Postoperative Outcomes of Acriva BB Toric T UDM 611 IOL Implantation in Cataract Patients with More Than 1.50 D Astigmatism

Mehmet Vural[1], Nilgün Solmaz[2], Ayşe Feyza Önder[3]

ABSTRACT

Purpose: To evaluate the refractive outcomes and intraocular stability of Acriva toric intraocular lens (T-IOL) (Acriva BB Toric UDM 611, VSY, Istanbul, Turkey) in patients with astigmatism of more than 1.50 diopters (D).

Materials and Methods: In this prospective study, we included twenty-five eyes of 21 cataract patients with corneal astigmatism more than 1.50 D. All patients underwent phacoemulsification surgery with T-IOL implantation and followed up to at least three months. Uncorrected distance visual acuity (UDVA), best-corrected visual acuity (BCVA), intraocular pressure (IOP), refractive parameters (spherical and cylindrical refractive error, spherical equivalent), and IOL axis rotation and were evaluated on the postoperative 1 day, 1 week, 1 month and 3-month visits. The measurements in the 3rd month were accepted as postoperative values. The distance spectacle prescription requirement was recorded.

Results: Twenty-five eyes of 21 patients were included (11 male, 10 female) with the mean age of 59.60±10.50 (48-71) years. Preoperatively, UDVA and BCVA were 0.93±0.41 and 0.55±0.40 logMAR, respectively while postoperative UDVA and BCVA were 0.05±0.034 logMAR and 0.03±0.03 logMAR, respectively. Preoperatively, the mean cylindrical refractive error was 2.66±1.03 D, the spherical equivalent was -2.91±2.00, and mean corneal astigmatism was 1.98±1.04 D. Postoperatively, the mean cylindrical refractive error and spherical equivalent decreased to -0.50±0.25 D and -0.33±0.24 D, respectively. Mean IOL rotation was 2.52±2.35° (0-10°). Six eyes (24 %) needed spectacle, while 19 eyes (76 %) were spectacle-independent for distant vision. None of the patients were required additional surgical intervention to correct postoperative astigmatism until the 3-months follow-up period.

Conclusion: Acriva BB Toric UDM 611 IOL has achieved satisfying refractive results and positional stability in cataract patients who expect a spectacle-independent distance vision with more than 1.50 D astigmatism in the postoperative period.

Keywords: Toric intraocular lens implantation, Astigmatism, Acriva toric intraocular lens, Cataract surgery.

INTRODUCTION

Cataract surgery is one of the most common procedures performed worldwide.[1] This surgery is also a refractive procedure for patients who expect a spectacle-independent lifestyle after surgery. As a result of development in intraocular lens (IOL) power calculations, (using partial coherence interferometry, formulas, specialized IOL production, etc.) postoperative refractive surprises have been decreased. However, 20% to 30% of cataract patients have corneal astigmatism more than 1.25 diopters (D).[2,3] During or after surgery, corneal surgical methods such as limbal relaxing incision (LRI),[4] steep axis corneal incision, photorefractive keratectomy (PRK), laser in situ keratomileusis (LASIK), etc. may be applied to correct astigmatism.[5] Unfortunately, all these methods have disadvantages such as unpredictable results related to the patient's age, corneal incision length/depth,[6,7] differences in wound healing.[8,9] Therefore, patients who have high astigmatism require safer and more predictable surgical methods, and toric intraocular lens (T-IOL) are significantly preferable choices for these patients. In recent years, various studies have imported that implantation of T-IOL is a safe and effective surgical method for cataract patients

1- MD, Ataturk State Hospital, Ophthalmology Department, Balıkesir, Turkey
2- MD, Haseki Training and Research Hospital, Ophthalmology Department, Istanbul, Turkey
3- Prof. MD, Haseki Training and Research Hospital, Ophthalmology Department, Istanbul, Turkey

Received: 04.10.2020
Accepted: 22.03.2021
Glo-Kat 2021; 16: 106-112
DOİ: 10.37844/glauc.cat.2021.16.18

Correspondence Adress:
Mehmet Vural
Balıkesir Ataturk State Hospital, 10020, Balıkesir, Turkey
Phone: +90 507 021 2046
E-mail: mehmetvural27@gmail.com

with preexisting corneal astigmatism.[10] This refractive correction provides a predictable method therewithal. The success ratio of T-IOL in astigmatism correction is related to both toric power and postoperative positional stability. Kim et al.[11] reported that performing an off-axis rotation in each degree will result in loss of cylindrical outcomes up to 3.3% and if misalignment of the T-IOL axis is increased up to 30°, preoperative astigmatism may not be corrected. Therefore, the T-IOL axis should be assigned preoperatively and implanted at the proper axis and it should retain intraocular positional stability to achieve desired residual astigmatism.

