Original Research Article

Study of visual and refractive outcomes in patients undergoing limbal relaxing incision during clear corneal phacoemulsification surgery with foldable intra ocular lens

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Abstract

Background: Phacoemulsification requires a smaller incision, few or no stitches are needed and the patient's recovery time is usually shorter when using a foldable IOL. Limbal Relaxing Incisions, or LRIs, are partial thickness corneal incisions strategically placed to reduce or eliminate pre-existing astigmatism during cataract surgery or refractive lens exchange surgery. Present study was aimed to evaluate the visual and refractive outcome in patients undergoing limbal relaxing incision during clear corneal phacoemulsification surgery with foldable intra ocular lens. **Material and Methods:** Present study was single-center, prospective, observational study, conducted in patients of age more than 18-75 years, with clear cornea and regular astigmatism on keratometry, with preoperative astigmatism more than or equal to 0.5D on keratometry, fit for phacoemulsification cataract surgery with foldable IOL. **Results:** A total of 44 eyes of 44 patients who for cataract phacoemulsification surgery, mean age of the patient was 56.98 ± 05.98 years. Refractive acceptance preoperatively was 0.50 D to 2.0 D. On slit lamp examination showed most common Cataract Nucleus grade is NS 3 with PSC preoperatively. We observed improved diopteric difference by automated keratometry on postoperative 90th day as compared to preoperative values. Majority of patients had Preop Keratometric Difference (K1-K2) of 1.5 D, all required LRI Incisions length of 4 clock hours (60°). **Conclusion:** Visual and refractive outcome changes as improved best corrected visual acuity (BCVA), decrease in Corneal Astigmatism was noted in patients undergoing limbal relaxing incision during clear corneal phacoemulsification surgery with foldable intra ocular lens.

Keywords: refractive outcome, limbal relaxing incision, clear corneal phacoemulsification, cataract surgery, foldable intra ocular lens

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INTRODUCTION

Phacoemulsification is a modern cataract surgery in which the eye's internal lens is emulsified with an ultrasonic hand piece and aspirated from the eye. The foldable IOL made of silicone or acrylic of appropriate power is inserted and because a smaller incision is required, few or no stitches are needed and the patient's recovery time is usually shorter when using a foldable IOL.[1,2] Surgically induced astigmatism (SIA) serves as a reference point for many surgeons in determining the astigmatism that is created by incisions in cataract surgery and can be useful in toric IOL

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selection. It is the change in both the power and to a lesser degree, orientation of the principal meridians following a corneal incision.[3] Limbal Relaxing Incisions, or LRIs, are partial thickness corneal incisions strategically placed to reduce or eliminate pre-existing astigmatism during cataract surgery or refractive lens exchange surgery.[4] With precise measurements and marking of the eye prior to surgery, an incision is fashioned at limbus (the junction between the corneal and sclera) in the axis of steepest curvature, thereby "relaxing" that axis and leaving the corneal in a rounder shape. Present study was aimed to evaluate the visual and refractive outcome in patients undergoing limbal relaxing incision during clear corneal phacoemulsification surgery with foldable intra ocular lens.

MATERIAL AND METHODS

Present study was single-center, prospective, comparative study, conducted in Department of Ophthalmology, Topiwala National Medical College and BYL Charitable Nair Hospital, Mumbai Central, Mumbai, India. Study duration was of 2 years (July 2018 to June 2019). Study was approved by institutional ethical committee.

Inclusion criteria: Patients of age more than 18-75 years, with clear cornea and regular astigmatism on keratometry, with preoperative astigmatism more than or equal to 0.5D on keratometry, fit for phacoemulsification cataract surgery with foldable IOL.

Exclusion criteria: Patients with Corneal opacities and Irregular astigmatism on Keratometry. Patients with Decompensated Cornea, Corneal Tear Repair, Corneal ulcers. Patients with Collagen Vascular Disease like Pterygium. Patients who are operated for Optical Keratoplasty, wound burn during Surgery. Patients who is not amendable to Phacoemulsification surgery with foldable IOL. Study was explained to patients and a written informed consent was taken for participation. Preliminary data of patient such as age, sex, occupation, detailed history, history of use of glasses, duration of onset of diminution of vision.

