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Rotational stability of AcrySof toric intraocular lens: high-precision method for lens axis control

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通过检测人工晶状体轴位评价 AcrySof 散光型人工晶状体的稳定性

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摘要

目的:通过一种高精度方法评价 AcrySof 散光型人工晶体的旋转稳定性。

方法:收录 90 例年龄相关性白内障伴中、高度散光患者(104 眼),施行白内障超声乳化联合 AcrySof 散光型人工晶体植入术。患者在规定的复查时间接受必要的检查。通过 KR-1W 视觉质量分析仪检测 AcrySof 散光型人工晶体的稳定性。观察指标包括裸眼远视力(UDVA)、最佳矫正远视力(CDVA)以及显然验光结果。通过配对 T 检验及 ANOVA 检验分析结果。

结果:研究共纳入 104 眼,从术前检查至最后一次术后复查持续 24 个月。7 次复查时间点观察到 AcrySof 散光型人工晶体的位置没有显著变化,$P=0.863$;所有患者的裸眼远视力(logMAR,4.39±0.27 至 4.77±0.22;$P<0.001$)、最佳矫正远视力(logMAR, 4.54±0.25 至 4.93±0.14;$P<0.001$)以及显然验光[度(D), -1.27±0.98 至-0.97±0.71, $P=0.003$]均有显著改善。术后调制传递函数(MTF)较术前提高。

结论:研究显示 AcrySof 散光型人工晶体具有很好的旋转稳定性。该种人工晶体可以减少显然验光的柱镜度数、提高视力并改善视力相关的生活质量。

关键词:白内障;散光;人工晶体植入;眼内;屈光不正

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Abstract

• AIM: To evaluate the rotational stability of AcrySof toric intraocular lens (IOL) after cataract surgery, by an high-precision method.

• METHODS: A total of 104 eyes of 90 patients with age related cataract and moderate to high regular astigmatism underwent phacoemulsification and implantation of AcrySof toric IOL (SN6AT series; Alcon, Fort Worth, TX, USA). Patients underwent comprehensive examinations at standard intervals. The rotational stability of AcrySof toric intraocular lens was evaluated using visual quality analyser KR-1W (Topcon, Tokyo, Japan). Uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA) and manifest refraction were also recorded. The outcomes were analysed by paired - samples T test and ANOVA Test.

• RESULTS: From preoperatively to the last visit (24mo), 104 eyes were included in the clinical trial. The AcrySof toric IOL axis orientation (at seven visits) did not show significant change, $P = 0.863$. All of the eyes had significant improvement in UDVA (logMAR, 4.39±0.27 to 4.77±0.22; $P<0.001$), CDVA (logMAR, 4.54±0.25 to 4.93±0.14; $P < 0.001$) and manifest refraction astigmatism [diopters (D), -1.27±0.98 to -0.97±0.71, $P=0.003$]. There was an increase in MTF results between preoperative and postoperative evaluations.

• CONCLUSION: The AcrySof toric IOL shows good rotational stability. It can reduce manifest refraction cylinder and improve visual acuity and vision - related quality of life permanently.

• KEYWORDS: cataract; astigmatism; lens implantation; intraocular; refractive errors