In the market, there are numerous T-IOLs made by acrylic or silicon material, with an open-loop haptic or plate haptic design. Acriva T-IOL (Acriva BB Toric 611, VSY, Istanbul, Turkey) is a recently introduced T-IOL, which is made by acrylic hydrophilic material, plate haptic design, and hydrophobic covered surface. Therefore, it is expected to have more positional stability due to the hydrophobic surface and plate haptic design. In the current study, it has been aimed to estimate refractive outcomes and postoperative positional stability of Acriva BB Toric UDM 611 IOL in patients with existing 1.50 D or more astigmatism.

MATERIAL AND METHODS

The study was conducted in accordance with the principles of Good Clinical Practice and with ethical principles set out in the Declaration of Helsinki. The written informed consent was provided from all patients. The hospital ethics committee approved the performance of the study (09R/2018; 13/04/2018, "Haseki Research and Training Hospital" in Istanbul, Turkey) with the agreement to cooperate being taken as consent to participate. This study included 25 eyes of 21 cataract patients with regular corneal astigmatism (with/against the rule) of 1.5 D and above. The patients underwent phacoemulsification surgery with Acriva BB Toric 611 implantation between January 01, 2016, and April 20, 2018. The minimum follow-up period was three months after surgery.

Exclusion criteria were previous ocular surgery, systemic and ocular disease that may decrease visual function or postoperative IOL stability (zonular deficiency, retinal detachment, ectatic corneal disease (keratoconus, keratoglobus, pellucid marginal degeneration), amblyopia, corneal disease, glaucoma, macular degeneration, irregular astigmatism and pseudoexfoliation, inadequate cooperation related with neurologic or psychologic pathologies or inadequate follow-up (less than three months).

Preoperative examination protocol

All participants underwent detailed ophthalmic examination including uncorrected distance visual acuity (UDVA) and best-corrected visual acuity (BCVA) with Snellen chart (Snellen visual acuity was converted to logarithm of the minimum angle of resolution-LogMAR), slit-lamp biomicroscopic examination, autorefractometry (Canon RFK2 autorefractometry, Japan), intraocular pressure (IOP) with Goldmann applanation tonometer, dilated fundus examination and corneal topography (Sirius Scheimpflug Corneal Topography, Costruzione Strumenti Oftalmici, Florence, Italy). Biometric measurements including anterior chamber depth and axial length (AL) were performed via partial coherence interferometry (IOL Master 500, Carl Zeiss Meditec). We aimed emmetropia as postoperative target refraction for all patients. The spherical power of planned IOL was calculated with SRK-T Formula. Calculation of toric power and placement axis of the IOL was performed under the guidance of the computer program "www.easytoriccalculator.com" which was recommended by the T-IOL manufacturer (VSY). Surgeon-induced astigmatism (SIA) has been accepted as 0.25 D for all formulas according to previous surgical outcomes. Before setting corneal markers, the patient sat upright on the slit lamp with the head carefully hereby surgeon may prevent cyclotorsion related to head position. The patient was induced to fix on a distant target with a contralateral eye. The horizontal slit beam light crossed the center of the pupil by lining between 0° and 180° limbal points of the cornea, main corneal incision area (at 135°), and the implantation meridian was made by marking with a sterile painted Sinskey hook (Katena, Denville, USA).

Surgical procedure

All patients were operated on by the same physician (MV) under topical or subtenon anesthesia. Standard phacoemulsification procedure was performed through a 2.8 mm clear corneal incision at the superotemporal quadrant on the right eye and the superonasal quadrant on the left eye. The T-IOL was inserted into the capsular bag and the cylindrical axis was aligned with the desired position. At the immediate postoperative period, alignment of T-IOL was rechecked after removing viscoelastic. If the axis was not seated at the proper position, the IOL was repositioned with BSS solution (Alcon, Fort Worth, USA). Operations have been terminated by intracameral cefuroxime axetil (0.1 ml, 10mg/ml) and subconjunctival dexamethasone (0.5 mg, 4mg/ml) injection. The standard postoperative treatment protocol, consisting of corticosteroids (Dexamethasone-Maxidex oft. gtt, Alcon, USA; 8 times per day for two weeks), antibiotics (Moxifloxasin, Vigamox oft gtt, Alcon,

USA; 4 times per day for two weeks) and cycloplegic (Tropicamide, Tropamid, Bilim, Turkey; 3 times per day for two weeks) eye drops, was administered to all patients and reduced gradually.

