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Original Research Paper

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A COMPARATIVE STUDY OF EFFECTIVENESS OF CUSTOMIZED TORIC INTRAOCULAR LENS IMPLANTATION VERSUS STANDARD TORIC INTRAOCULAR LENS

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ABSTRACT

Purpose -To compare the effectiveness of Customized toric intraocular lens implantation versus Standard toric intraocular lens implantation in cataract surgery done by phacoemulsification. **Methods**-This prospective, randomized, interventional and comparative study with parallel design enrolled 60 patients diagnosed with cataract and fulfilling the inclusion criteria, who presented to the Outpatient Department of Ophthalmology, Maharani Laxmi Bai Medical College, Jhansi, Uttar Pradesh between July 2020 and August 2021(14 months). **Results**-The mean UDVA (logMAR) significantly increased from 1.04±0.474logMAR preoperatively to 0.43±0.112logMAR 3 months postoperatively in Group-A (pvalue=0.002) and from 0.99±0.375logMAR preoperatively to 0.32±0.092logMAR 3 months postoperatively in Group-B (pvalue=0.004). The mean BCVA (logMAR) significantly increased from 0.82±0.370logMAR preoperatively to 0.25±0.051logMAR 3 months postoperatively in Group-A (pvalue=0.001) and from 0.80±0.288logMAR preoperatively to 0.25±0.051logMAR 3 months postoperatively in Group-B (pvalue=0.006). The mean refractive cylinder significantly decreased from 2.72±0.989D preoperatively to 0.22±0.163D 3 months postoperatively in Group-A (pvalue=0.001) and from 2.91±0.788 D preoperatively to 0.16±0.154 D 3 months postoperatively in Group-B (pvalue=0.002). The mean amount of toric IOL axis rotation after 3 months was 3.86±1.433Degree in Group-A and 1.64±0.731Degree in Group-B which was statistically significant (pvalue =0.0001). No eye had IOL rotation of more than 6Degree in Group-A and 3Degree in Group-B. **Conclusion**-All 56 patients received follow-up examinations for 3 months. Although, both standard and customized toric IOLs appear to be effective alternatives to correct preexisting astigmatism between 1.5D and 5D, the customized toric IOL showed less IOL rotation and was better in rotational stability (statistically significant) than standard toric IOL at 3 months follow up.

KEYWORDS : Cataract, Astigmatism, Toric intraocular lens

INTRODUCTION

It is clouding of lens in eyes which leads to decrease in vision[1]. Cataracts develop slowly and affect one or both eyes[1]. Symptoms include faded colors, blurred vision, halos around light, glare, trouble seeing at night[1], difficulty in driving[2]. Cataracts cause half of all cases of blindness and 33% of visual impairment worldwide[3,4]. Etiology includes age, trauma, radiation, smoking, alcohol, metabolic diseases like diabetes mellitus, steroids.

It is classified as-

A) Morphological classification:

1. Subcapsular cataract- Anterior and posterior subcapsular cataract
2. Nuclear cataract
3. Cortical cataract
4. Polar cataract

B) Based on degree of maturity:

- IMMATURE CATARACT-lens is partially opaque
- MATURE CATARACT-lens is completely opaque
- HYPERMATURE CATARACT-anterior capsule is shrunken and wrinkled or there is liquefaction of cortex and sinking of nucleus inferiorly(Morgagnian cataract)

Cataracts are classified by using **Lens Opacities Classification System LOCS III**. In this system, cataracts are classified based on type; nuclear, cortical, or posterior. The cataracts are further classified based on severity(**scale 1 to 5).**

Phacoemulsification is most widely used cataract surgery in developed world [14-15]. This procedure uses ultrasonic energy to emulsify cataract lens. Postoperative recovery period is short. Patient is ambulatory on day of surgery, but advised to move cautiously and avoid straining or heavy lifting for a month. Eye is patched on day of surgery and use of eye shield at night is suggested for several days after surgery[5].

