Original Article

Comparative evaluation of rotational stability and visual outcome of toric intraocular lenses with and without a capsular tension ring

Anju Rastogi, Samreen Khanam, Yashpal Goel, Kamlesh, Prolima Thacker, Prateek Kumar

Purpose: To evaluate the rotational stability of toric intraocular lens (IOL) when co-implanted with a capsular tension ring (CTR) as compared to that of a toric IOL without a CTR. **Methods:** This was a prospective randomized clinical trial performed in a tertiary care centre in India. Fifty adult human eyes with visually significant cataract and regular corneal astigmatism ≥1.5D divided into two groups of 25 eyes each, A and B by simple randomization. Eyes with corneal pathology, lens subluxation, and a specular endothelial cell count <2000/mm^2 were excluded from the study. The eyes in both the groups underwent standard phacoemulsification and were implanted with a toric IOL. In Group A, a CTR was put in the bag before IOL implantation. The groups were called for follow-up on day 1, 1 week, 1 month, and 3 months, postoperatively. The axis of the toric IOL on each visit was measured by slit lamp imaging in retroillumination and analyzed digitally. **Results:** Mean rotation of toric IOL at 3 months postoperatively was 1.85 ± 1.72° in Group A and 4.02 ± 2.04° in Group B. The difference was statistically significant (*P* = 0.003). **Conclusion:** Coimplantation of a CTR is a safe and effective technique for ensuring better rotational stability of toric IOLs.

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Modern cataract surgery has become more of a refractive procedure with emmetropia being the refractive target in most cases. A precisely done biometry is crucial to achieve this refractive target. However, preexisting corneal astigmatism, which is present in 20%–30% patients undergoing cataract surgery, needs to be addressed during the procedure itself.[1] Corneal incisional techniques such as opposite clear corneal incision, limbal relaxing incision, and arcuate keratotomy have been put into use in such patients.[2-4] A more predictable option that has been in clinical practice is the implantation of toric intraocular lens (IOL). Toric IOLs were first described in 1994 by Shimizu *et al*. and have undergone various modifications since then.[5] Postoperative rotation of toric IOL has been a major concern, as it has been found that every degree of rotation of toric IOL decreases the cylindrical correction by 3.3%.[6] The purpose of this study was to assess whether coimplantation of a capsular tension ring (CTR) has a role in conferring better rotational stability to the toric IOL and also to evaluate whether this has an influence on the visual and refractive outcome.

Methods

This prospective randomized controlled interventional study was conducted in the department of ophthalmology, in a tertiary hospital. The study was reviewed and approved by the institute's ethics committee, and an informed written consent was obtained from all the patients enrolled. The study included 50 eyes of adult (≥18 years) patients with visually significant cataract and regular corneal astigmatism ≥1.5D. These eyes were randomly divided into two groups: Group A and Group B. The eyes in both the groups underwent standard phacoemulsification. In Group A, a CTR was implanted along with a toric IOL (Auroflex Toric IOL). In Group B, only a toric IOL was put.

The exclusion criteria included any corneal pathology, subluxated lenses, acute/chronic uveitis, posterior segment pathology (e.g., macular degeneration or retinopathy), glaucoma, a specular microscopy endothelial count <2000 cells/mm^2, and prior corneal or ocular surgery.

Preoperatively, a complete ophthalmologic examination was done which included a detailed history regarding previous ocular and systemic complaints, uncorrected distance visual acuity (UDVA), best-corrected visual acuity, refractive cylinder, corneal astigmatism, intraocular pressure, posterior segment examination, and specular endothelial cell count.

The determination of corneal astigmatism was done using an autokeratometer (Potec Autoref keratometer PRK-5000) and was matched (wherever possible) with the keratometry done with an optical biometer (LensStar-LS 900) as well as the corneal topography (using OrbscanTM IIz, Bausch and Lomb). The axial length was measured with USG A scan (PAC SCAN 300P) and LensStar-LS 900 (wherever possible). The IOL power and axis of placement were determined using the online calculation program available from the manufacturer.

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To overcome the effect of cyclotorsion which occurs when the patient lies supine for the surgery, preoperative marking was done using the 3-step ink marking procedure.[7] The eye was anesthetized using topical proparacaine. The horizontal axis of the eye (0° and 180°) was marked preoperatively on a slit lamp with the patient in upright position. An air bubble marker was used for this purpose. It was ensured that the head was vertical, and any tilt was avoided. The slit beam was centered on the pupil.

Surgical technique

All the eyes underwent standard phacoemulsification using a clear corneal incision by a single surgeon. Before starting the surgery, marking of the axis of placement of IOL and the incision site was done with Mendez degree gauge, taking the marks made previously on the limbus as the reference marks for identifying the 0 and 180°. Capsulorhexis was done so that it would cover 360° of the rim of the optic of the IOL. Implantation and rotation of toric IOL were done till the IOL markings were aligned with the predetermined axis.