Intraocular lens

The Acriva BB Toric 611 IOL is a foldable, bitoric, monoblock, UV filtered monofocal lens. Plate haptic with any angulation has a biconvex 6.0-mm aspherical optic, 11 mm overall length, and 360˚all enhanced square edges. The lens is covered with a hydrophobic surface and made of hydrophilic acrylic material. The lens enables implantation through a sub 2.0 mm incision with soft material and plate haptic design. Acriva T-IOL has a wide diopter range which is referred to as Custom Made Perfection. Spherical dioptric power of IOL ranges from 0.00 D to 32.00 D and cylinder dioptres power range is available up to 10.00 D with half diopter increments.

Postoperative analysis / IOL rotation analysis

In addition to routine postoperative examinations including objective and subjective refraction, keratometry, UDVA, BCVA, and IOP, IOL axis position is checked after pupil dilatation by rotating the narrowed beam of slit-lamp until it is parallel to axis marks on the lens. The amount of axis misalignment was recorded on the first day, the first week, the first month, and the third month. In the third month, corneal topography and refractive evaluation were repeated, and spectacles were prescribed for patients who required refractive correction on distant vision. All examinations were made by the same physician (MV).

Statistical Analysis

Statistical analyses were performed using the SPSS version 23.0 (SPSS Inc., Chicago, USA) Descriptive analysis were defined as mean, standard deviation, and range. (min-max) The variables were investigated using Kolmogorov-Smirnov/Shapiro-Wilk test to determine distribution. Paired student *t*-test was used to compare preoperative and postoperative data, and *p value* ≤ 0.05 was determined as a statistically significant ratio.

RESULTS

We evaluated 25 eyes of 21 patients with a mean age of 59.6±10.5 years (48-71 years). The T-IOL was implanted in the right eye of eight patients (38%), the left eye of 9 patients (42%) and, the bilateral of 4 patients (20%). The mean of corneal astigmatism was 1.98±1.04 D, AL was 23.81±0.81 mm, spheric IOL power was 20.04±1.91 D and cylindric IOL power was 2.90±1.08 D. The astigmatism was with the rule in 10 patients, against the rule in 11 patients and oblique in 4 patients. IOL implantation axis was 82.24±57.79°. Demographics and preoperative data are summarized in Table 1.

Postoperatively, statistically significant improvement was observed in mean UDVA, BCVA, and refractive results. Mean UDVA increased from 0.93±0.41 logMAR to 0.05±0.034 logMAR (p <0.001), and BCVA increased from 0.93±0.41 logMAR to 0.03±0.03 logMAR (p <0.005) at third month. Mean spherical refractive error was reduced from -1.78±1.95 D to -0.16±0.29 D, the cylindrical refractive error from -2.66±1.03 D to -0.50±0.25 D and spheric equivalent from 2.91±2.00 D to -0.33±0.24 D (p <0.001). There were no significant changes in mean SimK and keratometry parameters. Preoperative and postoperative mean SimK was 43.27±1.73D vs 43.31±1.70 D respectively (p=0.721) and mean keratometry was 43.47±1.66 D vs 43.42±1.65 D respectively (p=0.689). On the third month visit, the mean IOP was 13.00±3.27 mmHg, which was significantly reduced (p≤0.001, paired t-test) from preoperative IOP values. (15.12±3.35 mmHg) (Table 2). Mean IOL misalignment was 2.52±2.35° (range, 0-10˚) and all eyes showed less than 5° of rotation except one eye. We observed an axis rotation of 10° in one patient but the patient did not want any adjustment on the IOL position, because he was satisfied with the final visual outcome. Therefore, none of the patients underwent repositional surgery for residual astigmatism. Six eyes (24%) needed spectacle, while 19 eyes (76%) were spectacle-independent for distant vision (Table 3).

DISCUSSION

T-IOL implantation is considered to be a beneficial option for cataract patients with astigmatism[12] and expecting a spectacle-free lifestyle. In literature, the rate of corneal astigmatism in patients undergoing cataract surgery is variable that range from 20% to 30%.[13-15] Based on these data, corneal astigmatism is a significant problem in patients who expect to be independent of spectacles after

Table 1: *Demografic features in patients.*

		Year	Year
Age		59.6±10.5	48-71
		n	%
Sex	Male	11	52.0
	Female	10	48.0
Side	Right	8	38.0
	Left	9	42.0
	Bilateral	4	20.0

