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Clinical outcomes of Toric IoL long term follow up and predictors of clinical outcome

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Abstract

Background: Cataract surgery is a common procedure, and correcting astigmatism during surgery is crucial for achieving spectacle independence. Approximately 20 -30% of cataract patients have significant corneal astigmatism. Toric intraocular lens (IOLs) will correct astigmatism by having different powers in different meridians and are designed to minimize postoperative rotation. Proper patient selection and precise placement are essential for success.

Study aim and objectives: To study the long term outcomes of intraocular toric IOL implantation after an uneventful cataract surgery. The study objectives to assess the role of posterior corneal astigmatism, corneal biomechanics, and surgically induced astigmatism on the long-term outcomes of toric IOLs. Outcomes measured include best-corrected visual acuity, residual astigmatism, and IOL rotational stability. The roles of surgically induced astigmatism (SIA), posterior corneal astigmatism, and corneal biomechanics on long-term toric IOL outcomes will be evaluated.

Methods: Detailed preoperative planning, including refractive state analysis, corneal topography, and keratometry, is necessary. Various marking tools and techniques are employed to ensure accurate IOL placement.

Results and Implications: The study evaluated the effectiveness of toric IOLs in managing pre-existing corneal astigmatism during cataract surgery. The mean uncorrected distance visual acuity (UDVA) at the end of one year was 0.18 ± 0.16 logMAR, and the mean best-corrected visual acuity (BCVA) was 0.05 ± 0.09 logMAR, with 92% of patients achieving a UDVA of 20/40 or better. The mean rotational stability of the toric IOLs, evaluated using iTrace, was 6.03 ± 4.43 degrees, with a maximum rotation of 20 degrees, and 15% of patients had a rotation of more than 10 degrees. Pre-operative mean refractive astigmatism was -2.21 ± 1.12, which improved to -0.71 ± 0.57 at the end of one year. The study also found a statistically significant correlation between deformation amplitude and surgically induced astigmatism (SIA). Overall, toric IOL implantation proved to be a reliable method for correcting corneal astigmatism during cataract surgery, resulting in improved visual acuity and stability. The study explores the effectiveness of different toric IOL models and the impact of misalignment. Proper surgical techniques and postoperative management are crucial to minimize complications and achieve optimal visual outcomes.

Conclusion: Toric IOL (Intraocular Lens) implantation is found to be an effective and predictable method for managing pre-existing corneal astigmatism, producing better visual outcomes in the post- operative period with good rotational stability. The study emphasizes the influence of corneal biomechanics on surgically induced astigmatism (SIA) and suggests that outcomes could be improved by incorporating these biomechanical factors into calculations for toric IOLs. Additionally, the research highlights the need for further studies on the relationship between deformation amplitude and refractive outcomes after toric IOL surgery, as well as the importance of considering corneal biomechanics in pre-operative assessments.

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Keywords: Astigmatism; Rotational stability; Intraocular lens; Toric; Cataract

1. Introduction

With the improvement of cataract surgery technology and the development of IOL, cataract surgery has changed from rehabilitation surgery to refractive surgery. According to statistics, among cataract patients, patients with corneal astigmatism > 1.0D accounted for 41%, and patients with corneal astigmatism > 1.5D accounted for 15– 29%.[1,2,3] Cataract remains the single largest cause of blindness with the number of cataract blind in India being 3.01% of the population and 20.2% of the individuals above 50 years.[4] Cataract surgery is a popular intraocular procedure, with modern surgery focusing on spectacle freedom and spherical lens power to address refractive errors. However, 20%-30% of cataract patients have corneal astigmatism of 1.25 D or higher, and 10% have 2.00 D or higher astigmatism.[5, 6] During cataract surgery, astigmatic power can be corrected through various methods such as adjusting the primary phaco incision axis, placing additional corneal relaxing incisions, or using a Toric IOLs.Toric IOLs are premium intraocular lenses designed to correct astigmatism, producing minimal or no postoperative IOL rotation. They have powers in different meridians and can be used to address corneal astigmatism after surgery. Proper patient selection, analysis of preoperative refractive state, corneal topography, keratometry, and correct marking techniques can help achieve spectacle freedom. This study aims to explore the impact of posterior corneal astigmatism, corneal biomechanics, and surgically induced astigmatism on the long-term outcomes of toric IOL, including best corrected visual acuity and residual astigmatism. Toric IOLs offer a significant advantage over LRIs or excimer laser surgery in treating existing corneal astigmatism and surgical aphakia, especially in cases of significant corneal astigmatism.[7-11] Eyecryl Toric IOL, a new toric intraocular lens, has been introduced in India. It is a single-piece, hydrophobic acrylic, aspheric lens with a 360 degrees square edge. While clinical outcomes have not been evaluated, this study reports on the safety, efficacy, predictability, rotational stability, complications, and overall results of this new toric intraocular lens. The lens is a promising solution for cataract patients with corneal astigmatism. Toric IOL is a reliable method for correcting preexisting corneal astigmatism in cataract surgery patients, resulting in improved postoperative visual outcomes. This led to the development of multifocal toric IOLs, which have proven effective at near, intermediate, and far distances. However, long-term prognosis, such as rotational stability, should be evaluated for each toric IOL, as the design of haptic, material, and surface affects postoperative stability. Clinical studies on rotational stability are needed to inform clinicians for better visual outcomes after cataract surgery.