General Examination: External examination for examination of adnexa and to rule out deviation of eyes. Slit lamp examination to assess cornea anterior chamber, iris tissue, and lens. Dilated fundus examination is done with Indirect Ophthalmoscopy. Bscan will be done in patients in whom fundus is not visible on Indirect Ophthalmoscopy. Pachymetry, Anterior Segment OCT, Gonioscopy, Intraocular pressure with applanation tonometer.

Investigations such as CBC, Fasting Blood Sugar, Post Prandial Blood sugar, Lipid profile, ECG were done in all patients.

Co-operative adult patients were operated under local anesthesia and uncooperative patients will be operated under general anesthesia. All patients underwent phacoemulsification cataract surgery and adequate precautions were taken to prevent infection and Wound Leak. Patients were followed up on postoperative day1, day 7, at the end of 1 month and 3 months. At every visit vision was assessed. Indirect ophthalmoscopy will be done for posterior segment, slit lamp examination wound integrity, wound leakage, anterior chamber depth, any infection. Primary Outcome Measures were Retinoscopy and Subjective Acceptance includes, Astigmatic refractive error (cylindrical power), Keratometry (Manual Keratometry and Auto Keratometry) while Secondary Outcome Measures were Best corrected visual acuity by Snellen's chart or ETDRs chart (BCVA), Spherical refractive error (spherical power), Fundus examination and Complications of Limbal Relaxing Incision if any. Data was collected and compiled using Microsoft Excel, analysed using SPSS 23.0 version. Frequency, percentage, means and standard deviations (SD) was calculated for the continuous variables, while ratios and proportions were calculated for the categorical variables. Difference of proportions between qualitative variables were tested using chi- square test or Fisher exact test as applicable. P value less than 0.5 was considered as statistically significant.

RESULTS

A total of 44 eyes of 44 patients who for cataract phacoemulsification surgery were included in this study. Mean age of the patient is 56.98 years with standard deviation of 05.98. There were 29 males and 15 females. Right eye surgery was done in 18 eyes and left eye surgery was done in 26 eyes. Refractive acceptance preoperatively was 0.50 D to 2.0 D.

Table 1: General characteristics

General characteristics	Frequency	Percentages
Age		
30-40 years	3	06.81
41-50 years	7	15.90
51-60 years	12	27.27
>60 years	22	50.00
Mean Age	56.98 years ± 05.98	
Gender		
Males	29	65

Females	15	35
Surgeries		
Right Eye	18	40.90
Left Eye	26	59.10
Mean IOL power	22.7 ± 0.801	

On slit lamp examination showed most common Cataract Nucleus grade is NS 3 with PSC preoperatively.

Table 2: Slit lamp examination showing Preoperative Lens changes.

Slit lamp Examination	Frequency	Percent
Nuclear sclerosis grade 1 plus posterior subscapular cataract	1	02.27
Nuclear sclerosis grade 2 plus posterior subscapular cataract	3	06.81
Nuclear sclerosis grade 2	3	06.81
Nuclear sclerosis grade 3	17	38.63
Nuclear sclerosis 3 plus posterior subscapular cataract	19	43.18
Nuclear sclerosis grade 4	1	02.27

Preoperatively mainly eyes had best visual activity between 6/24 to 6/18 while visual activity range from 6/60 to 6/12. Improved vision postoperatively day 90th where vision was 6/6 unaided in 24 eyes out of 44 eyes and 6/9 in 14 eyes respectively.

Table 3: Best corrected visual acuity.

BCVA as per Snellen's Chart (LogMAR)	Preoperatively		Postoperative 90th day	
	Frequency	Percentages	Frequency	Percentages
6/60 (0.10)	03	06.81	0	0
6/36 (0.17)	05	11.36	0	0
6/24 (0.25)	15	34.09	0	0
6/18 (0.33)	19	43.18	02	04.54
6/12 (0.50)	02	04.54	04	09.09
6/9 (0.67)	0	0	14	31.81
6/6 (1.00)	0	0	24	54.54

We observed improved diopteric difference by automated keratometry on postoperative 90th day as compared to preoperative values.