In all eyes in Group A, a CTR was implanted before toric IOL implantation using a disposable CTR injector. The CTR (size-13 mm) was loaded on a viscoelastic filled terminal end of the CTR injector and inserted before inserting the IOL. The use of an injector helped us to ensure a correct in-the-bag placement of the CTR. The bag was well inflated with the viscoelastic so as to facilitate its proper placement and avoid any instance of zonular damage.

While dialing, the IOL was kept about 5° short of the intended axis, after which a thorough viscoelastic removal was done. During viscoelastic removal, the IOL was stabilized with the second instrument to prevent gross rotations. Fine tuning of the axis of IOL was done after removal of viscoelastic.

Postoperatively, the UDVA, corneal astigmatism, and refractive cylinder were determined at day 1, 1 week, 1 month, and 3 months. On each visit, the toric IOL was imaged on a slit lamp in retroillumination. It was ensured that the head was erect during imaging. The axis of the toric IOL was analyzed on a computer using the ImageJ software made available by the US National Institute of Health at imagej.nih.gov.in/ij.[8] [Fig. 1a and b]. The slit lamp images were opened using ImageJ, the marks on the toric IOL were connected using a fine line and the angular position of the IOL was measured using these marks with the features in the application. On serial imaging, the angular position of the IOL was determined similarly and compared with the previous images as attached statistical analyses were done using Statistical Package for Social Sciences (SPSS, version 17.0, SPSS Inc., Chicago, IL, USA). The data were found to be having a nonnormal distribution. Mann–Whitney U-test was used for comparison between the groups and Friedman test was used for comparison within each group. $P < 0.05$ was considered statistically significant.

Results

The study included 50 eyes of 50 patients. Table 1 shows the mean demographic and preoperative data in Groups A and B.

Table 2 shows the mean rotation at the end 1 week, 1 month, and 3 months of follow-up in Groups A and B. Postoperative rotation of the IOL was more in Group B at all postoperative visits [Fig. 2]. At 3-month postoperatively, mean rotation of IOL in Group A was 1.85 ± 1.72°, and in Group B, it was 4.02 ± 2.04°. The difference was statistically significant ($P = 0.003$).

Mann–Whitney U-test was used for statistical analysis and difference between Group A (toric IOL with CTR) and Group B (toric IOL without CTR) at all postoperative visits was found to be statistically significant [Table 2].

The rotation of the toric IOL, as seen on subsequent visits, was compared within each group using Friedman test, the nonparametric counterpart of repeated measure ANOVA. For