2. Material and Methods

The study was conducted over two years, from June 2014 to June 2016, at Narayana Nethralaya, Bangalore, and employed a prospective non-randomized design. Consecutive patients visiting the outpatient department with cataract and regular corneal astigmatism who consented to the procedure were included. Sample size calculation was based on the formula for single proportion with absolute precision, adjusting for a finite population. Key assumptions included binary outcome measures and normal approximation of the sampling distribution of the sample proportion. The calculated sample size was adjusted to account for an estimated 10% loss to follow-up, resulting in a required sample size of 100 toric intraocular lenses (TIOL). Participants were selected based on specific inclusion criteria (e.g., patients with regular astigmatism of 1-5 diopters, clear cornea, visually significant cataract with intact zonules) and exclusion criteria (e.g., irregular astigmatism, history of previous intraocular surgeries, pre-existing ocular comorbidities). Informed consent was obtained from all participants, and ethics committee approval was secured prior to the study's commencement. Preoperative assessments included a comprehensive ophthalmic examination involving various tests such as Snellen visual acuity, auto keratometry, non- contact tonometry, slit lamp examination, fundoscopy, and Pentacam imaging. The surgical procedure was standardized, with all surgeries performed by a single surgeon under topical anesthesia. Detailed preoperative marking and intraoperative alignment techniques were employed to ensure accurate IOL positioning. Postoperative evaluations were conducted to assess outcomes and potential complications.

2.1. Statistical Analysis

Data entry was done on Excel worksheets (Microsoft Corp). Mean values and standard deviation values were obtained from the Excel worksheets. Statistical analysis was done using SPSS version 21 using appropriate tests. Vector analysis of astigmatism was performed using the Datagraph software. Postoperative residual astigmatism and spherical equivalent (SEQ) prediction errors were calculated and plotted using Astigmatism Double Angle Plot Tool (version 1.3.2, https:// ascrs. org/ tools/ barre tt - toric- calcu lator), while their differences between the type I and type II irregular corneal astigmatism were compared using independent samples t-test (normally distributed). A P-value of < 0.05 was considered statistically significant.

3. Results

A non-randomized prospective case study involved 81 patients with cataracts, who underwent cataract surgery with Toric IOL implantation. Post-operative visual acuity, residual astigmatism, and rotational stability were assessed at follow-up periods of 1 month, 3 months, 6 months, and 1 year after surgery. Demographics of this study was reported that median age was 60.5years (Range 25-79 years). 47 (58 %) were males and 34 (42 %) were females (Graph 1). Out of the 100 eyes, 55 (55 %) were right eyes and 45 (45%) were left eyes.

Table 1 Visual acuity

Follow-up periods	**Mean ± SD** **of Uncorrected Distance Visual Acuity (UDVA): (LogMAR)**	**Mean ± SD** **of Corrected Distance Visual Acuity (CDVA) (LogMAR)**
Baseline	1.2 ± 0.79	0.52 ± 0.59
1 month	0.20 ± 0.15	0.06 ± 0.1
3 months	0.18 ± 0.14	0.04 ± 0.06
6 months	0.15 ± 0.14	0.03 ± 0.06
12 months	0.18 ± 0.18	0.05± 0.08

The above table 1 shows that depicts Uncorrected Distance Visual Acuity (UDVA) and Corrected Distance Visual Acuity preoperative and postoperative at all follow ups. The slight decrease in visual acuity can be attributed to possibility of development of posterior corneal opacification, errors in refraction repeatability.

