quality of the retinal image^[12,13]. Retinal image quality was measured by means of the OQAS for a 4-mm artificial pupil with the subject's retinal image optimally focused. The size of the artificial pupil is controlled by means of a diaphragm wheel located inside the double-pass system. Previous studies have demonstrated the excellent repeatability and reproducibility of optical quality obtained with this double-pass system^[17,18].

The double-pass system provided the retinal image corresponding to a point-source object in near-infrared light consisting of a laser diode ($\lambda=780$ nm) coupled to an optical fiber. Near-infrared light is used because it is more comfortable for the subject and provides retinal image quality estimates that are comparable to those obtained with visible

light [19]. From the retinal image of each analyzed eye, the monochromatic modulation transfer function (MTF) was computed. The MTF represents the loss of contrast as a function of the spatial frequency. A two-dimensional radially averaged profile of the MTF is used to describe the complete eye's optical quality in the double-pass instrument. To simplify the data and facilitate the clinical comparison of retinal image quality between subjects, the system provides several parameters that are related to the MTF profile: the MTFcutoff, the Strehl^{2D} ratio, and the OQAS values (OV) at contrasts of 100%, 20%, and 9%.

The MTFcutoff [18] is calculated as that corresponding to a 0.01 MTF value, because there is a certain level of background noise in the MTF profile that is computed from the real recorded double-pass image. It is normally assumed that a cutoff frequency of 30 cycles per degree (c/deg) in the Contrast Sensitivity Function, which includes the contrast degradation imposed by the optics and posterior visual processing, corresponds to a decimal visual acuity of 1.0.

In the visual optics field, the Strehl ratio is often computed in the frequency domain as the ratio between the volume under the MTF curve of the measured eye and that of the aberration-free eye [20]. This provides overall information on the eye's optical quality. The double-pass system computes the Strehl ratio in two dimensions (Strehl^{2D} ratio). This computation has a lower cost in time, which makes it more suitable for clinical practice. A Strehl ratio of 1 is related to a perfect optical system that is only limited by diffraction. The ratio is commonly used to assess the performance of any adaptive optical correction system. The Strehl ratio has become a popular way to summarize the performance of an optical design because it gives the performance of a real system, of finite cost and complexity, relative to a theoretically perfect system, which would be infinitely expensive and complex to build and would still have a finite point spread function. It provides a simple method to decide whether a system with a Strehl ratio of, for example, 0.95 is good enough, or whether twice as much should be spent to try to get a Strehl ratio of perhaps 0.97 or 0.98.

The three OV_s are normalized values of three spatial frequencies, which correspond to MTF values that describe the optical quality of the eye for three contrast conditions, commonly used in ophthalmic practice^[15]: 100% (OV 100%), 20% (OV 20%), and 9% (OV 9%). These values can be used to obtain more specific information on the performance of the eye's optics at different contrasts, which may remain hidden when more global parameters that integrate the information along all available spatial frequencies are considered, such as the Strehl ratio. Specifically, OV 100% is directly related to the MTF cutoff frequency (it is the MTF cutoff frequency divided by 30 c/deg) and, therefore, to the patient's visual acuity, although it is not affected by retinal and neural

factors. OV 20% and OV 9% are computed in the same way from smaller frequencies that are linked to 0.05 and 0.1 MTF values, respectively, which maintain the proportion of contrasts of 20% and 9%. Therefore, they inform us about the shape of the MTF profile at lower frequencies than the MTF cutoff frequency. In addition, these two additional frequencies have been normalized so that the values obtained are comparable to standard decimal visual acuity values^[15]. Values higher than 1.00 are associated with high optical quality.

The system also quantifies intraocular scattered light from the double-pass image by means of the OSI parameter [18]. OSI is computed as the ratio of the amount of light within an annular area of 12 and 20min arc and that recorded within 1min arc of the central peak. Values of OSI below 1 are usually linked to eyes with low scattering^[17].