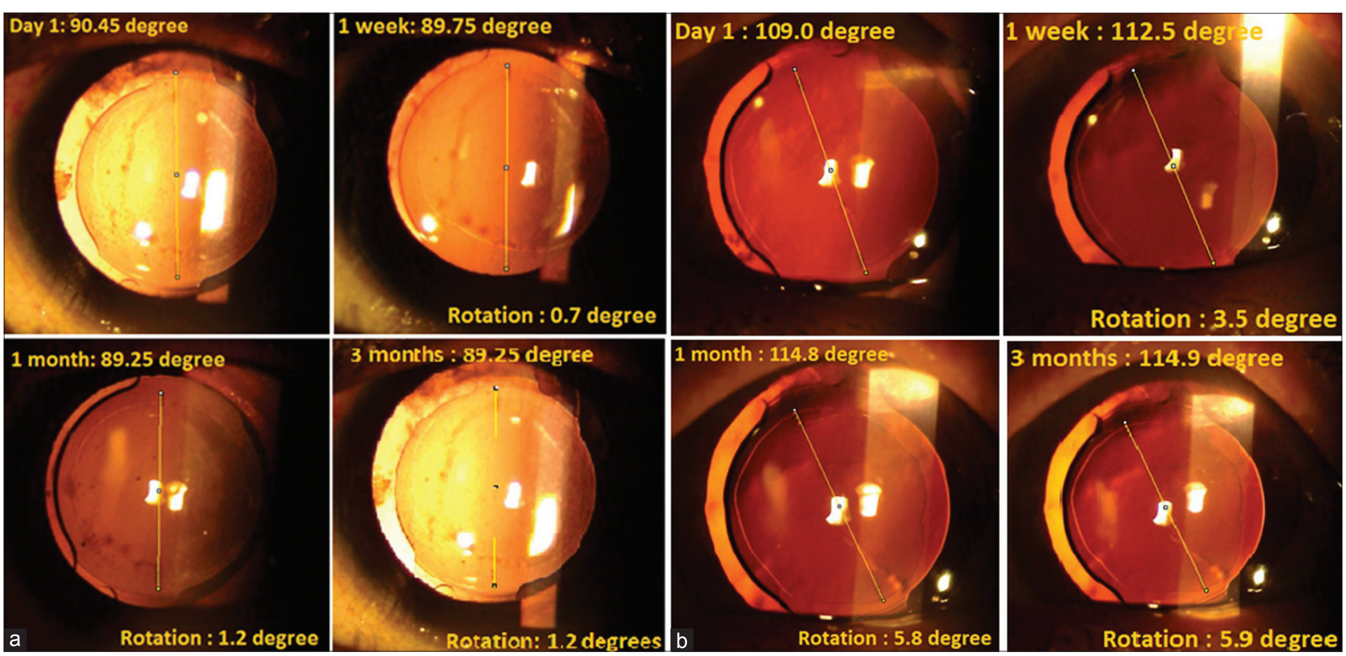

Figure 1: (a) Rotation of the toric IOL as measured using ImageJ in a patient (S. No. 8) of Group A. Rotation at the end of 3 months was 1.2°. (b) Rotation of the toric IOL as measured using ImageJ in a patient (S. No. 8) of Group B. Rotation at the end of 3 months was 5.9°

Table 1: Mean preoperative data in Groups A and B

	Group A (25 eyes)	Group B (25 eyes)	*P*
Mean age (years)	57	57.5	0.83
Male:female	10:15	10:15	1.0
Mean preoperative BCVA in LogMAR (Snellen)	1.30±0.32 (20/400)	1.34±0.34 (20/437)	0.94
Mean preoperative corneal astigmatism (diopters)	2.42±0.97	2.27±0.43	0.419
Mean axial length (mm)	23.17±1.58	22.88±1.05	0.95

BCVA: Best-corrected visual acuity

Table 2: Mean rotation of toric intraocular lens as seen on follow-up in Groups A and B

	Group A	Group B	Mean difference between A and B	*P*
Rotation (°) between day 1 and 1 week (mean±SD)	1.35±1.55	2.13±1.19	0.78	0.029
Rotation (°) between day 1 and 1 month (mean±SD)	1.64±1.57	3.28±1.58	1.64	0.004
Rotation (°) between day 1 and 3 months (mean±SD)	1.85±1.72	4.02±2.04	2.17	0.003

SD: Standard deviation

Table 3: Postoperative visual outcome in Group A and Group B

	Mean UDVA in logMAR (Snellen)		*P*
	Group A	Group B	
Day 1	0.39±0.26 (20/49)	0.38±0.29 (20/47)	0.816
1 week	0.28±0.06 (20/38)	0.22±0.12 (20/33)	0.097
1 month	0.25±0.08 (20/35)	0.20±0.09 (20/30)	0.109
3 months	0.20±0.11 (20/30)	0.21±0.10 (20/32)	0.831

UDVA: Uncorrected distance visual acuity

both the groups, it was found to be statistically significant (For Group A: χ^2 = 14.42, P = 0.002 and For Group B: χ^2 = 18.5, P < 0.0001).

Table 3 shows the mean visual outcome in both the groups at day 1, 1 week, 1 month, and 3 months of follow-up. The difference between the two groups in terms of visual outcome was not found to be statistically significant at a follow-up of 3 months (P = 0.831).

The residual astigmatism in Group A (0.62 ± 0.32 D) of our study was less than that in Group B (0.86 ± 0.29D). However, it was not found to be statistically significant (P = 0.107).

Discussion

Correction of astigmatism at the time of cataract surgery is important to achieve better refractive outcomes. Toric IOLs have become immensely popular for the same reason. However, postoperative rotation in a toric IOL has been identified to be a significant problem in the endeavor to achieve the desired cylindrical correction. A number of patient- and IOL-related factors have been identified to be affecting postoperative IOL rotation such as asymmetric capsular contraction, material and design of the IOL, capsulorrhexis size, incomplete removal of viscoelastic, axis of alignment, and Nd:YAG capsulotomy.[9-15] Asymmetric contraction of the capsular bag is an important cause of lens decentration and has the potential to cause rotation of IOL.[9]

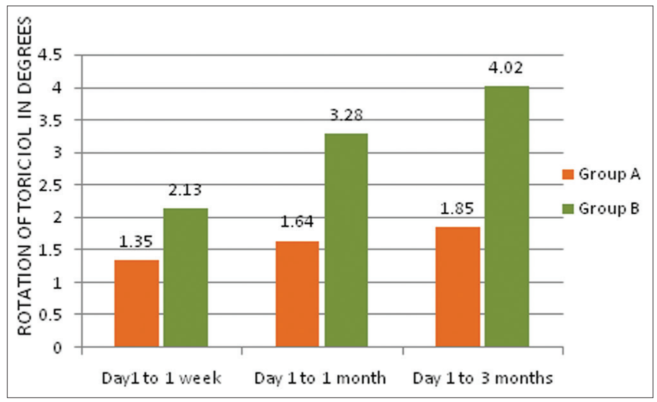

Figure 2: Mean rotation of toric IOL (in degrees) in Group A and Group B at postoperative visits from the baseline axis of day 1