Table 2 Visual acuity comparison of preoperative CDVA with Postoperative UDVA

Visual Acuity	**Pre-operative CDVA%**	**1 Month** **Post-operative UDVA%**	**3 Month** **Post-operative UDVA%**	**6 Month** **Post-operative UDVA%**	**12 Month Post-operative UDVA%**
20/20 or better	11	27	25	22	15
20/25 or better	12	36	42	43	46
20/32 or better	52	70	64	78	69
20/40 or better	59	88	89	91	92

The above table 2 shows that compares pre-operative Corrected Distance Visual Acuity with Post- operative Uncorrected Visual Acuity at follow up months. Majority of patients improved to 20/40 or better. Around 90% of patients improved to 20/40 or better and around 40% of patients improved to 20/25 or better.

Table 3 Visual acuity improvement at follow up visits

Visual acuity improvement (Snellens)	**1 month (%)**	**3 months (%)**	**6 months (%)**	**12 months (%)**
Stabilized	23	17	17	8
1 line improvement	12	8	4	0
2 line improvement	26	28	26	46
>2 line improvement	39	47	52	46

The above table 3 shows improvement in visual acuity at follow up visits. Majority of the patients improved >2 lines in Snellen visual acuity chart. All the patients had either improvement in visual acuity or stable visual acuity but none of the patients had loss of vision post-surgery which confirms the safety of procedure.

Table 4 Residual astigmatism post-surgery at follow up visits

Astigmatism	**Baseline**	**1month**	**3 month**	**6 month**	**12 month**
Mean	-2.21	-0.59	-0.63	-0.6	-0.71
Standard deviation	1.12	0.55	0.53	0.52	0.57

The above table 4 and figure 1 shows there was a change in mean residual astigmatism from -2.21± 1.12 preoperatively to -0.59 ± 0.55 at 1 month and eventually showed a mean residual astigmatism of 0.71 ±0.57 at 12 months follow up. The slight increase in residual astigmatism at the end of 1 year could be to influence of Against the rule astigmatism which increases with age and also might be due to delayed corneal wound healing.

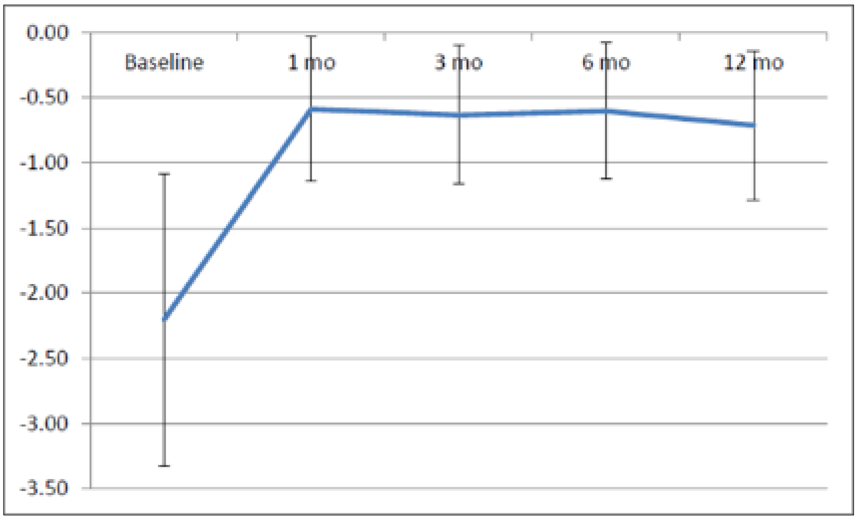

Figure 1 Change in mean post-operative residual astigmatism at various follow up visit Table 5: Distribution of Post-operative residual astigmatism

Table 5 Distribution of Post-operative residual astigmatism

Atigmatism (D)	**Pre-operative %**	**1 month %**	**3 month %**	**6 months %**	**12 months %**
>3	15	0	0	0	0
2.01-3.00	30	0	0	0	0
1.5-2.00	21	3	3	4	8
1.26-1.5	9	6	11	13	15
1.01-1.25	8	8	8	4	8
0.76-1.00	17	3	11	9	15
0.51-0.75	0	23	17	22	15
0.26-0.5	0	20	28	26	23
0.00-0.25	0	38	20	22	15

The above table 5 gives distribution of residual astigmatism at follow up visits. Percentage of patients with astigmatism in different ranges had been depicted. None of the patients had astigmatism more than 2.00D. Majority of the patients had astigmatism less than 1.00D.