Postoperative examinations Postoperative examinations were performed at 3mo and included UDVA, CDVA, subjective refractions, slitlamp evaluation, and an objective measurement of optical quality (optical quality analysis system OQAS II®). The postoperative orientation of the toric IOL axis was determined by slitlamp retro-illumination after pupillary dilation.

For the analysis of postoperative outcomes, patients were subdivided into groups according to the IOL model implanted as follows: T3 group (SN60T3); T4 group (SN60T4); T5 group (SN60T5); T6 group (SN60T6). UDVA and CDVA were converted into logMAR values for the mathematic and statistical calculations.

Statistical Analysis All data were collected in an Excel database (Microsoft Office 2003, Microsoft Corp.). Data analysis was performed using SPSS for Windows (version 13.0, SPSS Inc.). Normality of all data samples was first checked using the Kolmogorov-Smirnov test. When parametric analysis was possible, the Student's *t*-test for paired data was performed for all parameter comparisons. When parametric analysis was not possible, the Wilcoxon rank-sum test was applied to assess the significant of differences, using in all cases the same level of significance (*P*<0.05).

RESULTS

The study evaluated 52 eyes of 44 patients with a mean age of 74.36±7.55y (SD) (range 49 to 84y). Table 1 showed the patient's demographics and preoperative data.

Visual Acuity and Residual Refractive Cylinder Table 2 showed the postoperative UDVA, CDVA and residual refractive cylinder. In all eyes, 94% of eyes achieved a UDVA of 20/40 (logMAR 0.3) or better. There was no statistically significant improvement in UDVA and CDVA according to the cylinder power of the implantation (*P*=0.17, Wilcoxon test and *P*=0.15, Student's *t*-test, respectively). While, there was a statistically significant improvement in residual refractive cylinder (*P*<0.01, Wilcoxon test).

Table 1 Patient demographics and preoperative data

Parameters	All eyes	IOL group			
		T3	T4	T5	T6
Eyes (n)	52	19	18	10	5
Mean age (a)	74.36±7.55	73.71±6.26	72.39±9.11	79.44±5.55	75.60±3.64
Preoperative astigmatism (D)	1.63±0.49	1.15±0.15	1.62±0.18	2.12±0.11	2.53±0.17
Mean IOL sphere (D)	20.43±2.73	21.29±2.85	19.72±2.02	20.90±3.20	18.80±2.91
Mean IOL cylinder (D)	2.26±0.74	1.5	2.25	3.0	3.75

IOL: Intraocular lens.

Table 2 Visual acuity and residual refractive cylinder

Parameters	All eyes	Intraocular lens groups				P
		T3	T4	T5	T6	
logMAR UDVA	0.18±0.11	0.15±0.11	0.18±0.10	0.22±0.10	0.26±0.10	¹ 0.17
logMAR CDVA	0.07±0.08	0.05±0.07	0.06±0.09	0.10±0.08	0.10±0.07	² 0.15
Residual refractive cylinder (D)	0.50±0.29	0.34±0.28	0.47±0.24	0.57±0.19	0.90±0.29	< ¹ 0.01

UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity. ¹Wilcoxon test; ²Students *t*-test.

Table 3 Optical quality parameters

Parameters	All eyes	Intraocular lens group				P ¹
		T3	T4	T5	T6	
OSI	1.80±0.84	1.70±0.95	1.62±0.78	1.73±0.74	1.98±1.01	0.13
MTFcutoff	22.862±5.584	23.981±6.289	23.957±5.372	20.419±4.218	19.549±4.112	0.18
Strehl ratio	0.155±0.038	0.155±0.040	0.167±0.034	0.144±0.037	0.133±0.042	0.35
OV 100%	0.76±0.18	0.80±0.21	0.80±0.18	0.68±0.14	0.65±0.14	0.20
OV 20%	0.77±0.19	0.79±0.21	0.81±0.17	0.70±0.19	0.65±0.18	0.26
OV 9%	0.78±0.21	0.80±0.23	0.82±0.16	0.73±0.25	0.66±0.22	0.30

OSI: Objective scattering index; MTF: Cutoff frequency of modulation transfer function; OV: Optical quality analysis system value.
¹Wilcoxon test.