Table 2: *Visual and refractive issues at preoperative and postoperative third-month period.*			
	Preoperative	**Postoperative**	**p value**
UDVA	0.93±0.41.	0.05±0.034	<0.001
BCVA	0.55±0.40	0.03±0.03	0.02
IOP (mmHg)	15.12±3.35	13.00±3.27	<0.001
SimK	43.27±1.73	43.31±1.70	0.721
Keratometry	43.47±1.66	43.42±1.65	0.689
Spheric Refractive Error	-1.78±1.95	-0.16±0.29	<0.001
Spheric Equivalent	-2,91±2,00	-0,33±0,24	<0.001
Cylindric Refractive Error	-2.66±1.03	-0.50±0.25	<0.001
Corneal Astigmatism	1.98±1.04		
UDVA: Uncorrected Distance Visual Acuity, BCVA: Best Corrected Distance Visual Acuity, IOP: Intraocular Pressure, p value: Statistically significant ratio (paired t test)			

Table 3: *Postoperative evaluation.*				
Spheric IOL Power (Dioptre)				20.04±1.91
Cylindric IOL Power (Dioptre)				2.90±1.08
Axial Length (mm)				23.81±0.81
IOL Implantation Angle (Degree)				82.24±57.79
Axis of IOL Rotation (Degree)				2.52±2.35
		N	%	
Vector of IOL Rotation	Clockwise	3	12	
	Counter-Clockwise	14	56	
	None	8	32	
Spectacle (Distance) Prescription	Yes	6	24	
	No	19	76	
IOL: Intraocular Lens				

cataract surgery. Surgical options such as limbal relaxing incisions (LRI),[16] excimer laser methods, corneal relaxing incisions (CRI) may be applied for the management of astigmatism.[17] However, the rate of complication in all these methods is variable. T-IOL implantation has an advantage over other surgical procedures since it provides a predictable change in reducing astigmatism without additional intervention during cataract surgery.[18,19]

In this study, the efficacy and stability of Acriva BB Toric UDM 611 IOL in patients with cataract and astigmatism were evaluated with postoperative VA, astigmatic reduction, and distant spectacle requirement. Intraocular complications were not experienced, and in both UDVA and BCVA were increased significantly. In a retrospective study, Ucar et al.[20] compared the visual outcomes of Tecnis T-IOL and Acrysof T-IOL implantation in patients with cataract and astigmatism. They resulted that Acrysof T-IOL achieved slightly better outcomes. Mairot et al.[21] performed a comparative study with Alcon AcrySoft and Zeiss monofocal toric lenses. Similar to our results, postoperative SE was 0.01±0.13 D and 0.03±0.1 D, UDVA was 0.1 logMAR and 0.09 logMAR, BCVA was 0.003 logMAR and 0.001 logMAR, respectively. There was no statistically significant difference between monofocal toric lenses. They resulted that preoperative corneal astigmatism values were 0.93±0.05 D and 1.23±0.047 D; postoperative residual astigmatism was 0.38 D and 0.34 D, respectively which was statistically significant. In our study, preoperative corneal astigmatism was higher in patients and residual astigmatism was lower postoperatively. This could be related with that Mairot et al. performed the main incision at 120° in both eyes regardless of which eye was operated despite performing with smaller knives (2.2 mm). A larger incision may display surgically induced astigmatism (SIA) and may affect postoperative refractive results. Acriva toric plate haptic has an advantage of implantation through sub 2.0 mm incision owing to plate haptic design, hereby it can minimize SIA. Zhang et al.[22] reported that BCVA increased from 0.9±0.3 logMAR to 0.06±0.14 logMAR in patients with preoperative astigmatism value of 1.33±1.50 after Acriva T-IOL implantation. In the same study, the

spherical IOL was found to be lower effective in the other patient group with an average of 0.14±0.11 logMAR. No difference was detected between the two groups in terms of BCVA. In our study, we evaluated that mean astigmatism decreased from 2,66 D to 0,50 D after T-IOL implantation. Similar to our results, Mendicute et al.[23] declared a significant reduction in mean astigmatism after T-IOL implantation in 30 eyes with corneal astigmatism greater than 1,00 D (from 2,34±1,28 D to 0,72±0,43 D).Ernest et al.[24] reported a comparative study that postoperative astigmatism value was significantly lower in the T-IOL group (185 eyes) than spheric IOL implantation (138 eyes).The percentage of astigmatism reduction and visual acuity varies with the differences between IOL models and preoperative astigmatism. Cataract extraction plays a major role in the increase of VA after surgery and according to our results, T-IOL implantation is a reliable and effective surgery for visual and refractive gains. In this study, six eyes (24%) needed spectacle, while 19 eyes (76%) were spectacle-independent for distant vision after Acriva T-IOL implantation. In the meta-analysis, Kessel et al.[10] declared that the efficacy of T-IOLs was better than non-toric lenses. In 70% of cases using T-IOLs, no distant spectacles were needed. Yüce et al. reported that 50% of the cases needed distant spectacle. The need for spectacles may be depended on spherical value or residual astigmatism that is related to excessive IOL rotation. We claim that may be related to technical failures such as incorrect AL in the IOL power calculation phase and failure to take into account posterior corneal astigmatism. Other studies have been reported that T-IOL implantation reduces the need for distant spectacles at satisfying rates of 61% and 85%.[10,25] Our rate for spectacle-free patients was consistent with previous works because Acriva T-IOL has a wide diopter range (Spherical: 0.00-32.0 D, cylindrical up to 10.0 D with half diopter increments).