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INTRODUCTION

Cataract surgery has dramatically improved patients' visual acuity and vision - related quality of life[1-2]. However, corneal astigmatism is a key factor associated with good visual outcomes. It has been estimated that 30% of cataract patients have more than 0. 75 diopters (D) of corneal astigmatism, that 22% have more than 1. 50 D, and that 8% have more than 2. 00 D[3-4]. Data from China shows that 67. 7% of 60-90y old people have 0. 25-1. 25 D corneal astigmatism; and that 27. 5% have more than 1. 25 D[5]. Since post-surgical residual astigmatism can compromise uncorrected distance visual acuity (UDVA), correction of corneal astigmatism is a critical element of modern cataract surgery. Corneal astigmatism can be surgically treated with adjustment of wound size and location, peripheral corneal relaxing incisions, additional clear corneal cataract incision along the steep meridian, laser refractive surgery[6]. All these methods have limitations including the degree of astigmatism that can be treated and long-term mechanical instability. Postoperative outcomes are subject to many variables such as age; magnitude; and incision number, depth, and length[7]. Toric intraocular len (IOL) implantation is another valuable option for astigmatism correction. Previous researches indicate that phacoemulsification and AcrySof toric IOL (SN6AT series; Alcon, Fort Worth, TX, USA) implantation is an effective, predictable and safe option to correct pre-existing astigmatism in cataract surgery[7-11]. Shift of controlling axis could impair visual acuity significantly. Postoperatively, IOL misalignment from its intended position can be assessed using a slit-lamp with a rotating slit and rotational gauge. This method requires sufficient mydriasis to see the marks on the IOL optic. An obvious limitation in accuracy is the 10-degree steps on the slit-lamp's measuring reticule[6]. In our research, we used visual quality analyser KR-1W (Topcon, Tokyo, Japan), to measure the axis of AcrySof toric IOL in capsule. In our present study, we use KR-1W visual quality analyzer to measure ocular astigmatism and internal astigmatism. KR-1W visual quality analyzer use Hartmann-Shack principle, which could get computer optometry, wave front aberration and corneal topography data at the same time. It is much preciser than visual quality analyzer which based on Ray Trace principle. We got very precise data of the IOL position and analysed the change of the axis to evaluate the rotation stability. We also analysed the visual quality of the patients who received AcrySof toric IOL implantation.

SUBJECTS AND METHODS

This prospective observational study included 104 eyes of 90 consecutive patients with cataract and preexisting regular corneal astigmatism greater than 1.00 D who had implantation of the AcrySof toric IOL at the People's Liberation Army General Hospital, China, between Jan. 2012 and Apr. 2013. The tenets of the Declaration of Helsinki were followed in the research.

Informed consent was obtained from all patients. Institutional Review Board approval was obtained. Inclusion criteria included cataract, age between 50 and 75y, and preoperative regular corneal astigmatism greater than 1.00 D. Exclusion criteria included preoperative astigmatism greater than 5.00 D, history of glaucoma or retinal detachment, corneal disease, previous corneal or intraocular surgery, abnormal iris, pupil deformation, macular degeneration or retinopathy, neuroophthalmic diseases, and history of ocular inflammation.

Before cataract surgery, patients had a complete ophthalmologic examination including slitlamp examination, ophthalmoscopy through dilated pupils, manifest and cycloplegic refractions, applanation tonometry and keratometry. Axial length and keratometry were measured with the Zeiss Humphrey IOL Master (Carl Zeiss Meditec AG, Germany). Calculation of IOL power and axis placement to achieve emmetropia was performed using a program available from the IOL manufacturer (www.acrysoftoriccalculator.com). Preoperative keratometry and biometry data, incision location, and the surgeon's estimated surgically induced corneal astigmatism were used to determine the appropriate AcrySof toric IOL model, spherical equivalent (SE) lens power, and axis of placement in the eye. The SRK/T formula was used for spherical IOL power calculation in most patients. If axial length was over 28 mm, Haigis formula was used. If axial length was less than 22 mm, Hoffer Q formula was used for spherical IOL power calculation. The targeted refraction was emmetropia. All surgery was performed by the same experienced surgeon (Z. L.) using topical anesthesia. With the patient seated at the slitlamp, the corneal limbus was marked at the 0-degree and 180-degree positions with a sterile string needle and after vertical alignment of the patient's head. Next, with the patient lying on the surgical table, the steep corneal meridian was identified and marked using a sterile marker with the aid of the pre-placed reference points. Phacoemulsification was performed through a 2.4 mm temporal corneal incision. In all cases, the target capsulorhexis diameter was 5.50 mm to 6 mm, this to ensure overlap of the IOL border. After phacoemulsification, a foldable AcrySof toric IOL was inserted in the capsular bag using the Monarch Ⅱ injector (Alcon Laboratories Inc., USA). The IOL was rotated to align the cylinder axis with the marked steep corneal meridian. No sutures were used to seal the wound. The AcrySof toric IOL is an open-loop, modified single piece, acrylic polymer IOL with L-shaped haptics. In our research, selection of the adequate toric IOL is made using Acrysof toric calculator (www.acrysoftoriccalculator.com) which works on the basis of preoperative corneal astigmatism for the power and axis parameters. This program could consider a combination of relaxing incisions and toric IOL implantation depending on the astigmatism degree and power availability of the toric IOL. The IOL is available in 5 models: SN6AT2, SN6AT3, SN6AT4, SN6AT5, SN6AT6. After the operations, tobramycin and dexamethasone drop were used 4 times per day for 1wk and then 3 times per day for a second week. IOL axis, UDVA, corrected distance visual acuity (CDVA), refraction and keratometry were recorded. Intraocular lens rotation was measured by visual quality analyser KR-1W (Topcon, Tokyo, Japan). Postoperative assessments were performed at 1d, 1mo, 3mo, 6mo, 12mo, 1.5y and 2y intervals. All examinations were performed by the same ophthalmic technician. Data analysis was performed using SPSS (version 19.0 SPSS Inc., USA). The paired-samples T test and ANOVA Test were used to compare IOL axis position and refractive outcomes. Differences were considered statistically significant when the P value was less than 0.05.

