RESEARCH ARTICLE

Evaluation of visual outcomes with toric intraocular lens implantation using digital marker during cataract surgery

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Abstract

Objective: To assess the visual improvement and mean residual astigmatism in patients who underwent cataract surgery with toric intraocular lens.

Method: The retrospective, observational study was conducted at the Department of Ophthalmology, Aga Khan University Hospital, Karachi, and comprised data from January 1, 2018, to December 31, 2020, related to adult patients who had regular astigmatism of at least 0.75D and underwent cataract surgery with toric intraocular lens implantation using a digital marker. The patients were followed up on post-operative days 1, 7, 30, 90 and 180. Along with age, the degree of astigmatism was noted. The visual acuity was calculated pre- and post-operatively. The mean residual astigmatism was then noted for all patients post-operatively. Data was analysed using SPSS 22.

Results: The sample comprised 240 eyes of 177 patients; 99(55.9%) males and 78(44.1%) females. The mean age of the sample was 62.5±10.6 years. The mean unaided visual acuity improved post-operatively from 0.57±0.38 to 0.07±0.22 at 90 days. At the 30-day follow-up, mean residual astigmatism had reduced from 1.52±0.84 to 0.01±0.09 (p<0.001). The mean intraocular lens rotation from the intended axis was 0.73°±0.92° on day 30.

Conclusion: Toric intraocular lens implantation using a digital marker could effectively reduce the post-operative cylinder, and improve the unaided visual acuity following cataract surgery.

Keywords: Intraocular lens implantation, Cataract, Toric IOL, Accuracy of toric IOL. (JPMA 74: 450; 2024)

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Introduction

Astigmatism is one of the most common disorders known to affect the cornea and can lead to reduced visual acuity (VA)and increased dependence on spectacles. If left uncorrected, it could significantly affect patient's independence, quality of life and wellbeing.[1] Anderson et al. reviewed the burden of corneal astigmatism in patients undergoing cataract surgery. They reported pre-existing astigmatism ≥1D in up to 47% of the cataract eyes.[1] A study conducted on Indian population also documented astigmatism of >1.0D in most of the patients undergoing cataract surgery.[2] Sirang et al. published their data of northern Pakistani population and observed astigmatism in 18.3% of their patients.[3]

There are several methods currently in existence exist that can effectively treat corneal astigmatism. These include, but are not limited to, arcuate keratotomy, limbal relaxing incision, steep axis incision, cataract incisions and implantation of toric intraocular lens (IOL). Excluding toric IOLs, techniques for correcting astigmatism, present certain limitations, such as poor predictability in eyes with higher levels of astigmatism, owing to differences in corneal biomechanics and the occurrence of long-term mechanical instability.[4] Shimizu et al. conceptualised toric IOLs in 1941 to correct pre-existing astigmatism.[5] Present-day cataract surgery has the potential of correcting both the spherical and cylindrical refractive errors.

The cost burden of residual uncorrected astigmatism after cataract surgery is primarily due to the cost of spectacles. The lifetime cost of this was estimated to range from $1,786 to $4,629 in Europe and $2,151 to $3,440 in the United States.[1] In contrast, astigmatism correction during cataract surgery appears to improve visual outcomes and results in overall lifetime cost savings compared to astigmatism correction with post-operative vision correction.[1]

In healthy phakic eyes, increasing astigmatism follows exponential relationship to reducing distance VA, where eyes retain 20/20 Snellen acuity for 0.25D of astigmatism.[6] With increasing astigmatism, however, VA is observed to reduce to 20/25 with 0.75D, 20/40 with 1.50D, 20/100 with 3.00D and to 20/200 with 4.0D of astigmatism.[7] In cases

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where the level of astigmatism is 0.5D or greater, placement of a toric IOL shows greater improvements in the visual outcomes.[6]

Toric IOL is an effective choice in treating corneal astigmatism and has been reported to result in a predictable, stable and marked increase in VA. Toric IOL placement and correct alignment with the digital marker can offer increased predictability of the outcomes post-operatively. To the best of our knowledge, no studies have yet reported the effectiveness of implanting toric IOLs using a digital marker during cataract surgery to correct corneal astigmatism in a Pakistani population.