Rotational Stability The mean toric IOL axis rotation was 3.62 ± 1.76 degrees in all eyes; 3.52 ± 2.01 degrees in the T3 group; 3.55 ± 1.69 degrees in the T4 group; 3.70 ± 1.33 degrees in the T5 group; 3.60 ± 2.19 degrees in the T6 group. No required a second surgery to align the toric IOL axis during the 3mo follow-up period. No eye had IOL rotation >10 degrees. There was no statistically significant change in the mean toric IOL axis rotation between groups ($P=0.94$, Wilcoxon test).

Optical Quality Parameters Table 3 showed the postoperative optical quality parameters, including OSI, MTFcutoff, Strehl ratio, OV 100%, OV 20%, OV 9%. There was no statistically significant changes in the OSI, MTFcutoff, Strehl ratio, OV 100%, OV 20% and OV 9%, between groups ($P=0.13$, $P=0.18$, $P=0.35$, $P=0.20$, $P=0.26$ and $P=0.30$, Wilcoxon test, respectively).

DISCUSSION

The advent of toric IOL technology has given surgeons a safe, predictable way to manage patients with preexisting corneal astigmatism. Surgeons are routinely using toric IOLs as a treatment option for cataract patients with corneal astigmatism [10]. In clinical trials and practice, the AcrySof toric IOL has had excellent predictability and rotational stability, and high patient-satisfaction ratings[21].

AcrySof toric IOLs have been used in many studies to correct

low to moderate corneal astigmatism during cataract surgery. In a recent randomized controlled study of 256 eyes with a toric IOL by Holland *et al*[10], the UDVA was 20/40 or better in 92% of eyes and 20/30 or better in 79% of eyes. Approximately 90% of eyes had a residual refractive cylinder of 1.00 D or less. Smaller cohort studies report similar results as well, with a UDVA of 20/40 or better in 91% to 95% of cases and postoperative residual refractive cylinders ranging from 0.5 to 0.7 D [5,9]. In our study, the UDVA was 20/40 or better in 94% of eyes, which is comparable to the results in previous studies.

AcrySof IOL is made of an acrylic material that has been shown to form adhesions with the capsule, leading to rotational stability of the IOL in the capsular bag within approximately 2wk[22]. In addition, the AcrySof toric IOL has open-loop haptics, which is considered to make the IOL more stable than plate-haptic IOLs in the first 2wk after surgery[23]. If the toric IOL is misaligned from its intended axis, the cylinder correction is less effective and there is residual astigmatism [24]. Every degree of misalignment leads to approximately 3.5% of the preoperative astigmatism magnitude remaining, which means the more cylinder power addition on the IOL, the more residual astigmatism produced by axis orientation [25]. For example, in our study the mean axis rotation was 3.52 ± 2.01 degrees in the T3 group;

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3.55±1.69 degrees in the T4 group; 3.70±1.33 degrees in the T5 group; 3.60 ±2.19 degrees in the T6 group, which corresponds to a remaining astigmatism magnitude of approximately 12% of the preoperative magnitude in the T3 group; approximately 12% in the T4 group; approximately 13% in the T5 group and approximately 13% in the T6 group, respectively. In the case of a T3 toric IOL with a cylinder of 1.03 D at the corneal plane, this axis rotation would result in a remaining astigmatism magnitude of approximately 0.12 D, while the axis rotation would result in a remaining astigmatism magnitude of approximately 0.19 D in the T4 group, 0.27 D in the T5 group and 0.33 D in the T6 group, respectively. As a result, in our study, there was a statistically significant improvement in residual refractive cylinder according to the cylinder power of the implantation ($P < 0.01$, Wilcoxon test), since there was no statistically significant change in the mean axis rotation. ($P = 0.94$, Wilcoxon test).

