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A study on evaluation of acrysof toric intraocular lens implantation to correct pre-existing corneal astigmatism in patients undergoing cataract surgery- At a tertiary care hospital

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ABSTRACT

Aim: The current study evaluates the results of acrysof toric intraocular lens implantation to correct pre-existing corneal astigmatism in patients undergoing cataract surgery.

Materials and Methods: This study was done on Prospective interventional at Osmania Medical College, Sarojini Devi Eye Hospital, Hyderabad. The sample of the study is included 40 eyes of 38 consecutive patients with 1.5 D or more of pre-existing astigmatism consists of cataract surgery with toric open-loop IOL implantation (Alcon, Fort Worth, TX, USA). The pre-operative markings for the position of incisions and IOL placement were being done under the slit lamp. The visual acuity, residual keratometric and refractive cylinders, and toric IOL axis were being measured.

Results: 54.71 years was the mean age of the patients. All the 40 eyes at the final check-up had post-operative unaided visual acuity of 6/12 or better. 10 patients (25 %) had an unaided visual acuity of 6/6.37 eyes (92.5%) had best corrected post-operative visual acuity of 6/9 or better. The mean pre-operative refractive astigmatism in 40 eyes was 2.34D. 22 eyes had the Refractive astigmatism of >2D. No eyes had refractive astigmatism of <1.5D. The mean axial length was 24.22mm

Out of 40 eyes in which Toric IOL was implanted, the post-operative residual refractive sphere was seen in 4 eyes. Out of 40 eyes in whom Toric IOL was implanted, a post-operative residual refractive cylinder was seen in 30 eyes. 10 patients had No post-operative refractive cylinder. The mean post-operative residual refractive cylinder was 0.58D. The mean Post-operative Keratometric cylinder was 2.24D. The mean post-operative Keratometric cylinder was 2.34D. In comparison, both pre-operative and post-operative keratometric astigmatism, it was found that there was no statistically significant difference between them.

The misalignment of Toric IOL was 10 degrees or less in 36 patients (94.73%) and less than 5 degrees in 22 patients (57.89%). Misalignment of >10 degrees (11 degrees and 13 degrees) was seen in 2 patients. The mean IOL rotation among 38 patients was 4.55 degrees (Range 0-13 degrees, SD 3.43). None of the eyes required repositioning.

Conclusions: The results of this study show that implantation of AcrysofTor ic IOL is a good surgical method to evaluate pre-existing corneal astigmatism in cataract surgery. Acrysoftoric IOL has shown good rotational stability.

1. Introduction

Cataract surgery aims to provide the best visual quality and free the patient from using spectacles. Spherical refractive errors are being managed by using accurate keratometry and axial length measurements and appropriate formulae. Besides, the Spherical refractive error correction, astigmatism is being corrected to provide a post-operative independent spectacle.

It is estimated between 15-29% of patients with cataracts are >1.5D of pre-existing astigmatism.[1,2] Reducing this

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pre-existing astigmatism may further be improved its visual outcomes after cataract surgery. Several techniques like Positioning of incision in cataract surgery, Corneal relaxing incisions, Limbal relaxing incisions and excimer laser procedures are used to reduce Astigmatism. All of these techniques have certain limitations such as degree of astigmatism treated, long term mechanical stability and aberrations, etc.

Toric intraocular lens implantation is another valuable procedure for astigmatism correction in cataract patients. The modern Hydrophobic Toric IOLs have less tendency for rotation.[3]

The attempt is being made to examine the role of Toric IOLs in correcting pre-existing corneal astigmatism in patients who are being undergone cataract surgery. Further, it is also planned to study the rotational stability of the lenses.

Hence, the main objective of the present study is to amount of reduction of astigmatism after implantation of Acrysof Toric IOLs in patients with cataracts and pre-existing corneal astigmatism >1D and also assess the rotational stability of Acrysof Toric IOLs.

2. Materials and Methods

2.1. Design of the study

Prospective interventional.

2.2. The setting of the study

Osmania Medical College, Sarojini Devi Eye Hospital, Hyderabad.

The Sample Population of the Study: Patients who are being attended as an outpatient department of Sarojini Devi Eye Hospital were chosen for ToricIOL implantation.

2.3. Duration of the study

January 2018 to December 2018.

*2.4. Sample **size***

40 eyes.