The current study was planned to assess the visual improvement and mean residual astigmatism (MRA) in patients who underwent cataract surgery with toric (IOL).

Materials and Methods

The retrospective, observational study was conducted in October 2022 at the Department of Ophthalmology, Aga Khan University Hospital (AKUH), Karachi, and comprised data from January 1, 2018, to December 31, 2020.

After obtaining exemption from the institutional ethics review committee, data was retrieved using non probability convenience sampling technique. Those included were adult patients who had regular astigmatism of at least 0.75D and underwent cataract surgery with toric IOL implantation using a digital marker. All surgeries had been performed by a single surgeon. Patients who had irregular astigmatism, astigmatism of <0.75D, who underwent extra-capsular cataract extraction, had capsular rupture during surgery, were aged <18 years or had incomplete or missing records were excluded.

All patients who presented with cataracts had undergone standard eye examination that included unaided VA (UDVA), best-corrected visual acuity (BCVA), IOP measurements, dilated fundal examination, and slit lamp examination. IOL Master partial coherence inferometry (PCI) device (Carl Zeiss Meditec AG, Germany) was used to calculate axial length (AL), keratometry (K) readings along with their respective axes, and anterior chamber depth (ACD). Patients who had significant astigmatism of ≥0.75D were then subjected to corneal topography using Pentacam device. Online IOL manufacturer's tools and IOL calculation formula software (Kane – Australia, Barrett II - Australia, Alcon online toric calculator – Switzerland-USA) were used for appropriate IOL selection for each patient.

Patients were counselled in detail regarding all available lenses, including their respective advantages and drawbacks. The final decision of the IOL to be implanted after detailed assessment was dependent on the patient's choice.

IOLs included Acrysof IQ Toric SN6ATx (Alcon Laboratories Inc., Switzerland-USA), which is Alcon's one-piece aspheric hydrophobic acrylic monofocal lens having spherical correction range from +6.00D to +30.0D and astigmatic correction range from +0.75D to +4.17D.[8]

Standard surgical protocols were used in all cases. A 10% povidone-iodine solution was applied to the skin around the eye. A 5% solution was also applied to the conjunctival sac 5 minutes before surgery. The surgery was performed by a clear corneal phacoemulsification technique using Centurion Vision IOL Sytem (Alcon Laboratories Inc. Switzerland-USA). The incision and IOL placement were done using Verion digital marker (Alcon Laboratories Inc. Switzerland-USA).

The patients were followed up on post-operative days 1, 7, 30, 90 and 180. On each visit, UDVA, BCVA, dilated fundal examination and slit lamp examination were carried out and values were recorded. In case of a toric lens, its position was noted at the slit lamp using thin coaxial slit to ensure the lens was in correct alignment. If significant rotation >10 degrees was present, repositioning was considered.

Data was analysed using SPSS 22. A nominal distribution of the population was supposed as when the sample size is large, it is more likely to resemble the shape of the normal distribution curve. This helps with making inferences about the population based on the characteristics of the sample and to draw conclusions about the broader population based on their observations from the sample. It implies that with a sufficiently large sample, the data points are more likely to be distributed in a way that is similar to the entire population, making the sample a reliable representation of the population as a whole. Mean ± standard deviation were determined for continuous variables, such as age, logarithm of the minimum angle of resolution (logMAR) VA and astigmatism. Two-tailed t test was used to compare pre-operative and post-operative values for both was VA and MRA. P<0.05 was taken as statistically significant.

Results

The sample comprised 240 eyes of 177 patients; 99(55.9%) males and 78(44.1%) females. The mean age of the sample was 62.5±10.6 years (range: 26-87 years). A total of 196(81.6%) eyes had nuclear sclerotic (NS) cataract between grades 2 and 3. Comorbidities and baseline assessments were noted for the sample (Table 1). Mean astigmatism was 1.52±0.84D (range: 0.75-5.0D) as per subjective preoperative assessment. Biometry calculations done pre-operatively revealed a mean cylindrical value of 1.52±0.73D (range: 0.75-4.81D). All patients were followed

up for at least 6 months post-operatively with mean follow-up period being 11.6±4.9 months.