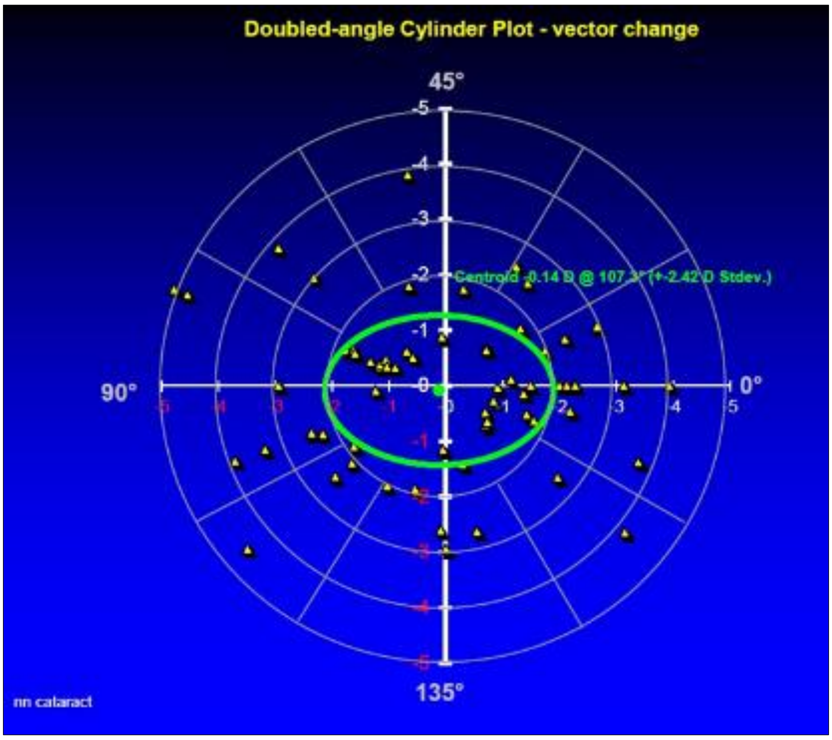

Figure 2 Centroid showing change of predicted residual astigmatism from baseline using Barrett's Formula

The above figure 2 shows that double angle plot shows the centroid with the 95% confidence interval oval. The predicted change of residual astigmatism from baseline using the Barrett formula was -0.14D @107 ± 2.42.