The most important feature for adequate refractive outcomes is the stability of T-IOL.[11] It is known that a 1° deviation in the IOL axis may cause a decrease of 3.3% in the cylindrical corrective effect of IOL and an IOL axis deviation above 30° resets cylindrical corrective effect completely.[11,26] Therefore, some authors reported that IOL should be repositioned to the aimed axis with a second surgical intervention in patients with more than 10° IOL axis rotation. According to the first T-IOL implantation results of Shimizu et al.[27] in 1992, 30% or more rotation was detected in 20% of the patients after PMMA material T-IOL implantation. After current surgical technique developments, the rate of T-IOL rotation has been decreased. IOL rotation variability is related to the T-IOL model and haptic design. In this study, we calculated the mean rotation of Acriva BB Toric T UDM 611 IOL as 2.52±2.35° (0-10°). In other studies with different T-IOL models, Domínguez et al.[28] reported that the mean degree of rotation was 3.1±2.8° (0-12°) consisting of 53 eyes after Technis T-IOL implantation, Entabi et al.[30] reported 3.44° after T-flex IOL(29), Dick et al. performed a mean rotation rate of 4° with Microsil IOL, Visser et al.[18] reviewed more than 10° has resulted in 20% of patients for Staar T-IOLs, 13% for T-flex (Rayner Intraocular Lenses Limited, USA) T-IOL, 9% for Microsil T-IOL, and 3% for Acrysof T-IOL. Compared to other studies, the stability of Acriva BB Toric T UDM 611 IOL was reasonably found successful. The authors recommend the implantation of Acriva T-IOL model because of proper rotational stability. Rotation of IOL during operation is easier because of markers on both sides. It is quite satisfactory that T-IOL holds on to posterior capsular bag in four points supplies rotational stability with plate haptic design. Solely, we found 10° of rotation in one patient within the follow-up period after surgery, but our patient did not want to adjust the IOL position because he was satisfied with the final visual outcome. We comment that rotation of small degrees in the early period may depend on marking error during the surgery (depending on the width of the marked place with marker pen) or malpositions during IOL implantation. The major parameter influencing postoperative spherical refractive change is the axial position of IOL. Failure to assuring rotation stability and possible cylindrical refractive change may be contributed by minimal axial IOL shift.

Our research has several limitations. The number of patients was limited due to difficulties in purchasing toric lenses. Additionally, there was no control group with non-T-IOL implantation to compare with the T-IOL group. Therefore, we are not able to claim the differences between spheric monofocal IOLs and T-IOLs. On both sides of the eyes, different quadrants (superotemporal and superonasal) have been preferred for the corneal incision. In previous studies, no difference was detected between two quadrants[31] so we have not divided all of the patients. Another limitation was not taking into account posterior corneal astigmatism. According to our calculation formulas, the posterior corneal astigmatism was not necessary. Even the effect of posterior corneal astigmatism is significant in the efficacy of T-IOL correction more than total corneal astigmatism calculations,[32,33] we did not perform Scheimpflug imaging to detect posterior corneal astigmatism for all participants. The effect of 2.0 mm corneal incision on postoperative astigmatism was lower than 2.8 mm incision. Because of our current phaco tips and surgical instruments, we

performed a 2.8 mm incision and we were unable to reduce SIA below 0.25 D. Besides, we have not reached data about the postoperative outcomes of cataract patients with astigmatism between 1 and 1.50 D.

After T-IOL implantation, spectacle-dependency is eliminated depended on reducing astigmatism and spherical errors. Since patients are used to blurred vision due to high astigmatism for a long time, they can get more clear vision with T-IOL implantation. Therefore, in patients with cataracts and astigmatism, visual outcomes are satisfactory after T-IOL implantation if that is performed with appropriate surgical technique and correct measurement.

This is to certify that:

The article has not been presented in a meeting.

The authors did not receive any financial support from any public or private sources.

The authors have no financial or proprietary interest in a product, method, or material described herein.

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