Astigmatism is type of refractive error in which eye does not focus light evenly on the retina[6]. This results in blurred vision at all distances [6]. Other symptoms include eyestrain, headaches, and trouble in driving at night[19].It is due to irregular curvature of cornea or abnormalities in lens of eye[6-7]

STEP LADDER APPROACH IN MANAGING ASTIGMATISM:

- <1D:Clear corneal surgical incision is placed on steeper corneal axis
- 1-4D:Toric IOL or limbal relaxing incision
- 4-6D:High powered toric IOL or combination of toric IOL with limbal relaxing incision
- >6D:High powered toric IOL or Customized toric IOL

Toric IOL: It is type of toric lens used to correct preexisting corneal astigmatism at time of cataract surgery. Cataract surgery with implantation of toric IOL is essentially same as cataract surgery with conventional IOL. Like toric contact lenses, toric IOLs have different powers in different meridians of lens, and must be positioned on correct meridian to reverse preexisting astigmatism. If toric IOL is on incorrect meridian, it may need to be repositioned in second procedure[9].

MEATHOD AND MATERIAL

This **prospective, randomized, interventional and comparative study** with parallel design enrolled **60 patients diagnosed with unilateral or bilateral cataract** and fulfilling inclusion criteria, who presented to **Outpatient Department of Ophthalmology, Maharani LaxmiBai Medical College, Jhansi, Uttar Pradesh** between **July 2020 and August 2021 (14 months).**

Ethical standards:

The study was in accordance with **Ethical Standards Committee** on human experimentation (institutional or regional) and abided by tenets of **Declaration of**

Helsinki(1975 and 2000 revision). Necessary permission from **Institutional Ethical and Research Committee** was obtained.

Study Groups:
The 60 patients included In the study were randomly divided into two groups before surgical intervention as follows:

- **Group-A** included 30 patients who were to be operated for cataract extraction by **Phacoemulsification** with "**Standard toric IOL**" implantation.
- **Group-B** included 30 patients who were to be operated for cataract extraction by **Phacoemulsification** with **"Customized toric IOL"** implantation. Randomization was done using computerized random number tables. Case record numbers were used as method of concealment.

Inclusion Criteria
All patients who complied to study protocols and were willing to give written consent in prescribed format were included In the study.

- Age 40 to 70 years
- Patients who agreed to participate In the study and were willing to give informed written consent
- Patients diagnosed with unilateral or bilateral cataract and having impaired visual acuity in Snellen Chart 6/12 or worse
- Patients with regular corneal astigmatism of 1.5D to 5D
- Patients with preoperative good corneal topography: good corneal endothelial cell counts, clear cornea, well dilated pupils under medication, intact zonular apparatus, and good ocular tone
- Patients with confirmed negative RTPCR report for covid 19 infection
- Patients with agreeable or open personalities(Type B) who tend to adapt better to toric IOL implantation

Exclusion Criteria
Patients who refused to give written consent or refused to abide by routine follow up protocols were excluded from study.

- Patient age <40 years or >70 years
- Irregular corneal astigmatism
- Corneal astigmatism <1.5D or > 5D
- Visually significant ocular pathology
- Previous ocular surgery(including refractive laser surgery) and/or trauma
- Signs of corneal endothelial
- decompensation present
- Subluxated lens, zonular instability and posterior capsular dehiscence
- Tear film instability
- Pupillary abnormalities
- Neuro-ophthalmic diseases
- Ophthalmic pathology that might affect postoperative visual function, such as corneal diseases(corneal dystrophies,keratoconus, epithelial basement membrane dystrophy/EBMB etc.), glaucoma, ocular trauma, Fuch's dystrophy, microphthalmos, Congenital anomalies, recurrent episodes of anterior uveitis with synechiae formation(complicated cataract), glaucoma or earlier filtration surgery, corneal dystrophy, scarring, retinal diseases, diabetes and hypertension
- Patients who developed intraoperative complications such as posterior capsule rent(PCR) or extension of Capsulorrhexis or zonular dialysis
- Pregnant females and lactating mothers
- Patients with Type A personality who are more likely to fare poorly with toric IOL implantation

Written consent:
Patients who satisfied inclusion criteria were asked to sign informed consent before participating In the study.

Baseline evaluation of patients:
Detailed history was taken and complete ocular examination was done in diffuse torch light. Uncorrected distance visual acuity(UDVA) and Best corrected visual acuity(BCVA) were recorded.