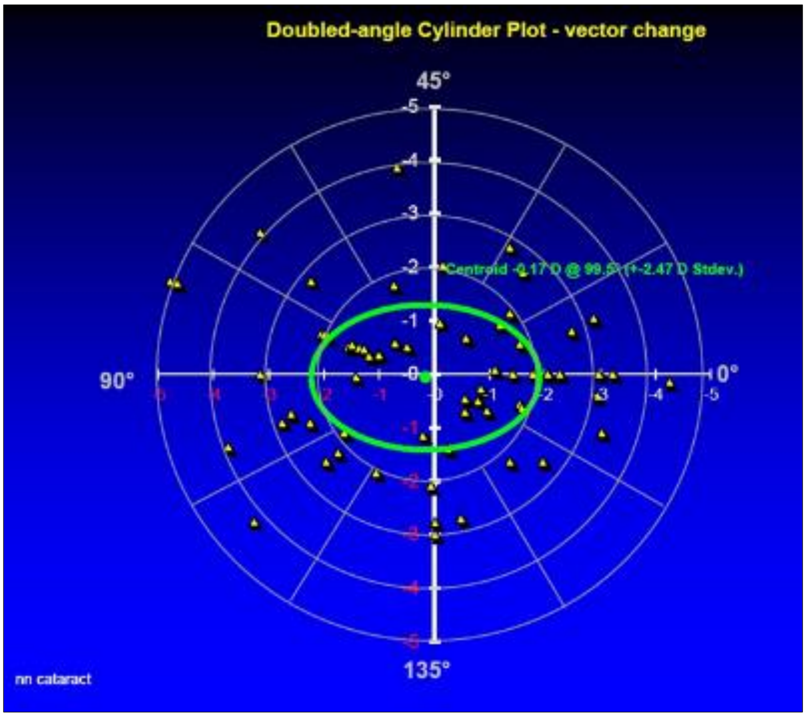

Figure 3 Centroid showing change of predicted residual astigmatism from baseline by company specific calculator

The above figure 3 shows that double angle plot shows the centroid with the 95% confidence interval oval. The change of predicted residual astigmatism from baseline using the company specific online calculator was -0.17D @99.5 ± 2.47.

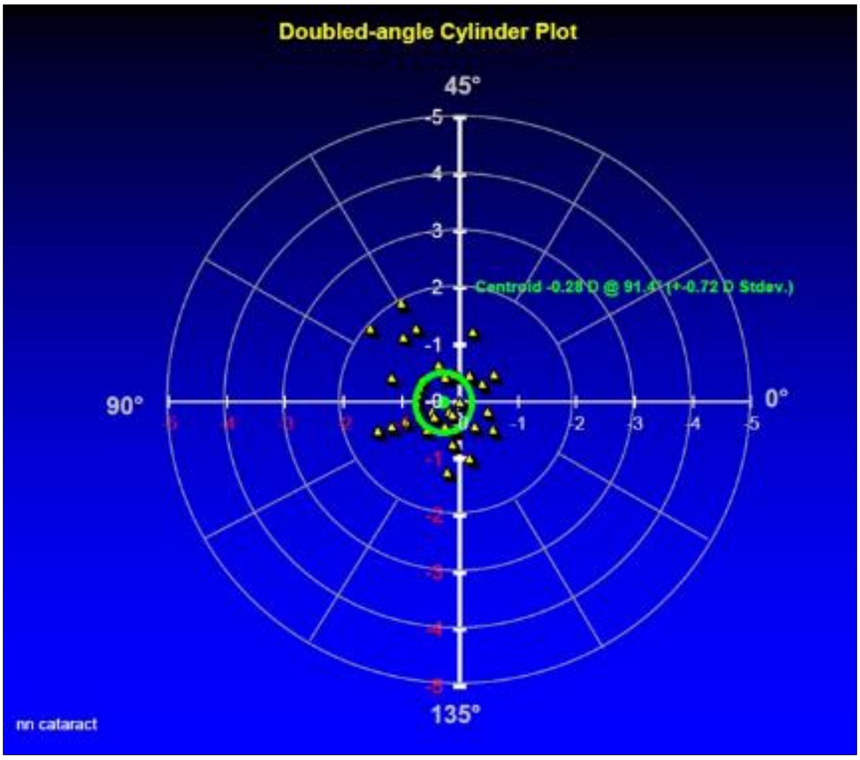

Figure 4 Centroid showing predicted residual astigmatism at 1 month post-surgery

The above figure 4 shows double angle plot shows the centroid with the 95% confidence interval. The predicted residual astigmatism at 1 month post surgery was -0.28D @91.4±0.72.