The mean UDVA improved post-operatively from 0.57±0.38 logMAR to 0.15±0.22 logMAR on day 7 post-operatively. This improved further to 0.07±0.22 logMAR on days 30 and 90. Both these differences were highly significant compared to baseline UDVA (p<0.001). Of the total eyes, 188(78.3%) had UDVA of 20/20 post-operatively, and 230(95.8%) had UDVA of 20/40 or better. The mean line improvement on the Snellen chart following toric IOL implantation was 5.1±3.1 (range: -1-13). There was post-operative worsening of one line on the Snellen chart in 1(0.56%) patient on day 90 secondary to the development of diabetic retinopathy. Post-operative UDVA and BCVA values for the entire sample were noted separately (Table 2).

Table-1: Patient demographics and preoperative biometrics (n=177).

Parameter	Value, (%, Mean or Range)
Eyes	240
Mean Age (years)	62.5±10.6
Gender	
Male	99 (55.9%)
Female	78 (44.1%)
Comorbid	
Diabetes	69 (38.9%)
Hypertension	80 (45.2%)
Glaucoma	3 (1.7%)
Retinal	8 (4.5%)
Others	34 (19.2%)
Nuclear Sclerotic (NS) Cataract	
NS 1	24 (10%)
NS 2	97 (40.4%)
NS 3	99 (41.3%)
NS 4	20 (8.3)
Keratometry (K) readings	
K1	43.44±1.56 (38.18-47.20)
K2	44.93±1.60 (39.06 - 49.20)
Biometry Cylinder	1.52±0.74 (0.75-4.81)
Subjective Cylinder	1.52±0.83 (0.75-5.00)
Auto-refraction Cylinder	1.85±1.05 (0.7-7.75)
Axial length	23.69±1.13 (20.95-26.81)
Spherical intraocular lens (IOL) power	20.63±3.27

Table-2: Mean visual acuity.

Day	Mean (Snellen)	Mean±SD (logMAR)	p-value (two tailed t-test)
Preoperative	20/74	0.57±0.38	
Day 7	20/27	0.14±0.22	<0.001
Day 30	20/23	0.07±0.22	<0.001
Day 90	20/22	0.06±0.22	<0.001
Preoperative	20/50	0.40±0.33	
Day 7	20/27	0.14±0.20	<0.001
Day 30	20/22	0.06±0.21	<0.001
Day 90	20/22	0.06±0.21	<0.001

SD: Standard deviation, logMAR: Logarithm of the minimum angle of resolution.
*Two tailed t test used to compare means.

Table-3: Mean residual astigmatism.

Cylinder	Preoperative (Mean±SD)	Postop Subjective Week 1	p-value	Postop Subjective Day 30	p-value
Subjective	1.52±0.83	0.03±0.25	<0.001	0.01±0.09	<0.001
Biometry	1.52±0.74	0.03±0.25	<0.001	0.01±0.09	<0.001
Autorefractive	1.85±1.05	0.03±0.25	<0.001	0.01±0.09	<0.001

SD: Standard deviation. *Post-operative subjective week 1 and 1 month compared to preoperative subjective, biometry and auto-refraction using two tailed t test to compare the means.

On post-operative day 7, MRA was 0.03±0.25D (range: 0-3D). On days 30 and 90, MRA had reduced to 0.01±0.09D (range: 0-1D). Compared to pre-operative auto-refraction, subjective refraction and biometry values, the reduction post-operatively was significant (p<0.001) (Table 3).

The mean IOL rotation from the intended axis was 1.01±1.81° (range: 0-11°). At 30 days post-operatively, the mean IOL rotation was 0.73±0.92° (range: 0-5°). There was no further change in the IOL axis after, signifying that most IOL rotations occurred in the first few weeks of toric IOL implantation. A total of 4(1.67%) eyes had IOL misalignment after surgery of >5°. Three (75%) of these patients had misalignment observed on day 7 and they were subjected to redialling, which corrected the IOL position. The IOL then remained stable on all subsequent follow-ups. The remaining 1(25%) patient had IOL rotation of 5° 2 weeks after surgery. Redialling was offered, but the patient expressed satisfaction with the results and opted not to undergo redialling as he had a UDVA of 20/30 and a residual astigmatism of 0.5D. All 4(100%) of these patients had axial lengths >25mm (range: 25.2-26.8mm).