All the eligible cases willing for toric IOL (Alcon, Fort Worth, TX, USA) and Hoya implantation during the study period of January 2018 to December 2018 were included in the study. The last case enrolled was on 22nd December 2018.

1. Informed consent was taken from all patients.
2. Ethical committee approval for this study was taken from the institute's ethical committee board.

2.5. Inclusion criteria

1. Patients with cataract with age 30years and above
2. Pre-operative regular corneal astigmatism >1.00D

2.6. Exclusion criteria

1. Pre-operative regular corneal astigmatism >5.00D
2. Presence of Corneal disease, Glaucoma or Retinal detachment.
3. Previous corneal or intraocular surgery
4. Abnormal iris
5. Pupil deformation
6. Macular degeneration or Retinopathy
7. History of ocular inflammation
8. Neuroophthalmic diseases

Patients selected for surgery underwent a complete ophthalmic examination including:

1. Pre-operative evaluation including visual acuity
2. Slit-lamp examination
3. Tonometry
4. Gonioscopy
5. Dilated fundus evaluation
6. Keratometry
7. Corneal topography
8. Scan biometry & IOL power calculation
9. Toric IOL calculation using an online calculator

A thorough pre-operative evaluation was done to the patients who were chosen for Toric IOL implantation for surgery. Pre-operative carbonic anhydrase inhibitor tablet Acetazolamide 250 mg OD and tablet Ciprofloxacin 500mg OD has prescribed them on the day of surgery. They are being subjected to dilatation of the pupil with tropicamide + phenylephrine.

Pre-operative Limbal marking was done at 6 o'clock limbus with the patient seated upright at the slit lamp and with a coaxial thin slit turned to 90 degrees.

Surgeries were carried out under Topical or Peribulbar anesthesia. Peribulbar injection of 3:2 mixture of 3ml of 2% Xylocaine (mixed with hyaluronidase and 1:1,00,000 adrenaline) and 2 ml of 0.75 % Bupivacaine.

Surgeries were done by an experienced surgeon. The operation was being performed through the operating microscope with coaxial illumination. Eyel ids, eyebrows, and forehead were being applied with betadine solution.

The surgical procedure was listed below:

1. Paracentesis, using an MVR blade was done
2. Injection of Viscoelastic
3. Capsulorhexis was done with a bent 26G needle. The target was to create a circular, well-cantered rhexis. The target capsulorhexis diameter was 5.5mm to ensure the overlap of the IOL optic.
4. Hydrodissection
5. Phacoemulsification done either by Direct chop technique or Divide & conquer technique.

6. Irrigation and aspiration of cortex done
7. Intraoperative marking: Using the pre-operative 6 o'clock limbal marking as a reference, the Marquez gauge was used to mark the desired axis of Toric IOL implantation.
8. IOL implantation: the capsular bag was inflated with viscoelastic & the IOL injected in a controlled fashion into the bag.
9. Aligning the Toric IOL: gross alignment was achieved by rotating the IOL clockwise while it was unfolding, approximately 20 to 30 degrees short of the desired position. Late r the viscoelastic was removed and the IOL was rotated to its final position by exact alignment of the reference marks on the toric IOL with the limbal axis marks.

Post-operatively, all the patients were given the course of Tab Ciprofloxacin 500mg BD for 5 days along with Gatifloxacin eye drops 0.3% 4 times a day for 3 weeks and Prednisolone acetate eye drops 1% in a tapering manner for 6 weeks.

Patients were keenly examined on post-op day 1, day 4, and 2^{nd} week, at the end of 1^{st} month and after 3 months. Each visit, the UCVA, BCVA, Toric IOL axis measurement through dilated pupil and keratometry has been carried out.

2.7. Statistical analysis

Descriptive data were presented as mean and frequency (percentage). A chi-square test was used to assess the difference between categorical variables. Differences were considered as statistically significant when P-value is $<$ 0.05.

3. Results

Demographic characteristics of patients' study

The total sample population of the study was 40 patients, of them 18 were males & 22 were females.

