Clinical Research

Comparative evaluation of rotational stability of toric IOLs with four-eyelet *vs* two-eyelet capsular tension rings in eyes with high myopia

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Received: 2020-03-05 Accepted: 2020-06-16

Abstract

• **AIM:** To compare the rotational stability of Toric intraocular lens (IOLs) implantation combined with foureyelet or two-eyelet capsular tension rings (CTRs) in eyes with high myopia and cataract.

• **METHODS:** This prospective randomized controlled interventional study included 33 eyes which had preoperative corneal astigmatism \geq 1.5 D and ocular axial length \geq 25.5 mm. These eyes were randomly divided into two groups to undergo phacoemulsification and toric IOL implantation with either four-eyelet CTR implantation (group A, *n*=16) or two-eyelet CTR implantation (group B, *n*=17). Uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), phoropter examination results, and toric IOL rotation degrees were tested 6mo after the surgery.

• **RESULTS:** In both groups, the toric IOL was in the capsular sac 6mo after surgery. The difference between the two groups in terms of visual outcome was not found to be statistically significant (P>0.05) at a follow-up of 6mo. The mean residual astigmatism values were 0.56±0.22 D and 0.92±0.24 D in A and B groups, respectively (P<0.001). The mean rotation degree of IOL was 1.00°±0.73° in group A and 3.53°±1.46° in group B (P<0.001).

• **CONCLUSION:** In cataract patients with high myopia and astigmatism, four-eyelet CTR can effectively increase the rotation stability of toric IOLs, achieving the desired goal of correcting corneal astigmatism.

• **KEYWORDS:** capsular tension ring; toric intraocular lens; cataract; axial myopic astigmatism

DOI:10.18240/ijo.2021.03.07

Citation: Jiang HM, Liang K, Tao LM. Comparative evaluation of rotational stability of toric IOLs with four-eyelet *vs* two-eyelet capsular tension rings in eyes with high myopia. *Int J Ophthalmol* 2021;14(3):378-382

INTRODUCTION

• oric intraocular lens (IOLs) have become immensely popular for patients with astigmatism in cataract surgery. However, postoperative rotation of the toric IOL has become a significant problem in the endeavour to achieve the desired cylindrical correction^[1]. It has been found that every degree of rotation of a toric IOL decreases the cylindrical correction by 3.3%^[2]. Lately, capsular tension rings (CTRs) have been widely used for stable implantations of toric IOLs, especially for hyper myopic patients whose capsule is lax and where the toric IOL could easily rotate^[3]. Implanting a CTR can not only keep the shape of the capsule but also prevents the rotation of the IOL, thus effectively correcting the astigmatism and improving postoperative visual acuity. Previous studies have reported the co-implantation of a two-eyelet CTR with a toric IOL, which is now the main approach used, with positive results. However, the toric IOLs had various degrees of rotation postoperatively. It was reported that the largest rotation degree reached 5 degrees 6mo after the surgery^[4], which may influence visual acuity. We therefore introduce the usage of four-eyelet CTRs, which increase the stability of the toric IOL and decrease the rotation angle. The purposes of this study are to assess whether the four-eyelet CTR provides better rotational stability of the toric IOL and to evaluate any influence on the visual and refractive outcomes.

SUBJECTS AND METHODS

Ethical Approval This prospective randomized controlled study was conducted at a tertiary hospital from June 2019 to December 2019 and completed six months of follow-up. The study was reviewed and approved by the institute's ethics committee, and an informed consent was obtained from all the patients enrolled. The trial registration number is ChiCTR2000029963.

Patients Totally of 33 eyes with visually significant cataracts, regular corneal astigmatism ≥ 1.5 D and axial length ≥ 25.5 mm

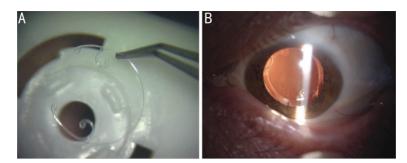


Figure 1 Example of images showing the four-eyelet CTR (A) and after implanting of four-eyelet CTR and toric IOL (B).

were enrolled in this research. These eyes were randomly divided into groups A and B. Both groups underwent standard phacoemulsification surgery by the same surgeon. In group A, a four-eyelet CTR was implanted along with a toric IOL. In Group B, a two-eyelet CTR was implanted along with a toric IOL. The exclusion criteria included any corneal pathology, subluxated lenses, uveitis, posterior segment pathology (*e.g.*, macular degeneration or retinopathy), glaucoma, a specular microscopy endothelial count <2000 cells/mm² and prior corneal or ocular surgery.

Preoperative Assessment and Preparation A complete ophthalmologic examination was done before the surgery, which included a detailed history regarding previous ocular and systemic complaints, uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA), the refractive cylinder, corneal astigmatism, the corneal topography, anterior chamber depth (ACD), the intraocular pressure (IOP), the specular endothelial cell count and B-ultrasounds. UCVA and BCVA were measured using a standard logarithmic eye chart. The Haigis formula was used to calculate the spherical equivalent of the toric IOL. The desired IOL degree and axis of placement were determined using an online calculator (www.acrysoftoriccalculator.com) provided by Alcon. The postoperative refractive status was set at -3 to -1 D of myopia to nearly clear vision. These settings were fully accepted by the patients after explanations were provided to them prior to the surgery. The toric IOL target axis and the incision site were preoperatively marked using a marking pen on a slip lamp with the patient in an upright position.