Discussion

Corneal astigmatism can be addressed by various means, including, but not limited to, surgical intervention on the cornea to achieve corneal flattening or implantation of toric IOL. Using surgical means to correct corneal flattening and treating astigmatism can pose a risk owing to unpredictability and variability during healing that can affect the final outcomes.[9] Implantation of toric IOL is undertaken during cataract surgery itself without any additional procedures. Toric IOLs for astigmatic correction have been found to improve post-operative UDVA and have a higher spectacle independence and lower residual astigmatism compared to non-toric IOLs.[9] Holland et al. concluded that patients with a pre-operative astigmatism >0.75D benefited more from toric IOL implantation.[10] In the current study the cut-off of astigmatism was 0.75D, as determined by an agreement among at least two of the following: pre-operative biometery, auto-refraction and

subjective refraction.

Various studies have evaluated the visual outcomes after implantation of toric IOL. Huang et al. reported a UDVA of 20/25 or better in 80% of eyes.[11] Similarly, using a different IOL model, DeSilva et al. showed that 79% of eyes had UDVA of 20/40 or better.[12] Alio et al. on the other hand used Acri. Comfort 646 TLC (Acri. Tec GmbH) and Acrysof toric models (Alcon Laboratories, Inc.) and achieved a UDVA of 20/40 or better in 76.1% eyes.[13] In the current study, Acrysof SN6ATx IOL was used for all patients. Our study found a post-operative UDVA of 20/25 or better in 87.1% of the eyes, and 20/40 or better in 95.8% of the eyes. This difference was significant compared to the pre-operative UDVA. Only 1 patient had loss of 1 line after the surgery compared to pre-operative values. This was secondary to the development of diabetic retinopathy 4 months post-operatively. These results were maintained on 3-month and 6-month follow-ups. This shows that the outcomes of toric IOL were in agreement with global data. Moreover, the eyes with early onset macular degeneration were not excluded, showing that toric IOl can potentially be used in early macular degeneration for the correction of astigmatism.

The MRA in the current study decreased to 0.03±0.25 at 1 week, which further reduced to 0.01±0.09 post-operatively from pre-operative values of 1.52±0.74 using biometry and 1.52±0.84 subjectively (p<0.001). This demonstrated that the use of toric IOL was an effective means of reducing corneal astigmatism inserted using Verion digital marker in treating corneal astigmatism of 0.70D or more.

The efficacy and outcome of toric IOL depends on many factors, including surgically-induced astigmatism, anterior and posterior corneal astigmatism, and the accuracy of IOL positioning during implantation.[14] In the current study, every patient underwent corneal topography in order to determine anterior and posterior corneal astigmatism, keratometery readings, and ruled out irregular astigmatism. The surgically-induced astigmatism was kept into account during IOL power calculations, using biometery readings (IOL Biomaster 500). IOL power was calculated using Barrett's II Universal Formula,[15] Kane,[16] Alcon online toric calculator and Verion digital marker. The incision angle and IOL placement angle were also determined using Alcon online toric calculator and Verion digital marker.

In order to achieve optimal correction of astigmatism, it is of utmost importance that the toric IOL is precisely aligned during surgery. The toric IOL has marks along the flat meridian to enable its placement in the correct position. These marks can serve as a guide in the post-operative period in order to assess the IOL mal-rotation as well.[17] A limitation to the effectiveness of toric IOL in achieving the best possible outcomes is post-operative rotational stability or mal-alignment. Prior studies have shown that for every degree of rotation from the target axis, the effectiveness of toric IOL reduces by ~3.3%, with a 3° rotation reducing it by 10%. If a rotation of >30° occurs, it will lead to an increase in astigmatism.[18] Traditionally, manual marking has been used pre-operatively to mark the calculated flat meridian on the anterior surface of the patient's eye. Manual marking has to be undertaken with the patient sitting upright as there is cyclorotation of 2-3° once the patient is in the supine position. This can even extend up to 14°.[19] Manual marking used alone, therefore, can result in significant post-operative refractive errors.[20]