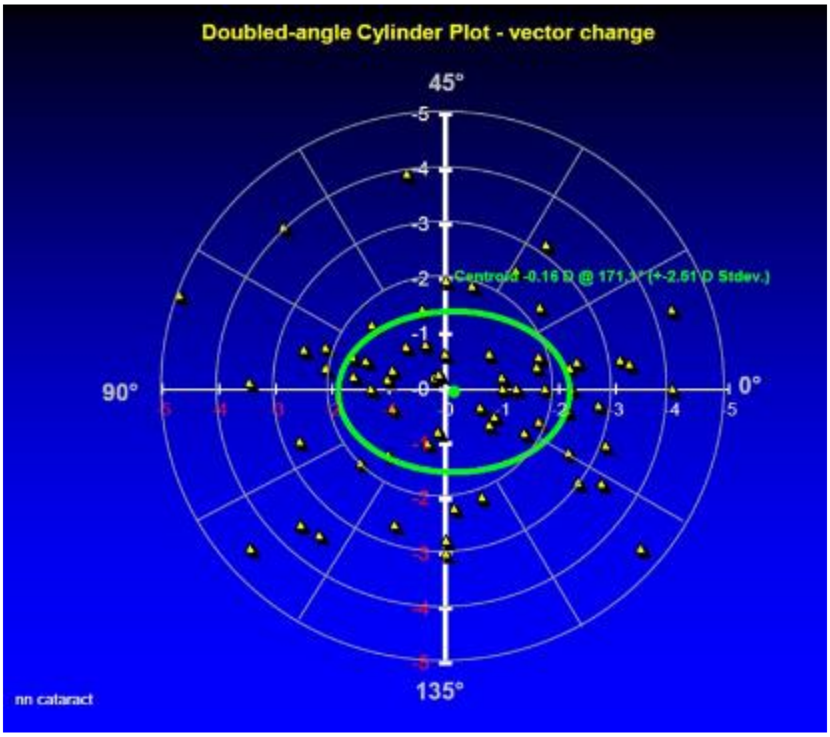

Figure 5 Centroid showing change of residual astigmatism from baseline 1 moth post-operative

The above figure 5 shows double angle plot shows the centroid with the 95% confidence interval oval. The change between achieved residual astigmatism and baseline was -0.16D@171 ± 2.51. In our study we proved that there is statistically significant correlation between deformation amplitude and SIA (Spearman's rho = 0.463, p= 0.004 significant at the 0.01 level). There was a wide fluctuation in best corrected visual acuity in the group which had poor deformation amplitude at 6 months, which came back to normal by 1 year. Patients with good DA stayed stable throughout the year. Mean spherical refractive equivalent also showed more stability throughout the year in the group with good deformation amplitude as opposed to the other group where it kept fluctuating. Rotational stability of the Toric IOLs implanted was evaluated using iTrace (Tracey Technologies). In our study, the mean rotation at one month was 6.03 ± 4.43 degrees and the maximum rotation was 20 degrees. 15 % of the patients had significant rotation of more than 10 degrees. The mean axial length (Lenstar) was 24.03mm±1.79. The mean IOL spherical power calculated by the company specific online calculator was 19.34D ± 5.55D and the mean cylinder power was 3.11D ± 0.93D. The mean IOL spherical power calculated by the Barrett online calculator was 19.11D ± 5.68D and the mean cylinder power was 2.90D ± 1.12D.

4. Discussion

Modern cataract surgery emphasizes spectacle freedom, with emetropia achievable for patients with myopic or hyperopic refractive errors. However, 20%-30% of patients have corneal astigmatism of 1.25 diopters or higher, and 10% have 2.00 diopters or higher. Not correcting astigmatism during cataract surgery prevents spectacle independence. Toric intraocular lenses (IOLs) allow patients to correct corneal astigmatism during cataract surgery, achieving spectacle independence for distance vision.

4.1. Refractive outcome

The study found that uncorrected distance visual acuity (UDVA) can significantly improve patients' success with toric IOLs. The mean UDVA at the end of one year was 0.18 + 0.16 logMAR, and the mean BCVA at the end of one year was 0.05 + 0.09 logMAR. 92% of patients had UDVA 20/40 or better, similar to Mendicute's12 et al study and Myung Hun Kim[13] et al study, which showed 93.3% of eyes showed 20/40 or better UCVA at the final follow-up.

4.2. Rotational stability

In our study we analysed 100 eyes of 81 patients who had cataract and astigmatism >1D who underwent cataract surgery with implantation of toric IOL The mean rotational stability evaluated by using iTrace (Tracey Technologies) at the end of 1 month is 6.03 ± 4.43 degrees and the maximum rotation was 20 degrees. 15 % of the patients had rotation of more than 10 degrees. Venkatraman[14] et al studied 122 eyes of 77 patients for a period of 1 year and found that at 12 months, 96.7% of the IOLs were within 10 degrees of the target axis. There was no rotation seen after 6 months. The position of IOL is assessed in the slit lamp by adjusting the slit to the axis of markings on the IOL after dilatation. However this method of slit lamp based assessment is vulnerable to observer bias and also limited in accuracy by the system which has a ± 5 degree error. A similar study conducted on 30 eyes of 20 patients by Alexander Bachernegg15 et al showed that mean IOL misalignment at 3 months was 2.12 ± 3.45 degrees; range -2 to

± 5 degrees. But in their study they evaluated postop rotational stability using postoperative photographs compared with the picture indicating the torus position directly at the end of surgery where as in our study we assessed the rotational stability based on iTrace. The study by Kim[13] et al assessed the long-term effectiveness and rotational stability of the AcrySof toric intraocular lens (IOL) in correcting preoperative astigmatism in cataract patients. The results showed a significant reduction in refractive astigmatism and a consistent rotation of the IOL.