In their study on AcrySof toric IOL (without CTR), Holland *et al*. found that after a period of 1 year, the rotation of the IOL ranged from 3.6° to 3.9°, with an overall mean of 3.8°. The median IOL rotation at 1 year was 3.0°.[16] Waltz *et al*. studied the TECNIS toric IOL (without CTR) and found that the mean absolute rotation at the end of 6 months was 2.70 ± 0.51°.[17] There was a rotation of 10° or less in 96.8% of lenses at the end of 6 months. Scialdone *et al*. found a mean toric IOL rotation of 3.0 ± 3.1° at 3 months postoperatively,[18] and Bascaran *et al*. found a mean toric IOL rotation of 4.42 ± 4.31° at the end of 6 months.[19] In both these studies, CTR was not used. In our study, the magnitude of rotation of toric IOL seen in Group B (toric IOL without CTR) was 4.02 ± 2.04°. This is comparable to the above-mentioned studies. On the other hand, the magnitude of rotation in Group A (toric IOL with CTR) was 1.85 ± 1.72°. This was significantly less than that seen in Group B (without CTR) and other studies assessing rotation of toric IOL.

CTRs are polymethylmethacrylate intraocular implantation devices introduced in 1993 by Witschel and Legler.[20] CTR helps to distribute stress around the entire equatorial area of the lens capsule whenever tension is placed on any section of the capsule.[21] CTRs have been known to enhance capsular bag symmetry and control capsular contraction.

The role of CTR in conferring rotational stability to a toric IOL has been earlier described by Wiley.[22] He termed it as "the IO Lock technique" and claimed to have markedly reduced the number of toric IOL rotations requiring surgical correction at a follow-up of 16 months from 3% (series of 128 eyes) to zero (series of 75 eyes). However, he did not do any comparative study. The magnitude of rotation of toric IOL and astigmatism seen in his patients has not been mentioned. Steven G Safran has reported two cases with high axial myopia, bilateral cataracts, and astigmatism that were implanted with toric IOL without CTR in the first eye, wherein rotation of the IOL occurred shortly after surgery. In the second eye of both the patients, toric IOL of the same type and power and with a similar axial orientation was used, along with a CTR. In both the cases, there was no IOL rotation in the second eye at follow-up.[23]

Sagiv and Sachs have also described a case in which a primary CTR and a toric IOL was implanted in a highly myopic eye.[24] However, the IOL was found 90° from the required position, with a consequent high amount of astigmatism. Thereafter, a second in-the-bag CTR was inserted to stabilize the toric IOL and was found to be stable till last follow-up. The rationale cited is increased symmetry of the bag and flattening of the bag in the anterior-posterior axis, thus increasing the contact area between the anterior and posterior capsule. CTR rounds out the oval shape of the capsular bag, reducing the tendency of the IOL to rotate toward the narrowest position. It provides a contact point for the haptics that is less wide than the actual diameter of the capsular bag resulting in increased friction on the IOL haptics and increased stability. Asymmetric capsular bag shrinkage is already known to cause lens decentration,[9] and CTR counteracts this asymmetry.

More recently, the outcome of IOLs in 34 highly myopic eyes when implanted with a CTR (16 eyes) vis-à-vis without a CTR (18 eyes) has been studied by Zhao *et al*.[25] They have found that at 6 months postoperatively, the mean residual astigmatism in the group with CTR was -0.5 ± 0.25D, which is significantly less than that seen without CTR (-1.25 ± 0.33D). Furthermore, fewer instances of gross rotation were seen in the CTR group. They concluded that in patients with axial myopic astigmatism, CTR can effectively increase the rotational stability of a toric IOL.

We did not come across any complications during CTR insertion such as damage to the continuous curvilinear capsulorrhexis or entanglement of CTR with the bag. In the postoperative evaluation, there was no instance of extrusion of CTR into the ciliary sulcus, CTR-induced zonular damage, hyphema, or dislocation of CTR.

High axial length and capsular bag diameter also affect postoperative rotation of toric IOL.[13,14] We could not find any linear correlation between axial length and magnitude of rotation of toric IOL as has been noted by Shah *et al*. and Miyake *et al*.[13,26]

Our study was conducted on a relatively small sample size of 50 eyes, with a short follow-up of 3 months. We believe that a larger sample and a longer follow-up might be more representative of the effect of CTR on the rotational and visual outcome of toric IOLs.

Conclusion

The results in our study indicate that better rotational stability and thus more predictable results can be conferred to a toric IOL by coimplanting a CTR. However, the visual outcome in our study did not differ significantly between the two groups.

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Conflicts of interest

There are no conflicts of interest.

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