Table 4: Change in Diopteric difference by Automated Keratometry.

Diopteric difference in Keratometric value (K1-K2)	Preop day		Postop 90th day	
	Frequency	Percentage	Frequency	Percentage
0.50D	01	02.27	24	54.54
0.75D	01	02.27	14	31.81
1.00D	10	22.75	02	04.85
1.25D	09	24.45	02	04.85
1.50D	15	34.04	01	02.22
1.75D	05	11.36	01	02.22
2.00D	03	06.81	00	00.00

Majority of patients had Preop Keratometric Difference (K1-K2) of 1.5 D, all required LRI Incisions length of 4 clock hours (60°).

Table 5: Comparisons of length of LRI according to Preop Keratometric Difference.

LRI Incisions length	Preop Keratometric Difference (K1-K2)					
	0.50D	0.75D	1.00D	1.50D	1.75D	2.00D
2 clock hours (30°)	01	-	-	-	-	-
3 clock hours (45°)	-	01	10	-	-	-
4 clock hours (60°)	-	-	-	24	05	-
6 clock hours (90°)	-	-	-	-	-	03

In 05 out of 10 patients above 50 years (50 %) got residual keratometric difference of 0.50D (emmetropic) as compared to 19 out of 34 (55.88%) patients below 50 years. So, from above we conclude that LRI is slightly more effective in patients above 50 years as compared to in patients below 50 years.

Table 6: Comparison of Effectiveness of LRI among Age groups.

Age (years)	Preop (without LRI)	Postop (LRI with Emmetropia of residual error 0.50D)
Below 50	10	05
Above 50	34	19

In 08 out of 18 LE (44.44%) got residual keratometric difference of 0.50D (emmetropic) as compared to 16 out of 26 RE (61.53%) thus, LRI was more effective in LE as compared to RE.

Table 7: Comparison of Effectiveness of LRI between Eyes.

Eyes	Preop (without LRI)	Postop (LRI with Emmetropia of residual error 0.50D)
RE	18	08
LE	26	16

The mean dioptric power of the central cornea before surgery at presentation was +42.88920± 0. 886D. The mean dioptric power of the cornea at postoperative day 1 after surgery was 42.80114 ±0.646614D and at postoperative day 7 was 42.72727 ± 0.652741 D and at postoperative day 30 was 42.7216 ± 0.80913 and at postop day 90th was 42.71556 ± 0.54454 D. The mean astigmatic power of the central cornea before surgery was 1.707 ±0.5481 D. At postoperative day 1 after surgery, the mean astigmatic power of the cornea was 0.548 ± 0.810 D and 2.08 ± 0.609D at postoperative day 7 after surgery and at postoperative day 30 was 1.416 ± 0.0001D and 90th day was 0.254 ± 0.210 D. There was decrease in corneal astigmatism after limbal relaxing incisions. The statistical analysis of the central corneal diopteric power using ANOVA (Analysis of Variance) was found to be statistically significant ($p<0.001$). Change in Refractive Index preop and postop is statistically significant (p-value <0.001).

Table 8: Mean diopteric power and astigmatic power of the cornea preoperatively and postoperatively according to Automated Keratometry.

Visits	Mean Diopteric Difference Power	Mean Astigmatic Power
Pre-op Visit	42.88920± 0.88622	1.707 ±0.548D
Postop day 1	42.80114 ±0.64661	0.948±0.810D
Postop day 7	42.72127±0.65274	0.508±0.509D
Postop day 30	42.72516 ±0.80913	0.416±0.406D
Postop day 90	42.71556 ±0.54454	0.254±0.210D

Change in BCVA preop and postop is statistically significant (p-value <0.001). The mean preoperative best spectacle corrected Visual Acuity was 0.3 with a standard deviation of 0.1138 (in log MAR) and the best spectacle corrected visual acuity was 0.207 with a standard deviation of 0.258 on the postoperative day 1 and 0.177 with a standard deviation 0.001 at 1 week whereas the Best Spectacle Corrected Visual Acuity was 0.099 with a standard deviation of 0.6049 at postop day 30, mean BCVA 0.0544 with standard deviation 0.0252 on postop day 90$^{th.}$ The difference between the visual acuity preoperatively and post operatively was found to be statistically significant with a $p<0.01$ by employing the statistical test Analysis of Variance (ANOVA). Visual outcome a change after limb relaxing incisions statistically significant. Keratometry changes preop and postop is statistically significant with p value <0.001

Table 9: Visual acuity Preop, day 1, day 7, day 30 and day 90 postop.