4.3. Refractive astigmatism

In this study found that the mean refractive astigmatism improved from 2.21 + 1.12 to 0.71+ 0.57 at the end of one year. Bachernegg[15] et al study revealed that after implantation of a toric IOL, the mean refractive astigmatism decreased from 1.93D + 0.90 to 0.30 + 0.54D at 3 months. Venkatraman et al. assessed residual astigmatism in 122 eyes of 77 patients, finding a post-operative residual cylinder of 0.36 D at 12 months, with 94% of eyes having less than 1 D residual astigmatism.

4.4. Posterior corneal astigmatism

In our study found that posterior corneal astigmatism has minimal impact on final refractive outcome. It compared predicted residual astigmatism with Barrett's toric calculator and a company-specific online calculator, which did not consider posterior corneal astigmatism. In our study the change in predicted refractive astigmatism from baseline by the company specific calculator was -0.17D at 99.5 ± 2.47 while that by the Barrett formula taking in to account the posterior corneal astigmatism was -0.14D at 107 ± 2.42. This difference was not statistically significant (Hotellings t test). Koch[16] et al study found that incorporating posterior corneal astigmatism can improve the results of residual astigmatism.

4.5. Surgically induced astigmatism & corneal biomechanics

The study used the Alpins method for vector analysis of astigmatism, focusing on 0.2 SIA with incisions at 20 degrees for left eye and 180 degrees for right eye. The method uses three fundamental vectors: target-induced astigmatism (TIA), surgically induced astigmatism (SIA), and the difference vector. TIA represents the intended astigmatic change, SIA the actual amount and axis of astigmatic change, and the difference vector represents the difference between the two. The study by Bachenergg[15] et al. did not consider the SIA when calculating toric IOL power. The study found a significant correlation between deformation amplitude and SIA, indicating the cornea's viscous damping and its biomechanical nature. The deformation of the stroma at the incision site affects the cornea's viscoelasticity, which is linked to surgically induced astigmatism and final cataract surgery outcome. Abnormal corneal biomechanics may influence toric IOL calculations and toric IOL outcome.

4.6. Post-operative outcomes & corneal biomechanics

The study found fluctuating best corrected visual acuity and refractive spherical equivalent in patients with poor deformation amplitude at 6 months, returning to normal by 1 year. Patients with good deformation amplitude showed stable visual acuity and refraction throughout the year. Further research is needed on factors contributing to refractive outcomes. Kim EC16 et al study found that corneal marking can cause post-operative toric IOLs misalignment, resulting in a loss of effectiveness of the toric IOLs.

Limitations

The final refractive outcome of toric IOLs is influenced by the accuracy of keratometric astigmatism measurement, the choice of TIOL power calculation formula, TIOL positioning and rotational stability over time, changes in keratometric astigmatism due to surgery, and post-operative refraction accuracy. Our study confirms the role of the formula used for TIOL power calculation and also shows that the change in Keratometric Astigmatism by the surgery is a function of the corneal biomechanics when identical incisions are used.

5. Conclusions

Toric IOL implantation is an effective and predictive way of managing pre-existing corneal astigmatism. It also produces better visual outcomes in the post-operative period and showed good rotational stability.

SIA is influenced by the corneal biomechanics and the outcomes could be improved by taking this into our calculations.

Recommendations:

In our study we did theoretical calculation of influence of posterior corneal astigmatism. For better understanding of the relative contribution of various parameters like posterior corneal astigmatism, surgically induced astigmatism and corneal biomechanics, we need to randomize patients into above mentioned subgroups and perform a multivariate analysis of the predictors.