Table 1: Sex distribution of the patients

Sex	No of patients	Percentage
Male	18	45%
Female	22	55%
Total	40	100%

Table 2: Age distribution of the patients

Age interval (years)	No. of patients	Percentage
30-40	5	12.5%
41-50	5	12.5%
51-60	20	50%
61-70	5	12.5%
71-80	5	12.5%
Total	40	100%

The mean age of the patients was 54.71 years. Among them, the youngest patient operated was 30 yea rs and 79 yea rs was the oldest patient. The majority (50%) of them were between 51 years to 60 years.

3.1. Laterality

Out of 40 eyes of 38 patients, the Right eye was operated in 13; Left eye in 20, and 5 patients underwent bilateral Toric IOL implantation.

Table 3: Side of the eyes operated

Eye operated	No of Patients	Percentage
Right	13	34.21%
Left	20	52.63%
Both	5	13.15%
Total	38	100%

37 eyes (92.5%) had been uncorrected visual acuity of $<$6/18. 10 eyes (25%) had UCVA of CF3M or less. None of the eyes had been uncorrected visual acuity of 6/9 or better.

Table 4: Pre-operative unaided visual acuity

Visual acuity	No of eyes	Percentage
3mt or less	10	25%
$>$3mt – 6/60	08	20%
$>$6/60- $<$6/18	17	42.5%
6/18– $<$6/9	6	15%
6/9 – 6/6	0	0
Total	40	100%

30 out of 40 eyes (75%) had pre-operative best corrected visual acuity of 6/60 or better.

16 eyes (40%) had best corrected visual acuity of 6/18 or better.

None of the eyes had the best corrected visual acuity of better as 6/9.

Table 5: Pre-operative BCVA

BCVA	No of eyes	Percentage
3mt or less	6	15%
$>$3mt – 6/60	4	10%
$>$6/60 – $<$6/18	16	40%
6/18- 6/9	14	35%
$>$6/9	0	0%
Total	38	100%

3.2. Preoperative refractive astigmatism

The mean pre-operative refractive astigmatism in 40 eyes was 2.34D (SD 0.85, Range 1.50D – 4.50D). 22 eyes had refractive astigmatism of $>$2D. No eyes had refractive astigmatism of $<$1.5D.

Mean pre-operative keratometric astigmatism in 40 eyes was 2.47D (SD 0.75, Range 1.0 – 4.5D). 17 eyes had

Table 6: Pre-operative astigmatism

Pre-op Refractive Cylinder	No. of eyes	%
0 – 0.50D	0	0%
>0.50 – 1D	0	0%
>1 – 2D	18	45%
>2 -3D	15	37.5%
>3 – 4D	6	15%
>4D	1	2.5%
Total	40	100%

keratometric astigmatism of >2D, 23 eyes had keratometric astigmatism of 1 – 2D. No eyes had keratometric astigmatism of <1D.

Table 7: Preoperative keratometric astigmatism

Pre-op Keratometric astigmatism	No. of eyes	%
<1D	0	0%
1 – 2D	23	57.5%
>2 – 3D	7	17.5%
>3 -4D	8	20%
>4D	2	5%
Total	40	100%

The mean axial length was 24.22mm (SD 1.27, Range 20.45mm to 25.12mm)

Table 8: Axial length

Axial Length (mm)	No. of eyes	%
20 – 21mm	3	7.5%
>21 – 22mm	4	10%
>22 – 23mm	4	10%
>23 – 24 mm	13	32.5%
>24 – 25mm	15	37.5%
>25mm	1	2.5%
Total	40	100%

The IOLs implanted had spherical power in the range of 12.50D to 28.50D, with a mean power of 20.82D (SD 3.95).

Table 9: IOL spherical power

IOL spherical power	No. of eyes	%
12 – 15D	2	5%
>15 – 18D	5	12.5%
>18 – 21D	17	42.5%
>21 – 24D	5	12.5%
>24 – 27D	8	20%
>27D	3	7.5%
Total	40	100%

The Toric IOLs used were SN60AT3 to SN60AT9. Most of the patients were implanted SN60AT3 model (13 eyes)

All the 38 eyes had post-op unaided visual acuity of 6/12 or better. 30 eyes (75%) had unaided visual acuity 6/9 or better. 10 patients (25%) had Unaided Visual Acuity of 6/6.