Slit lamp biomicroscopy:
Slit lamp biomicroscopy with diffuse illumination, focal illumination and retroillumination was done. Grading of cataract was done by LOCIII[117]

- **Nuclear opalescence/Nuclear colour:** Grading(NC1 to NC6)
- **Cortical spokes:** Grading(C1 to C5)
- **Posterior subcapsular cataract:** Grading(P1 to P5)

Each eye was graded for nuclear sclerosis on scale of 1 to 5 by comparing observer's findings to standard photographs based on Emery Little classification:

- **Grade 1:** Soft nucleus-Transparent to pale grey
- **Grade 2:** Slightly hard nucleus-Grey to yellow grey
- **Grade 3:** Moderately hard nucleus-yellow with tinges of grey
- **Grade 4:** Hard nucleus-yellow amber
- **Grade 5:** Very hard nucleus-Amber to brown/black

Biometry:
An accurate biometry is prerequisite for precise IOL power calculation. Axial length was estimated by either ultrasonic biometry or optical systems like IOL Master(Carl Zeiss Meditec, Germany) and Lenstar(Haag Streit, Switzerland).

Keratometry estimation is of importance to determine power and axis of toric IOL. Various instruments based on different principles were used for keratometry estimation, like manual and automated Keratometers. Preoperative keratometry was performed by same operator using two different methods: optical coherence biometer(Lenstar LS 900®, Haag–Streit AG, Koeniz, Switzerland) and manual keratometer, to assess magnitude and axis of astigmatism. Keratometry was calculated by two methods to look for concordance and avoid great differences in preoperative keratometry values to avoid postoperative refractive surprise. Values of optical keratometry were relied upon. Axial length was measured by optical coherence biometry. Axial length was matched in both groups as bag size tends to be larger in long eyes and this is an important factor in toric IOL rotation. Four formulas were used(SRK-T, Holladay, Hoffer Q, and Universal Barrett formula) to calculate standard error(SE) of toric IOL. Four formulas were employed to look at concordance of calculated IOL power(spherical equivalent). We used Universal Barrett formula for SE calculation as this is more accurate than other formulas for all axial lengths.

The determination of model of toric IOL to be implanted and axis at which it should be placed with an aim of minimum residual cylinder was performed using online calculator (www.acrysoftoriccalculator.com and www.zcalc. meditec. zeiss.com). We did not do any vector analysis.

Surgically induced astigmatism(SIA) of 0.37 was incorporated in each calculation(based on his previous surgical results using 2.8 mm incision).

Surgical procedure:
All surgeries were performed by single surgeon. Toric marking was done under topical anesthesia at 3, 6, and 9 O'clock using Bubble marker from Appasamy, while patient was made to sit to avoid cyclotorsion errors. Patient was made to lie supine and prior to initiation of surgery, site of main incision and placement axis was marked using Mendez ring and toric marker. Phacoemulsification surgery was performed as routine procedure. Toric IOL was implanted in the bag with

orientation of IOL just few degrees short of intended axis as per toric calculator. After thorough aspiration of viscoelastic, IOL axis was aligned to premarked placement axis.

Figure 1: Showing procedure of toric IOL implantation during phacoemulsification cataract surgery.

Statistics:

Data was analysed by Statistical Package for Social Sciences(SPSS for windows, version 25.0). Descriptive statistics included mean and standard deviation for numerical variables, and percentage of different categories for categorical variables. Comparision of results of two types of IOLs by Student's unpaired 't'test, "p"value of < 0.05 was indicative of significant association.

Follow-up:

Postoperative evaluation was done at day 1, 1 week, 1 month, and 3 months. UDVA, BCVA, keratometry and IOL position after full mydriasis were noted at 1 week, 1 month, and 3 months by masked observer on slit lamp biomicroscope. Because iTrace Aberrometry was not available at our institute, position of IOL was checked after full dilatation of pupil, using retroillumination on photo slit lamp and using reticule on slit lamp to measure angle of placement.

RESULT

Total of 60 patients who fulfilled inclusion criteria were selected for this study, out of which 4 patients(2 patients of each study group) were excluded(drop outs) at initial stage of study. Both study groups finally included 28 eyes of 28 patients(total 56 eyes of 56 patients).

The results of study are summarized as follows-

1. Mean age was 59.71±7.850years in Group-A and 60.64±7.238years in Group-B.

2. Mean UDVA(logMAR) significantly increased from 1.04±0.474logMAR preoperatively to 0.43±0.112logMAR 3 months postoperatively in Group-A (pvalue=0.002) and from 0.99±0.375logMAR preoperatively to 0.32±0.092logMAR 3 months postoperatively in Group-B (pvalue=0.004).