RESULTS

One hundred and four eyes of 90 consecutive patients were enrolled in this study. Table 1 shows the patients' demographics. The mean age was 67.4±10.7y (SD) (range 50 to 75y). The mean preoperative cylinder was −2.51±1.27 D (range −1.00 to −3.50).

Visual Outcomes Table 2 shows the mean preoperative and postoperative UDVA and CDVA. Two years postoperatively, the mean UDVA (logMAR) was 4.76±0.22. The CDVA (logMAR) improved slightly to 0.39±0.23 (approximately 20/20). Figure 1 summarizes the last visit UDVA and CDVA values. A total of 61.8% had UDVA≥20/30, and 97.1% had CDVA≥20/30. There was an increase in MTF results between preoperative and postoperative evaluations. Figure 2 shows modulation transfer function curve at preoperative and postoperative. Figure 2 shows the mean MTF at 5, 10, 15, 20, 25, and 30 c/pd. There was an obvious increase in the MTF between preoperation and postoperation values at any spatial frequency with 3.0 mm pupils (5, 10, 15, 20, 25, and 30 cpd; P=0.000, P=0.000, P=0.000, P=0.000, P=0.002, and P=0.003, respectively) and 5.0 mm pupils (P=0.000, P=0.000, P=0.000, P=0.000, P=0.004, and P=0.002, respectively).

Rotational Stability One-way ANOVA was used to analyze change in axial lens position after AcrySof toric IOL implantation. F=0.019, P=1.000. Figure 3 shows change in IOL axel position after implantation. We analysed the differences between groups and found that most IOL rotation occurred in the first month. Figure 4 shows that for 2.9% of the eyes, 20 rotation occurred after a period of 2y, with 1.9% occurring in the first month. None of the eyes had secondary surgery to reposition the IOL axis within the 2y postoperative period. The mean toric IOL axis rotation was 4.12±4.35 degrees (range 0 to 36 degrees). Seven eyes (6.7%) had significant IOL rotation (≥10 degrees), the rest of the eyes (93.3%) had rotation less than 10 degrees (Figure 5).

DISCUSSION

Corneal astigmatism can be surgically managed using corneal, relaxing, or limbal incisions and excimer laser keratectomy. Limitations, advantages, and disadvantages have been fully discussed in the literature[12]. The use of toric IOLs to correct corneal astigmatism is one surgical option. The major requirement for a toric IOL is rotational stability. Several researches measure the IOL axis as described by Javier Mendicute *et al*[7]. Intraocular lens rotation is measured at the slitlamp in 1-degree steps using an eyepiece for angle measurement through pupils dilated with tropicamide. A thin coaxial slit is projected in front of the eye and rotated until the thin slit projection overlapped the axis marks of the IOL. Results from this method could be influenced by several factors, such as the skill of investigator and the position of patient's head and eyes. In addition to this, the degree scale of slitlamps are not accurate and this also leads to inaccurate data. All these factors influence the consistency of results. In our research, we measured IOL axis shift by visual quality analyser KR-1W. Precise data was used to report the efficacy and rotational stability of this toric IOL. KR-1W by measuring IOL axis directly. This avoided the inaccuracies of manual measurement. The data from this method was more precise and more consistent.