Table 10: IOL cylinder power

Toric IOL model	Cylinder Power		No. of Eyes	%
	At IOL plane	At corneal plane		
SN60AT3	1.50D	1.03D	13	32.5%
SN60AT4	2.25D	1.55D	5	12.5%
SN60AT5	3.00D	2.06D	8	20%
SN60AT6	3.75D	2.57D	7	17.5%
SN60AT7	4.50D	3.08D	4	10%
SN60AT8	5.25D	3.60D	1	2.5%
SN60AT9	6.00D	4.11D	2	5%
Total			40	100%

Table 11: Post-operative unaided visual acuity

Visual acuity	No of eyes	Percentage
3mt or less	0	0%
>3mt – 6/60	0	0%
>6/60- <6/18	0	0%
6/18– <6/9	10	25%
6/9 – 6/6	30	75%
Total	40	100%

38 eyes (95%) had the best-corrected visual acuity of 6/9 or better. Two eyes had the best-corrected visual acuity of 6/9P.

Table 12: Postoperative best-corrected visual acuity

Visual acuity	No of eyes	Percentage
3mt or less	0	0%
>3mt – 6/60	0	0%
>6/60- <6/18	0	0%
6/18– <6/9	2	5%
6/9 or better	38	95%
Total	40	100%

Comparison among the pre-operative best corrected visual acuity and post-operative uncorrected visual acuity, post-operative uncorrected visual acuity was proved significantly better.

chi-square = 41.1121. The P-Value = < 0.00001. The results are found significant at $p < 0.05$.

Table 13: Comparison between pre-op BCVA & Post –op UCVA

	Pre-op BCVA	Post –op UCVA
3mt or less	6	0
>3mt – 6/60	4	0
>6/60 – <6/18	16	0
6/18- <6/9	10	10
6/9 – 6/6	4	30
Total	40	40

The comparison between the best corrected visual acuity of pre-operative and post-operative was significantly proved better.

The chi-square = 57.9246. The P-Value = < 0.00001. The result is remarkable at $p < 0.05$

Table 14: Comparison between the best-corrected visual acuity of pre-operative and post-operative

	Pre-op BCVA	Post-op BCVA
3mt or less	6	0
>3mt – 6/60	4	0
>6/60 – <6/18	16	0
6/18- <6/9	10	2
6/9 – 6/6	4	38
Total	40	40

Out of 40 eyes in which Toric IOL was implanted, the post-operative residual refractive sphere was seen in 4 eyes.

Table 15: Post-operative residual refractive sphere

Post-operative residual sphere	No. of eyes	%
0	36	90%
0.50D	4	10%
Total	40	100%

Out of 40 eyes in whom Toric IOL was implanted, a post-operative residual refractive cylinder was seen in 30 eyes. 10 patients had No postoperative refractive cylinder. The mean postoperative residual refractive cylinder was 0.58D (Range 0 – 1.25D, SD 0.39).

Table 16: Post-operative residual refractive cylinder

Post-op refractive Cyl	Patients	%
0	10	25%
0.50D	7	17.5%
0.75D	12	30%
1.00D	10	25%
1.25D	1	2.5%
Total	40	100%

The mean post-operative Keratometric cylinder was found as 2.24D (SD 0.80, Range 1.00 – 4.00D)

Table 17: Post-operative keratometric cylinder

Pre-op Keratometric astigmatism	No. of eyes
<1D	0
1 – 2D	20
>2 – 3D	15
>3 -4D	5
>4D	0
Total	40

Comparison of the pre-operative refractive cylinder and post-operative residual refractive astigmatism:

In comparison, the pre-operative refractive cylinder with a post-operative Refractive cylinder, postoperative refractive cylinder was found significantly less. The chi-square =72.5. The P-Value is< 0.00001. The result is proved significant at $p < 0.05$.

Table 18: Comparison of the pre-operative refractive cylinder and post-operative residual refractive astigmatism

	Pre-op Refractive Cylinder	Post-op Residual Refractive Cylinder
0	0	10
< 0.50D	0	8
>0.50 – 1D	0	20
>1 – 1.50D	8	2
>1.50 – 2D	10	0
>2D	22	0
Total	40	38

The comparison between the pre-operative and post-operative keratometric astigmatism has proved that there was no statistically significant difference between them. The chi-square statistic is 2.8049. The P-Value is 0.422693. Hence, the result has shown that there is no sign at $p < 0.05$.