Previous studies of AcrySof toric IOLs reported mean misalignments less than 4 degrees [9,10]. The mean misalignment in our study was 3.62±1.76 degrees and there was no statistically significant change in the mean absolute misalignment according to the cylinder power of the implantation ($P=0.94$, Wilcoxon test). In our study, we use the method of slitlamp retro-illumination after pupillary dilation to measure the postoperative orientation of the toric IOL axis, rather than using a specially designed grid and software to assess the postoperative rotation [26]. We believe that the relative accuracy of the conventional method of evaluating postoperative IOL orientation through a dilated slitlamp examination is subjected to the observer's experience and bias and has inherent precision limits.

In this study, we evaluated the results of toric IOL implantation in patients with optical quality analysis system. We believe this is the first study using optical quality analysis system to analyze the optical quality after implantation of AcrySof toric IOL. A previous study [27] evaluated the outcomes with optical quality analysis system after implantation of Lentis L313T toric IOL in 13 eyes with a mean preexisting corneal astigmatism of -1.85±0.72 D. One hundred percent of eyes achieved a UDVA of 20/40 or better. The mean residual refractive cylinder was -0.66±0.56 D. The mean misalignment was 4.40 ±3.69 degrees. The mean postoperative MTFcutoff and OSI was 27.28 ±8.45 and 1.76±0.64. Our postoperative results in our study are comparable. Besides, the study includes more eyes and compares the values of MTFcutoff, OSI, Strehl ratio, OV 100%, OV 20% and OV 9% depending on the power of the cylinder of the implantation, which were not significantly different.

Vilaseca *et al* [16] accessed the *in vitro* optical quality of AcrySof SA60AT before and after implantation in an artificial eye with a double-pass system (OQAS). They found

that the mean MTFcutoff, Strehl ratio, OV 100%, OV 20% and OV 9% after implantation of this toric IOL were 59.29±0.18, 0.336±0.001, 1.96±0.02, 2.60±0.07 and 3.70±0.11. By contrast, it seemed a little bit worse optical quality after toric IOL implantation in our study. However, that study was accessed *in vitro* in an artificial eye which consisted of an optical achromatic doublet lens, an artificial cornea, an IOL support and a mobile artificial retina. The mobile retina allowed the correction of small mismatches of the IOL position in the artificial eye, obtaining the best retinal image quality. Furthermore, optical quality parameters measured *in vivo* were affected by tear film, anterior and posterior corneal surface aberrations, vitreous opacity and other related retinal retrogradation [28-30]. And that, when an IOL is implanted, the quality of the retinal image could be degraded because of a defocus due to induced astigmatism, and further, because of a diffraction phenomenon at the pupil margin, light scattering, and corneal and intraocular lens aberrations [31]. The MTF showed a systematic decline in optical performance with age because of an increase in optical aberrations and intraocular scattering that caused a deterioration of retinal image with age [13]. This might be the reason that worse optical quality were recorded since most subjects were more than 60 years old in our study. Moreover, several sources of possible errors in the procedure could have contributed to an worse optical quality: uncorrected amounts of defocus and astigmatism, errors in pupil centering, abnormal eyes movements during double-pass image recording, or small changes in accommodation that occur even in the presence of cycloplegia.

However, the current study does have some limitations. First, artificial tears were not instilled before each double-pass measurement because it has been suggested that retinal image quality is influenced by tear-film quality [32]. After artificial tear were instilled, the increasingly regular tear film decreased higher-order aberrations, improving optical quality [33]. In our study, subjects were asked to rest and blink before each measurement, we thought this would minimize the impact of tear-film on optical quality. Second, we only analyze the optical quality after implantation of toric IOLs of correcting mild to moderate corneal astigmatism, not including high corneal astigmatism. Perhaps, in the ensuing study, we could involve much more patients and take them into consideration.

In conclusion, we found that double-pass technique was useful for characterizing the optical quality of AcrySof toric IOL implantation. Our results indicate that implantation of an AcrySof toric IOL is an effective and safe method to correct corneal astigmatism during cataract surgery.

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