Group	BCVA
Preoperative day	0.312 ± 0.1138
Preoperative day 1	0.207 ± 0.0258
Preoperative day 7	0.177 ± 0.001
Preoperative day 30	0.099 ± 0.0649
Preoperative day 90	0.054 ± 0.0252

DISCUSSION

Preexisting corneal astigmatism at the time of cataract surgery can be treated by manipulation of cataract incision, limbal relaxing incisions (LRIs), astigmatic keratotomy, paired opposite clear corneal incision, implantation of toric intraocular lens, photorefractive keratotomy (PRK), laser in situ keratomileusis (LASIK) and recently penetrating limbal relaxing incisions (PLRIs).[5] There are several approaches for reducing preexisting astigmatism during cataract surgery; perhaps the most basic is placement of incision along the steep corneal meridian taking the advantage of wound induced flattening. There are two major limitations of this approach. First with small incisions the with the rule flattening is insufficient to correct existing astigmatism in excess of approximately 2.00 D. Second, centering the incision on certain meridians is techniqually difficult (e.g. superonasal or inferotemporal in left eye. Limbal Relaxing Incisions are an effective way to reduce astigmatism at the time of cataract surgery. No adjustment to the surgeon's preferred position of the cataract incision is needed with LRIs. Due to their placement at the outermost periphery of the cornea and

their similarity to conventional cataract incisions, these incisions are simple to perform and unlikely to cause complications. The forgiving nature of the procedure represents another advantage.[6] Disadvantages of the LRI includes requiring special instrumentation (diamond knife, or preset depth guarded disposable blades), possible weakening of the integrity of the globe and moderate variability in accuracy, presumably resulting from variations in individual wound healing pattern. LRIs can correct astigmatism up to 2D. LRIs also leave the central cornea untouched for other corneal refractive interventions for residual ametropia.[7] To our advantage these LRIs did not lead to corneal haze that interfered with phaco surgery as the incisions were placed in the most peripheral cornea as reported by other studies. Advances in cataract and refractive surgery techniques, nomograms and intraocular lens (IOL) technology allow greater control over the patient's postoperative refractive outcome and visual resolution. A surgeon may become more comfortable with one particular technique as compared to another and should, therefore, choose an approach which works best in his or her hands. In our study, in the LRI group we found that the mean preoperative astigmatism at postoperative day 1 after surgery, the mean astigmatic power of the cornea was 0.948±0.810D and 0.508±0.509D at postoperative day 7 after surgery and at postoperative day 30 was 0.416±0.406D and day 90th was 0.254 ± 0.210 D respectively. There was decrease in corneal astigmatism after limbal relaxing incisions. Visual outcome a change after limb relaxing incisions statistically significant. Corneal astigmatism improved and 24 eyes were emmetropic (0.50 DC) on postop day 90th with remaining residual cylindrical power ranges between 0.75 DC to 1.25 DC respectively. On postoperative day 44 all eyes were emmetropic with refractive power of 1.416 In a study titled Refractive outcomes after limbal relaxing incisions or femtosecond laser arcuate keratotomy to manage corneal astigmatism at the time of cataract surgery. The mean target induced astigmatism was 1.50 D and 1.38 D respectively, with 1.02 D and 1.23 D surgically induced astigmatism (P = .21), resulting in the femtosecond arcuate keratotomy group having a smaller difference vector (1.17 D versus 0.89 D; P = .02) and a greater correction index (0.48 versus 0.73; P = .02). Forty-four percent of patients in the femtosecond arcuate keratotomy group and 20% in the LRI group attained a postoperative cylinder of less than 0.50 D (P = .01). These results were statistically significant. The femtosecond arcuate keratotomy group achieved a higher correction index and a smaller difference vector. The femtosecond arcuate keratotomy patients showed less postoperative cylinder than LRI patients.[8] The visual and refractive data are reported. UDVA and CDVA improved statistically (P<0.01). CYL value decreased by 78.1%. Analysis of KP90 and KP135 polar values show a statistical difference. (P=0.22 and P=0.24, Wilcoxon rank-sum test).[7] Three years after procedure, it can be assumed that if an incisional procedure, such as LRIs, is added during phacoemulsification surgery, third-order aberrations in cornea are only partially affected. If the unaltered indices of corneal irregularities – such as SRI and SDP – are taken into account, it may be assumed that LRIs can be considered safe, thus not causing significant irregularities in corneal morphology.[9] Budak *et al.*,[10] reported an absolute decrease in mean astigmatism by 44%, Bayramlar *et al.*,[11] as 52%, Kaufmann *et al.*,[12] as 25% and Carvalho *et al.*,[13] as 50%. Average central corneal power was not significantly modified by LRIs, thus confirming the value of the coupling ratio of approximately 1:1 previously published. Previously, Lindstrom found a 1:1 coupling ratio when a straight 3 mm keratotomy or a 45°–90° arcuate keratotomy incision is performed, thus showing that coupling ratio depends on the length, location, and depth of incision.[14]