Compliance with ethical standards

Disclosure of conflict of interest

There are no conflicts of interest to declare

Statement of ethical approval

The Narayana Nethralaya Ethics Committee (ECR/187/Inst/KAR/2013, EC Ref. No.: C/2014/06/02), Rajajinagar, Bangalore-560 010 approved the study.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

References

[1] Fam HB，Lim KL.Meridional analysis for calculating the expected spherocylindrical refraction in eyes with toric intraocular lenses. Cataract Refract Surg，2007,33（12）：2072–2076.

[2] Yoon JJ, Misra SL, McGhee CN, Patel DV. Demographics and ocular biometric characteristics of patients undergoing cataract surgery in Auckland, New Zealand. Clin Exp Ophthalmol 2016;44:106–13.Page 9/11

[3] Pan CW, Cheng CY, Sabanayagam C, et al. Ethnic variation in central corneal refractive power and steep cornea in Asians. Ophthalmic Epidemiol 2014;21:99–105.

[4] Semmens J, Li J, Morlet N, Ng J. Trends in cataract surgery and postoperative endophthalmitis in Western Australia (1980-1998): the Endophthalmitis Population Study of Western Australia. Clinical and Experimental Ophthalmology. 2003;31(3):213-219.

[5] Murthy G, Gupta S, John N, Vashist P. Current status of cataract blindness and Vision 2020: The right to sight initiative in India. Indian Journal of Ophthalmology. 2008;56(6):489.

[6] Hayashi K, Manabe S, Yoshida M, Hayashi H. Effect of astigmatism on visual acuity in eyes with a diffractive multifocal intraocular lens. Journal of Cataract & Refractive Surgery. 2010;36(8):1323-1329.

[7] Fan YY, Sun CC, Chen HC, Ma DH. Photorefractive keratectomy for correcting residual refractive error following cataract surgery with premium intraocular lens implantation. Taiwan J Ophthalmol 2018;8:149-58.

[8] Lam DK, Chow VW, Ye C, Ng PK, Wang Z, Jhanji V. Comparative evaluation of aspheric toric intraocular lens implantation and limbal relaxing incisions in eyes with cataracts and ≤ 3 dioptres of astigmatism. Br J Ophthalmol 2016;100:258-62.

[9] Lake JC, Victor G, Clare G, Porfírio GJ, Kernohan A, Evans JR. Toric intraocular lens versus limbal relaxing incisions for corneal astigmatism after phacoemulsification. Cochrane Database Syst Rev 2019;12:CD012801. doi: 10.1002/14651858.CD012801.pub2.

[10] Nagpal R, Sharma N, Vasavada V, Maharana PK, Titiyal JS, Sinha R, et al. Toric intraocular lens versus monofocal intraocular lens implantation and photorefractive keratectomy: A randomized controlled trial. Am J Ophthalmol 2015;160:479-86.e2.

[11] Nanavaty MA, Bedi KK, Ali S, Holmes M, Rajak S. Toric intraocular lenses versus peripheral corneal relaxing incisions for astigmatism between 0.75 and 2.5 diopters during cataract surgery. Am J Ophthalmol 2017;180:165-77.

[12] Mendicute J, Irigoyen C, Aramberri J, Ondarra A, Montés-Micó R. Foldable toric intraocular lens for astigmatism correction in cataract patients. Journal of Cataract & Refractive Surgery. 2008;34(4):601-607.

[13] Kim M, Chung T, Chung E. Long-Term Efficacy and Rotational Stability of AcrySof Toric Intraocular Lens Implantation in Cataract Surgery. Korean Journal of Ophthalmology. 2010;24(4):207.

[14] Venkataraman A, Kalpana. Visual outcome and rotational stability of open loop toric intraocular lens implantation in Indian eyes. Indian Journal of Ophthalmology. 2013;61(11):626.

[15] Bachernegg A, Ruckl T, Riha W, Grabner G, Dexl A. Rotational stability and visual outcome after implantation of a new toric intraocular lens for the correction of corneal astigmatism during cataract surgery. Journal of Cataract & Refractive Surgery. 2013;39(9):1390-1398.

[16] Kim EC, Hwang KY, Lim SA, Yi R, Joo CK. Accuracy of toric intraocular lens implantation using automated vs manual marking. BMC Ophthalmol 2019;19:169.