Table 1　Patients' demographics

Characteristic	Value
Patients (n)	90
Mean age (a) ± SD	67.4±10.7
range(y)	50 to 75
Sex (M/F)	26/64
Eyes (n)	104
OD/OS	49/55
Preoperative cylinder (D)	
Mean±SD	−2.51±1.27D
Range	−1.00 to −3.50D
Mean preoperative keratometry (D) ±SD	
K1	43.19±1.57
K2	45.57±1.79
Spherical IOL power (D)	
Mean±SD	20.63±2.35
Range	16.00 to 24.50

OD: right eye; OS: left eye; IOL: intraocular lens.

Figure 1　Cumulative UDVA and CDVA.

Follow up extended to 2y after IOL implantation in the first eye. The mean toric IOL axis rotation was 4.12±4.35 degrees (range 0 to 36 degrees). This is consistent with the results of other researches[13-15]. Weinand *et al*[16] researched rotational stability of intraocular lens by a digital fundus camera, which was also reported as an high-precision rotation control. In their report, the median IOL rotation was 0.7 degree (range 0.1 to 1.8 degrees), which is less than ours. However, they included only 17 eyes.

It was identified that all three patients, who had significant IOL rotation (>20 degrees), had suffered trauma of head or face. Two of them were struck by an infant. This is an interesting phenomenon, as in China it is common for older people to take care of their grandchildren. They spend a lot of time taking care of their grandchildren, hence several accidents and severe cases occurred because of the grandchildren

Table 2　Visual acuity before and 2y after AcrySof toric IOL implantation (Mean±SD)

Parameter	Preoperative	Postoperative	Differences	*P*
UDVA (logMAR)	4.38±0.27	4.76±0.22	0.38±0.26	<0.001
CDVA (logMAR)	4.54±0.25	4.92±0.13	0.39±0.23	<0.001

UDVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity.

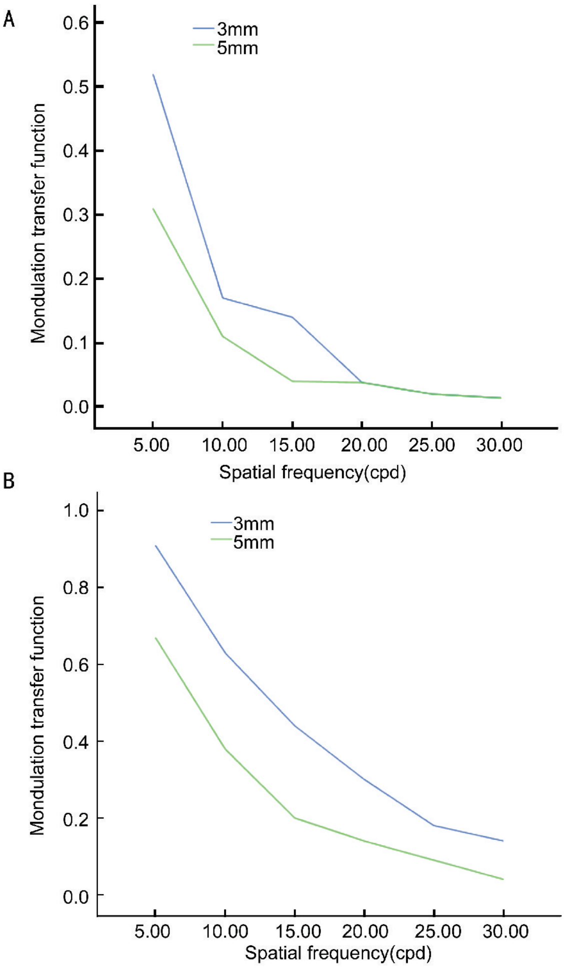

Figure 2　The modulation transfer function curve at preoperative and postoperative visits　There was an increase in MTF results between preoperative and postoperative evaluations. A is the MTF curve before cataract operation; B is the curve after cataract operation. The MTF results increase no matter in 3mm pupil or 5mm pupil, which suggested the improvement of visual quality.