Table 19: Comparison between pre-operative and post-operative keratometric astigmatism

	Pre-op KeratometricCyl	Post-op KeratometricCyl
1 – 2.00D	20	20
>2.00 – 3.00D	10	14
>3.00- 4.00D	8	6
>4.00 D	2	0
Total	40	40

The misalignment of Toric IOL was 10 degrees or less in 36 patients (94.73%) and less than 5 degrees in 22 patients (57.89%). Misalignment of >10 degrees (11 degrees and 13 degrees) was seen in 2 patients. The mean IOL rotation in 38 patients was 4.55 degrees (Range 0-13 degrees, SD 3.43).

Table 20: Rotational stability of Toric IOL

Rotation (degrees)	No. of Eyes	%
<5	20	50%
5 – 10	16	40%
>10	4	10%
Total	40	100%

4. Discussion

The study was done to using toric IOL to correct corneal astigmatism is a relatively new surgical choice in patients with cataract and previous corneal astigmatism. Though Toric IOLs have high predictability in ensuring accurate astigmatic correction, it is proved that they are not suitable to correct irregular corneal astigmatism. Conditions that affect the long term stability of IOL centration like zonular

weakness can result in loss of effect due to decentration over some time.

In the present study, 40 eyes of 38 patients have undergone Toric IOL implantation in this prospective study. The mean follow-up duration was 4.5 months. It was ranged from 3 – 20 months. Out of 30 patients 18(45%) were Male, 22(52%) were Females. Their age varied from 30yrs to 79yrs with a mean of 54.71 yrs. The majority (50%) of the patients were between 51yrs to 60yrs age. The above age is comparable with the age group of patients as reported by Ivanka Petric and colleagues[4] (46-78years). Reports in the literature show wide variability in age groups of patients undergoing phacoemulsification and toric IOL implantation. Visser et al.[5] analyzed 40 eyes that underwent toric IOL implantation with a mean age of 52.3 + 19.1 years. In a similar study carried out by Venkataraman et al.[6] in South India the average age of 77 patients undergoing toric IOL implantation was 56 + 13.88 years.

Out of 40 eyes operated, 37 eyes (92.5%) had pre-operative Uncorrected Visual Acuity of <6/18.9 eyes (23.68%) had uncorrected visual acuity of 3/60 or less. None of them had Uncorrected Visual Acuity of 6/9 or better. Our studies accordance with the previous studies Bauer et al.,[7] in a case series of 53 eyes of 43 patients reported more than 90% of patients with UCVA of 20/40 or better and 80% achieved UCVA of 20/25 or better with AcrySof toric IOL implantation. Kim et al.,[8] in their case series of 30 eyes of 24 patients reported 73.3%patients with UCVA of 20/25 or better after AcrySof toric IOL implantation.

Out of 38 eyes operated, 30 eyes (75%) had pre-operative best corrected visual Acuity of 6/60 or better. 16 eyes (40%) had best-corrected visual acuity of 6/18 or better. None of them had the best corrected visual acuity of better than 6/9.

All the 38 eyes at the final check-up had post-operative unaided visual acuity of 6/12 (20/40) or better. 30 eyes (75%) had unaided visual acuity 6/9 (20/30) or better. 10 patients (25%) had unaided visual acuity of 6/6 (20/20).

37 eyes (95%) had post-operative visual acuity of 6/9 or better. 31 eyes (81.57%) had best corrected visual acuity of 6/6. In an eye with posterior capsular tear, anterior vitrectomy was being done and Toric IOL implanted in the bag. Best-corrected visual acuity at the final check-up has resulted in 6/9P. The present findings significantly revealed that postoperative uncorrected visual acuity proved better than pre-operative best-corrected visual acuity.

The mean pre-operative refractive astigmatism in 38 eyes was 2.57D (SD 0.78, Range 1.50D – 4.50D). 22 eyes had refractive astigmatism of >2D. No eyes had astigmatism of <1.5D. Mean pre-operative keratometric astigmatism in 38 eyes was 2.47D (SD 0.75, Range 1.0 – 4.5D). 17 eyes had keratometric astigmatism of >2D. No eyes had astigmatism of <1D.