Table 1:follow-up Of Mean Udva (logmar) In Operated Eye

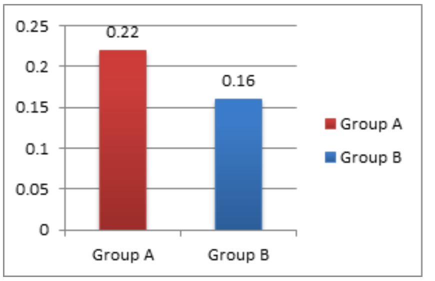
UDVA (logMAR) ON FOLLOW-UP	Group-A	Group-B	pVALUE
1 week	0.57±0.081	0.54±0.084	0.20(NS)
1 month	0.43±0.112	0.42±0.099	0.80(NS)
3 months	0.43±0.112	0.32±0.092	**0.003(S)**

Mean BCVA (logMAR) significantly increased from 0.82±0.370logMAR preoperatively to 0.25±0.051logMAR 3 months postoperatively in Group-A (pvalue=0.001) and from 0.80±0.288 logMAR preoperatively to 0.25±0.051 logMAR 3 months postoperatively in Group-B (pvalue=0.006).

Table 2:follow-up Of Mean Bcva (logmar) In Operated Eye

BCVA (logMAR) ON FOLLOW-UP	Group-A	Group-B	p VALUE
1 week	0.41±0.086	0.40±0.074	0.62(NS)
1 month	0.28±0.086	0.25±0.058	0.07(NS)
3 months	0.25±0.051	0.25±0.051	0.60(NS)

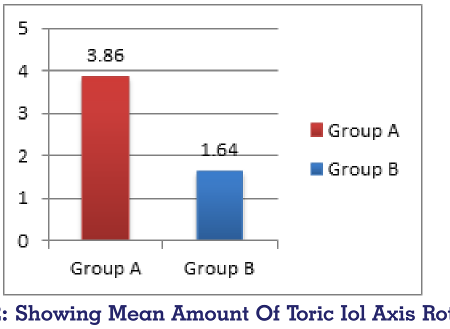
The **mean refractive cylinder significantly** decreased from 2.72±0.989D preoperatively to 0.22±0.163D 3 months postoperatively in Group-A (pvalue=0.001) and from 2.91±0.788D preoperatively to 0.16±0.154D 3 months postoperatively in Group-B (pvalue=0.002).



Graph 1: Showing Mean Residual Astigmatism (degree) In Operated Eye

In the last **follow up at 3 months, mean UDVA** in **Group-B**(0.32±0.092) was better (**statistically significant** pvalue= 0.003) than Group A(0.43±0.112).

The **mean amount of toric IOL axis rotation** after 3 months was 3.86±1.433Degree in Group-A and 1.64±0.731Degree in Group-B which was **statistically significant** (pvalue =0.0001). No eye had IOL rotation of more than 6Degree in Group-A and 3Degree in Group-B



Graph 2: Showing Mean Amount Of Toric Iol Axis Rotation (degree) After 3 Months

DISCUSSION

Improved in both groups. **Mean UDVA (logMAR)** significantly increased from 1.04±0.4741 ogMAR preoperatively to 0.43±0.112logMAR 3 months postoperatively in Group-A (pvalue=0.002) and from 0.99±0.375logMAR preoperatively to 0.32±0.092logMAR 3 months postoperatively in Group-B (pvalue=0.004). **Mean BCVA (logMAR)** significantly increased from 0.82±0.370logMAR preoperatively to 0.25±0.051logMAR 3 months postoperatively in Group-A (pvalue=0.001) and from 0.80±0.288logMAR preoperatively to 0.25±0.051logMAR 3 months postoperatively in Group-B (pvalue=0.006). **Mean refractive cylinder significantly** decreased from 2.72±0.989D preoperatively to 0.22±0.163D 3 months postoperatively in Group-A (pvalue=0.001) and from 2.91±0.788D preoperatively to 0.16±0.154D 3 months postoperatively in Group-B (pvalue=0.002). In the last **follow up at 3 months, mean UDVA** in Group-B (0.32±0.092) was better **(statistically significant** pvalue=0.003) than Group-A(0.43±0.112).