Material The Acrysof SN6ATX IQ toric IOL (Alcon Laboratories, Fort Worth, Texas, USA) is a one-piece, hydrophobic acrylic, aspheric, biconvex, clear optic IOL. Different models of toric IOL from SN6AT3 to SN6AT7 were used according to result of the online calculator. The four-eyelet CTR (size: 12.00×11.00 mm²; CROMA GmbH Company, Canada) and the two-eyelet CTR (size: 12.00×11.00 mm²; OPTHEC BV Company, The Netherland) were made with polymethylmethacrylate (PMMA) material.

Surgical Technique All surgeries were performed by a single surgeon under topical anaesthesia (proparacaine

eye drops). Based on the preoperative localisation of the incision, the surgeon used a 3.0 mm stab knife to make a clear corneal incision from the corneal limbus and a 15° stab knife auxiliary incision at the 2 o'clock position and then inserted a viscoelastic material into the anterior chamber. A continuous circular capsulorhexis (CCC), measuring approximately 5.0-5.5 mm in diameter, was generated to ultrasonically emulsify the lenticular nucleus. Then, the I/A system was conducted to absorb the residual cortex. Thereafter, for group A, the foureyelet CTR was gradually implanted into the capsular sac, while the two-eyelet CTR was implanted in group B patients. Afterwards, a toric IOL was implanted into the posterior chamber. The lens hook was used to adjust the toric IOL till the IOL markings were aligned with the predetermined axis. The two inner loops of the four-eyelet CTR were adjusted in front of the toric IOL. If the lens position shifts in this process, it can be adjusted again. Finally, the viscoelastic material was removed using the I/A system and the corneal incision was closed with stromal hydration.

Postoperative Treatment and Examination Tobramycin dexamethasone eye drops was applied to the eyes 4 times daily for 2wk. Visual acuity, phoropter aspects and the IOL rotation degree were examined 6mo after the surgery. The toric IOL was imaged on a slit lamp in retro-illumination to record the toric IOL axis (Figure 1). It was ensured that the patient's head was erect during imaging. Then, under the narrow slit, the slit rotation button was rotated, and the slit light was transferred to the toric axis. The degree of the current toric axis was obtained through the goniometer of the slit lamp microscope. Compared with the target axis, the rotation degree of the toric IOL can be calculated.

Statistical Analysis Statistical analyses were done using Statistical Package for Social Sciences (SPSS). A *t*-test, a rank sum test and a χ^2 test were used to analyse the data. *P*<0.05 was considered statistically significant.

RESULTS

The patients' characteristics and the demographics of the preoperative data are presented in Table 1. No significant differences were detected in the patients' characteristics and preoperative data between the two groups (all P>0.05).

Index	Group A	Group B	Statistic value	Р
Gender (male/female, eye)	6/10	8/9	0.31	0.73
Age (y)	65.8±11.0	63.8 ± 8.8	125.5	0.71
Axial length (mm)	28.5±2.6	27.9±2.3	-0.69	0.49
ACD (mm)	2.64±0.33	2.59±0.23	-0.50	0.62
SE (D)	-7.1±2.0	$-7.0{\pm}1.8$	-0.17	0.86
Estimated residual SE (D)	-1.45 ± 0.38	-1.34 ± 0.32	-0.92	0.37

Table 1 Preoperative data in groups A and B

ACD: Anterior chamber depth; SE: Spherical equivalent.

Table 2 Visual acuity in groups A and B

Group	UCVA (logMAR)		BCVA (logMAR)	
	Preop.	Postop.	Preop.	Postop.
Group A	0.97±0.42	0.54±0.19	0.54±0.31	0.20±0.13
Group B	$1.02{\pm}0.40$	0.66 ± 0.18	0.53 ± 0.30	0.27±0.15
t	-0.39	-1.86	0.06	-1.43
Р	0.70	0.07	0.96	0.16

Preop.: Preoperative; Postop.: Postoperative; UCVA: Uncorrected visual acuity; BCVA: Best-corrected visual acuity.

Table 3 Astigmatism and	rotation degree of toric IOL	in groups A and B

Group	Astigmatism (D)			Datation daguas
	Preop.	Estimated residual	Postop.	Rotation degree
Group A	2.29±0.64	0.18±0.10	0.56±0.22	1.00±0.73
Group B	2.05 ± 0.71	0.23±0.11	$0.92{\pm}0.24$	3.53±1.46
t	0.70	-1.45	-4.4	-6.22
Р	0.50	0.16	< 0.001	< 0.001

Preop.: Preoperative; Postop.: Postoperative.

The UCVA and BCVA were significantly improved compared with the preoperative stage, while the difference between the two groups in terms of visual outcome was not found to be statistically significant at a follow-up of 6mo (Table 2).