The Verion digital marker offers many advantages over manual marking. It incorporates reference image capturing pre-operatively, obtaining kertatometery readings, determining toric IOL power, planning of incision and implantation site for the IOL and an overlay system that can be used live intra-operatively for accurate guidance both for incision and IOL implantation and alignment. Even though many studies have not found a significant difference in the post-operative VA and residual astigmatism between manual and digital markers, many studies have found that toric IOLs placed with the help of a digital marker have better post-operative alignment and improved rotational stability.[21-23] In the current study, toric IOL was implanted using Verion digital marker where the mean IOL rotation at 1 week was 1.01±1.81°. This reduced further to 0.73±0.92° at 1-month follow-up after which it remained mostly stable. This shows that most of the IOL rotation occurred within 1 week and 1 month post-operatively. Only 4 of the patients required redialling of IOL after a rotation of 8-10°. All four of the patients had relatively larger axial lengths (>25mm), which could have contributed to the IOL misalignment. A study conducted in Portugal reported a mean IOL rotation of 2.43±1.55° with no patient needing realignment.[24] Similarly, a nationwide survey done in Italy reported a mean arithmetic rotation of toric IOLs to be –0.2±3.5° and the mean absolute rotation was 1.6±3.1°.[25]

There are several other factors that influence rotational stability of toric IOLs, the shape and size of IOL being the most evident. Chang et al. evaluated the post-operative rotation for 2 toric IOLs, Acrysof and Tennis, and concluded that, compared to Tennis, the Acrysof IOL was less predisposed to rotate with 91.9% of Acrysof IOLs rotating <5° compared to 81.8% of Teniis IOLs.[26] A California-based study comparing 4,203 TL/TF IOL (Star) and the Acrysof SN60T at 1 month found the mean rotation of 5.6G 8.49° and 3.4G 3.4°.26 Entabi et al. reported a mean rotation of

3.4º at 16 weeks with the T-flex 623T IOL (Rayner) in a patient population from the United Kingdom.[27] The current study used Alcon Acrysof SN6ATx and showed a relatively lower IOL rotation. All the cases of misalignment were detected within the 1st week, further reinforcing the understanding that most IOL rotations occur earlier in the post-operative course.

The other factors that can contribute towards decreasing the toric IOL stability include capsular bags having a large diameter. These can have a positive correlation with the axial length. Many studies have indicated that axial length is positively related to misalignment of the IOL axis.[18] Possible reduction of equatorial friction in larger capsular bags might contribute towards IOL reducing their stability.[14] In longer axial lengths, the IOL power is lower and the lens is itself thinner which could further decrease the stability.[14] Moreover, patients with higher axial myopia can additionally have weaker zonules, which can impact stability. In the current study, all 4 patients who had rotation of >5º causing residual astigmatism had axial lengths >25mm which could reinforce the correlation.

The strengths of the studies were its tertiary care setting that ensured good medical practice, and the fact that all surgeries were done by a single surgeon, reducing the inter-technique variability. The study had a relatively larger number of eyes undergoing toric IOL implantation. Thorough pre-operative assessment was carried out for all patients to make the calculations of astigmatism more accurate and planning for an improved outcome. Even though many studies have been undertaken comparing manual and digital markers, to the best of our knowledge, the current study is the first of its kind in the region evaluating the outcomes of toric IOL with the digital marker alone.

The current study has limitations, like having a retrospective design, relying on data collection through patient records. Besides, the digital marker was not compared with the manual marking technique, hence, it cannot be conclusively stated that digital marker offers better precision than manual marking in the region. Larger randomised trials are needed to evaluate the relationship better.

Conclusion

Toric IOL implantation can effectively reduce post-operative astigmatism and improve UDVA following cataract surgery. Use of a digital marker might lead to lesser IOL rotation, increasing IOL stability.

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IKJ: Conceptualization, writing, reviewing, editing, supervision, project administration, data interpretation.

SM: Literature search, methodology, writing original draft and preparation with discussion, writing, reviewing, editing, data collection and interpretation, formal analysis.

TSA: Reviewing, editing, discussion, analysis, supervision.

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AAW: Literature search, data collection and analysis.

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