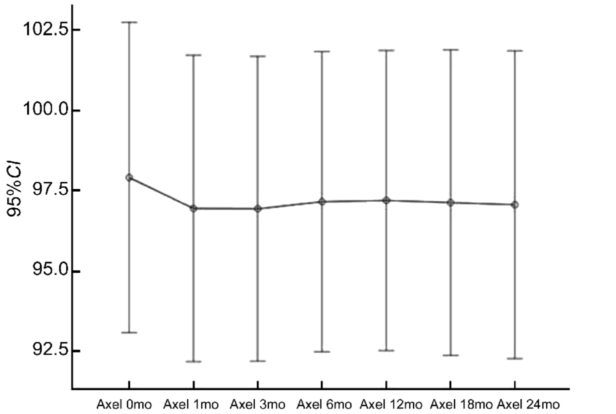

Figure 3　Mean postoperative IOL axel position　IOL rotation was 4.12±4.35 degree 2y after implantation. Error bars indicate 1 standard deviation (SD). Axel = Mean postoperative AcrySof toric IOL axel position.

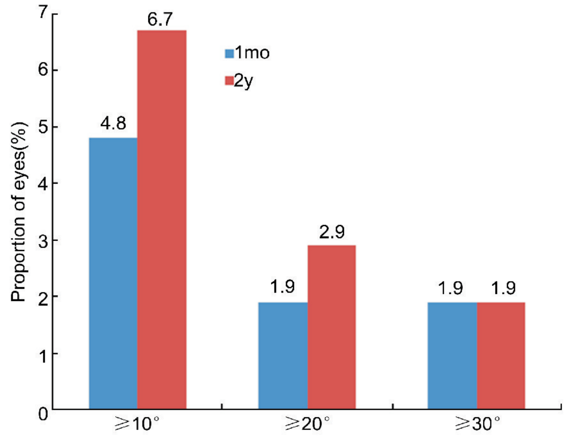

Figure 4　Cumulative IOL rotation degree.

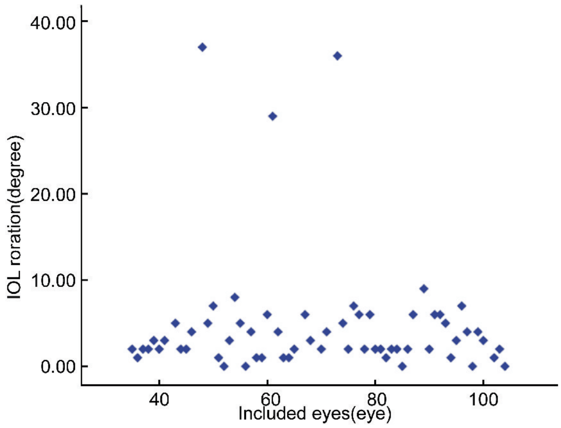

Figure 5　Toric IOL axis shift 2y after surgery. Scattergram of toric IOL axis shift in each eye.