In the study by Na Yeon Jung et al[10], after cataract surgery, UDVA, BCVA, and cylindrical errors were significantly (pvalue<0.05) improved in both groups. **Mean UDVA (logMAR)** significantly increased from 0.50±0. 17logMAR preoperatively to 0.09±0.09logMAR 3 months postoperatively in Group-I and from 0.38±0.13 logMAR preoperatively to 0.08±0.12 logMAR 3 months postoperatively in Group-II. **Mean BCVA(logMAR)** significantly (pvalue<0.05) increased from 0.30±0.18logMAR preoperatively to 0.02±0.02logMAR 3 months postoperatively in Group-I and from 0.21±0.13 logMAR preoperatively to 0.01±0.02 logMAR 3 months postoperatively in Group-II. **Mean refractive cylinder** significantly decreased from 1.06±0.94 D preoperatively to 0.31±0.29 D 3 months postoperatively in Group-I and from 1.83±1.29 D preoperatively to 0.41±0.33 D 3 months postoperatively in Group-II. UDVA in Group I tended to be better compared to that of Group B. However, the difference was not statistically significant (pvalue=0.147).

In the study by Yueqin Chen et al[11], after surgery, UDVA improved significantly in all patients(pvalue<0.001). Three months postoperatively, mean UCVA was 0.19±0.11logMAR in Group-I and 0.19±0.12logMAR in Group-II. There was no statistically significant difference in UDVA between two group (pvalue=0.550). There was significant reduction of refractive astigmatism in two groups after surgery (pvalue<0.001). Three months postoperatively, the mean refractive astigmatism was 0.45±0.24D in Group-I and 0.49±0.29D in Group-II. There was no statistically significant difference in refractive astigmatism between the two groups (pvalue= 0. 49 2).

In the study by Sheetal A Seth et al[12], the visual acuity as assessed by mean logMAR UDVA at 1 month was 0.33 in Group-I and 0.27 in Group-II (pvalue=0.59) and at 3 months was 0.2 in both the groups(pvalue=0.7). The mean logMAR BCVA at 1 month was 0.12 in Group-I and 0.18 in Group-II (pvalue=0.05) and at 3 months was 0.09 in Group-I and 0.12 in Group-II (pvalue=0.14). Mean residual cylindrical refractive error at 1 month follow-up visit in Group-I was 0.53±0.31D and Group-II was 0.58±0.23D(pvalue=0.06), while at 3 months follow-up, it was 0.40±0.31D in Group-I and 0.45±0.33D in Group-II (pvalue=0.64).

Mean amount of toric IOL axis rotation after 3 months was 3.86±1.433Degree in Group-A and 1.64±0.731Degree in Group-B. No eye had IOL rotation of more than 6Degree in Group-A and 3Degree in Group-B. The pvalue is **statistically significant(**0.0001). No eye required a second surgery for toric IOL axis correction.

In the study by Na Yeon Jung et al[11], the mean amount of toric IOL axis rotation was 1.50±0.84Degree in Group-I, which was statistically significantly(pvalue=0.01) lower than that of 2.56±0.68Degree in Group-II . No eye had IOL rotation of more than 4Degree. No eye required a second surgery to correct the IOL axis during the 3 months of follow-up period

In the study by Yueqin Chen et al[11]; three months postoperatively, mean absolute IOL rotation relative to the intended meridian was 4.77±2.32Degrees in Group-I and 4.70±1.95Degrees in Group-II. There was no statistically significant difference in IOL rotation between two groups (pvalue =0.334).

In the study by Sheetal A Seth et al[12]; average IOL rotation in Group-I was 3.52±3.84Degree and 2.05±2.56Degree in Group-II at 3 months follow-up. There was no statistically significant difference in IOL rotation between Group-I and Group-II during follow-up(pvalue=0.25).

CONCLUSION:

- This study was done to compare the postoperative visual outcome and rotational stability of standard toric IOLs and customized toric IOLs. Both standard and customized toric IOLs appear to be effective alternatives to correct preexisting astigmatism between 1.5D and 5 D. Customized toric IOL showed less IOL rotation and was better in rotational stability than standard toric IOL at 3 months follow-up, which was statistically significant.
- This study however had certain limitations like less number of patients in both study groups due to high cost of toric intraocular lenses and difficulty in conducting the study and follow up due to covid 19 pandemic. Future studies on related subject can overcome these shortcomings if awareness regarding cataract surgery and toric intraocular lenses is increased. Cost of toric IOL ,being a major limitation, should also be tried to be decreased so as to increase its availability to patients belonging to all socioeconomic status in society.

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