In study titled Effect of Limbal relaxing incisions during phacoemulsification surgery, the mean uncorrected distance visual acuity (UDVA) and the best corrected visual acuity (BCVA) demonstrated statistically significant improvement after surgery. At the end of the follow-up period, the UCVA was statistically better for the patients with LRIs. [15] The LRIs group showed significant reduction in the mean topographic astigmatism from 1.48 ± 0.35 D preoperatively to 0.37 ± 0.14 D postoperatively (P < .0001) after one month. The mean magnitude of the surgically induced astigmatism (SIA) read 0.416 ± 0.406 D and 0.254 ± 0.210D by the end of the 1st, the 3rd month postoperatively in LRIs group, which was slightly lower than the target-induced astigmatism (TIA). The difference in SIA between the LRI statistically significant by the end of the 1st and 3rd month postoperatively (P < 0.001). The mean correction index (CI) was less than 1, which indicated under- correction effect of limbal relaxing incision. No difference was observed in the postoperative endothelial cell count between the two groups. There was no intraoperative and postoperative ocular or systemic complication.[16] Different techniques are available to correct astigmatism, such as arcuate keratotomy, limbal relaxing incisions, laser vision correction, and Toric Implantable Collamer Lens (TICL) implantation. One popular approach to correct corneal astigmatism simultaneously to cataract surgery is to treat pre-existing astigmatism by creating limbal relaxing incisions. The limbal relaxing incisions (LRIs) technique involves the placement of incisions corresponding to the steep meridian, resulting in corneal flattening and the reduction of astigmatic power. LRI is a safe and an inexpensive procedure, which is simple for experts to perform. It can

effectively reduce astigmatism up to 2.0 D and result in a rapid visual rehabilitation. Although the LRI astigmatism correcting capability was affirmed, vector analysis with the SIA lower than TIA and CI < 1, which means under-correction effect of limbal relaxing incision. As a method that is less dependent on the surgeons' technical experience. The potential drawbacks of corneal incisions include risk of perforation, infection, unpredictability of results, creation of irregular astigmatism and disruption of the ocular surface as knowing that the regression of astigmatism can be as much as 1.00D, but in this study, it was found the regression of astigmatism would remain stable after 3 months postoperatively. Recently, the Toric hyperopic IOLs currently represents an alternative method to the incisional technique for the slight and moderate astigmatism during ICL surgery. However, the misalignment of the TICL might be a critical error.

CONCLUSION

Visual and refractive outcome changes as improved best corrected visual acuity (BCVA), decrease in Corneal Astigmatism was noted in patients undergoing limbal relaxing incision during clear corneal phacoemulsification surgery with foldable intra ocular lens. This technique is cheap, safe, quick, and helpful in reducing preexisting astigmatism till 2D and also in patients who are non-affording to pay for surgery with Toric lenses which is costly.

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