Out of 40 eyes in which Toric IOL was implanted, the post-operative residual refractive sphere was seen in 4 eyes. Post-operative residual refractive sphere ranged from -0.5D to +0.50D. A similar trend in post-operative astigmatism 0.28 ± 0.38 D is reported by Kim et al., in their study.[8]

Out of 40 eyes in which Toric IOL was implanted, a post-operative residual refractive cylinder was seen in 30 eyes (75 %). 10 patients (26.31%) had no post-operative refractive cylinder. The mean post-operative residual refractive cylinder was 0.58D (SD 0.39, Range 0 – 1.25D). There was a 77.43% reduction in the refractive cylinder after toric IOL implantation.

Our results accordance with that to previous studies done by Patel et al.,[9] mean pre-operative refractive cylinder was 1.92D (SD 0.68, range 0.75 to 6D) and mean post-operative residual refractive cylinder was 0.36D (SD 0.57, range 0 – 1.5D). There was an 81% reduction in the refractive cylinder after toric IOL implantation was examined. Another study conducted by Javier Mendicuteet al,[7] a mean pre-operative refractive cylinder was 2.34 ± 1.28 and mean post-operative residual refractive cylinder was 0.72 ± 0.43. There was a 70% reduction in the refractive cylinder after toric IOL implantation was done .

Comparison between the pre-operative refractive cylinder with the post-operative Rrefractive cylinder, post-operative refractive cylinder was proved significantly less. Our results far better compared to those reported by Mendicuteet N et al.[10]

In the present study, the Toric IOLs used were SN60AT3 to SN60AT9. Most of the patients were implanted SN60AT3 model (13 eyes). The misalignment of Toric IOL was 10 degrees or less in 36 patients (94.73%) and less than 5 degrees in 22 patients (57.89%). Misalignment of >10 degrees(11 and 13 degrees) was seen in 2 patients. No eyes had been significant IOL rotation ($\geq$ 20 degrees). The mean IOL rotation in 38 patients was 4.55 degrees (Range 0-13 degrees, SD 3.43). None of the eyes required repositioning.

The misalignment of Toric IOL in our study compares well with other studies. In a study done by Mendicuteet et al.,[10] the mean Toric IOL rotation was 3.63 ± 3.11degrees (range 0 to 12degrees). 96.7% of an eye had an IOL rotation of fewer than 10 degrees. None of the eyes required repositioning. A study was done by Patel et al.,[9] 96.7% of eyes had stayed with in 10 degrees of placement.

The Eyes examine in this study had a 77.43% of reduction in astigmatism after Toric IOL implantation. 37(97.37%) of 38 eyes were within $\pm$ 1.00 D. No astigmatism was recorded in 10 (26.31%) eyes. The result has been proved that no statistically significant difference between pre-operative and post-operative keratometry readings was found. Thus, it is revealed that the reduction of astigmatism was the consequence of toric IOL implantation.

Our findings correlated to previous studies done by Bauer et al.[7] reported residual refractive astigmatism after implantation of AcrySof to be less than 0.75 D in 74% of eyes and less than 1.00 D in 91% of eyes. In Ahmed's

study,[11] residual astigmatism was 1.00 D or less in 90% of eyes. Bauer[7] reported 91% of eyes with residual astigmatism of 1.00 D or less.

Good rotational stability has achieved in our patients. The misalignment of Toric IOL was 10 degrees or less in 36 patients (94.73%) and less than 5 degrees in 22 patients (57.89%). Misalignment of >10 degrees (11 and 13 degrees) was seen in 2 patients. IOL model and haptic design play a very important role in the amount of IOL rotation; for example, in Shimuzu's study, 41% of eyes had IOL rotation greater than 10° with C - LOOP haptic.[12]

The other findings were also according to our study, in Mendicute's study, 77% of eyes had a rotation of 5° or less and 97% of them had 10° or less.[10] Chang et al.[13] also showed that 99% of eyes had 10° or less rotation with AcrySof IOL implantation

The short follow-up may be a source of bias. The average follow-up was 4.5 months. But most IOL rotations happened formerly in the post-operative period. The anterior and posterior capsules fuse IOL rotations are found less frequently.

5. Conclusion

This study showed that the AcrySof toric IOL implantation is an effective, safe, and predictable method of correcting astigmatism in cataract surgery. Proper patient selection, surgical technique, and biometry are the key factors determining the success of toric IOL implantation.

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7. Conflict of Interest

The author declares that they have no conflict of interest.

8. Financial Support

Nil.

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