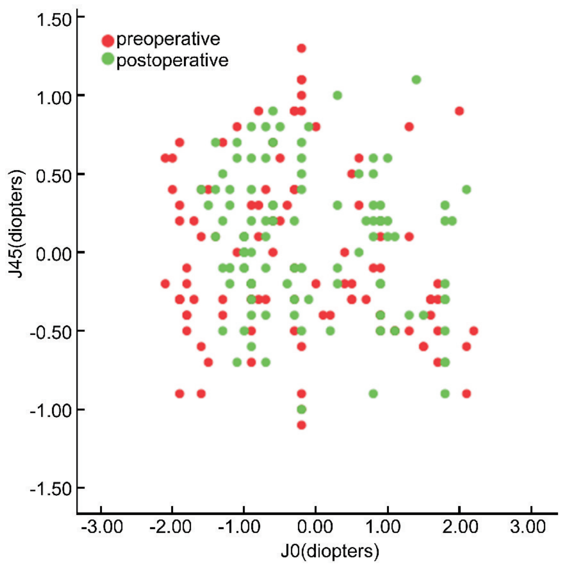

Figure 6　Vector analysis of keratometric data. Keratometric changes were minimal before and after operation; thus, the reduction in astigmatism was the result of toric IOL implantation.

were uncontrollably active and subconsciously caused the traumas which could lead to luxation of lens and retinal detachment. All of the three patients examined had subluxation of lens. There were 12.7% of the patients, who had IOL rotation more than 10 degrees. This finding was above expectations, however it is felt that, now identified, it might relate to traditional Chinese culture and this phenomenon will reoccur repeatedly in future. Additionally, the number of patients who need cataract surgery is very large and therefore it is necessary for Chinese Ophthalmology surgeon to warn the population of the potential of this kind of accident.

There is a high variability in IOL rotation as a function of the toric IOL model and haptic design. C-loop or plate haptics are prone to rotate from the intended axis postoperatively[17-19]. While Z-design haptics have good stability[15]. With improvement of material and facture technique, rotation stability of IOL has been better and better. We used AcrySof toric IOL in this research. It is an open-loop, modified singlepiece, acrylic polymer IOL with L-shaped haptics. Our data showed this IOL had low rate of postoperative rotation (5.77% ≥10°). The axis rotation was 4.12±4.35 degree, which was slightly higher than Javier Mendicute *et al*[7] reported. However, this included three patients who suffered trauma to the head or face. Modified mean axis rotation, the axis rotation was 3.73±2.77 degree. Our results suggested that the modified L-shaped haptic design of the AcrySof toric IOL showed satisfactory rotation stability. Trauma, severe coughing or some other movements could lead to IOL rotation. Thus, surgeons should inform the patients to avoid these factors. It has been reported that rotation of toric IOLs depends on the implantation axis[20]. However, in our study, we did not find statistically significant correlation between intraoperative axis alignment and postoperative rotation. Figure 4 showed that most rotation happened in the first month after IOL implantation. During this period, the attachment between the IOL and the capsular bag was not very tight. Once the anterior and posterior capsules fuse, IOL rotation is less frequent. To reduce IOL rotation in early stage, viscoelastic need to be washed away completely, with our experience, stick a dual irrigation-aspiration probe under IOL then irrigate and aspirate carefully, after all, press IOL gently next to posterior subcapsular. Also to reduce astigmatism, a minimal incision on corneal should be carefully designed, we analysed the confounding variables according to it. Figure 6 assess whether surgically induced corneal refractive change plays a role in surgically induced refractive change. The figure shows that keratometric astigmatism was distributed randomly before and after IOL implantation without significant differences (P>0.1).

In our study, 94.2% of patients achieved 20/40 or better UDVA. In a study by Sun *et al*[21], 98.4% of eyes achieved 20/40 or better UCVA after Staar TF IOL implantation. Ruhswurm *et al*[20] reported a lower percentage (67.6%) using the same IOL. Till *et al*[13] reported that 66% of patients had an UCVA of 20/40 or better after Staar TF or TL IOL implantation. Eyes in our study had a 61% reduction in astigmatism after toric IOL implantation (mean preoperative corneal astigmatism -2.38±1.36D). This is consistent with reported results[14,21]. Differences between IOL models and preoperative astigmatism values are responsible for the variability in the percentage of astigmatism reduction and visual acuity outcomes between toric IOLs[7].

Data from KR-1W were high precise. The results in our study show that implantation of the AcrySof toric IOL is an effective surgical option to correct preexisting corneal astigmatism during cataract surgery. In addition to this, apart from regular postoperation care, we also remind patient to be extra precautious in avoiding ocular trauma caused by their grandchildren in the daily activities.

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