There was an obvious decrease when compared with preoperative astigmatism values in both groups. The residual astigmatism in group A (0.56 ± 0.22 D) was less than that in group B (0.92 ± 0.24 D) at 6mo postoperatively (P<0.001). The mean rotation degrees at the 6mo follow-up in group A and B were $1.00^{\circ}\pm0.73^{\circ}$ and $3.53^{\circ}\pm1.46^{\circ}$, respectively (P<0.001; Table 3).

DISCUSSION

In cataract surgery, fully correcting low optical aberrations is crucial in achieving the best optical and visual quality. Astigmatism is considered the most difficult refractive error to cure, not only because astigmatism exhibits variable degrees but also because of axial factors^[5]. The American Academy of Ophthalmology suggests that between 15% and 29% of cataract patients have more than 1.5 D of keratometric astigmatism^[6]. Given such many patients, an effective way to correct astigmatism is particularly important. A growing body of research has proved that the usage of toric IOL is a better approach to correct astigmatism comparing with limbal relaxing incisions, laser in situ keratomileusis (LASIK) or spectacles, because of its stability and predictability^[7-14]. However, we can only achieve the best correction when the toric IOL axis is at the predetermined position. Its misalignment may reduce the refractive effect or even increase the overall astigmatism^[15-16]. Therefore, the rotational stability of the toric IOL is applied to evaluate its clinical effect^[17]. Zhu et al^[18] found a positive correlation between IOL rotation and axial length at 1y after surgery. Shah et al^[3] reported that the early rotation of a toric IOL was more common in highly myopic eyes. One of the reasonable explanations is that axial length is positively correlated to the diameter of the capsular bag^[19-20], which might reduce the equatorial friction for a given IOL and therefore decrease IOL stability^[21]. Moreover, a long axial length results in the increasing gap between the IOL optical component and the posterior capsule, where the residual lens epithelial cells are easy to transmit and proliferate. As a consequence, formation of posterior capsule opacification (PCO) and shrinkage of the capsule leads to IOL rotation^[22-23]. In conclusion, for cataract patients with high axial myopia and astigmatism, toric IOLs need to be used with caution.

CTRs have been proposed to improve IOL stability. It is a polymethylmethacrylate intraocular implantation device introduced in 1993^[24] for the first time. A CTR helps to enforce symmetry on the capsule bag, stretch the bag's equator and thus flatten the bag on the anterior-posterior axis to control capsular contractions^[25]. And it helps to block the migration of lens epithelial cells and the posterior invasion of deformed fibroblasts, thus effectively suppress PCO^[26]. In our study, six months after surgery, all posterior capsules of operated eyes were flat and smooth.

Wiley^[27] used a two-eyelet CTR in combination with a silicone plate-haptic toric IOL; Safran^[28] used a two-eyelet CTR with a loop-haptic hydrophobic acrylic IOL; Sagiv and Sachs^[29] inserted two CTRs in a patient with a long axial length to achieve rotational stability; and Larkin^[30] proposed suturing the IOL to the CTR. Such researchers have claimed that toric IOLs with the co-implantation of CTRs provide ideal stability. More recently, the outcomes of IOLs in 34 highly myopic eyes when implanted with a CTR or without a CTR were studied by Zhao *et al*^[4]. They found that the mean residual astigmatism in the group with CTRs was significantly less at 6mo after surgery than that without CTRs. However, the maximum degree of rotation in the group with CTRs reached 5 degrees. Tataru *et al*^[31] reported on a case involving the insertion of a</sup>four-eyelet CTR and a toric IOL. He claimed the toric IOL showed micro rotation or even no rotation. However, the study involved only one case and a plate-haptic toric IOL was used. In our study, we have searched for a better way to decrease the postoperative rotation. We compared the outcome of using two different CTRs when implanting toric IOLs during cataract surgery, one with two eyelets and the other with four eyelets. We believe that the rotational stability of the four-eyelet CTR is better. It has two extra eyelets which can press the IOL on the posterior capsule and provide more contact area with toric IOL so that friction is increased and the risk for rotation is reduced. We found that 6mo after surgery, the rotation degrees and residual astigmatisms of two groups were statistically different. However, postoperative visual acuity in the two groups were not significantly different. Further research needs to be conducted to resolve the issue. But we still believe the implantation of four-eyelet CTRs will provide better visual acuity in the long term. We found that postoperative residual astigmatism degrees were more than we expected. We suppose measurement errors with alignment axis marking or IOL alignment cannot be totally avoided. The degree limitation of the toric IOL and the posterior corneal astigmatism may prevent the elimination of astigmatism.

In our study, we did not come across any complications during CTR insertion. In the postoperative evaluation, there were no instances of CTR extrusion into the ciliary sulcus, CTR- induced zonular damage, hyphema or dislocation of the CTR. Our study was conducted on a relatively small sample size, with a short follow-up of 6mo. We believe that a larger sample and a longer follow-up might be more representative of the effect of four-eyelet CTR on the rotational and visual outcomes of toric IOLs.

ACKNOWLEDGEMENTS

Conflicts of Interest: Jiang HM, None; Liang K, None; Tao LM, None.

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