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Research Article

# A Prospective Study on Visual Outcomes of Cataract Surgery after Phacoemulsification with Foldable vs Non Foldable Intraocular Lenses

**Shavina Garg[1], Harsimran Singh[1], Rajinder Khalsa[1], Usha Aggarwal[2], Anand Aggarwal[1]*, Indu Khosa[1], Kamlinder Kaur[1] and Shubham Mittal[1]**

[1]*Department of Ophthalmology, Government Medical College, Patiala, Punjab, India*

[2]*Director, Harnam Satsangi Clinic, Civil Lines, Ludhiana, Punjab, India*

***Corresponding Author:** Anand Aggarwal, Department of Ophthalmology, Government Medical College, Patiala, Punjab, India.

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## Abstract

**Purpose:** To compare the visual outcomes of cataract surgery with foldable vs non foldable Intraocular lenses after phacoemulsification, at a tertiary Eye centre in Department of Ophthalmology, Government Medical College, Patiala.

**Methods:** In a prospective, comparative, randomized clinical trial of phacoemulsification cataract surgery, 200 patients received hydrophilic foldable intraocular lenses through 2.8mm clear corneal incision and 100 patients received non foldable Polymethyl Methacrylate (PMMA) intraocular lenses through 5.25mm clear corneal incision. Preoperative and postoperative visual acuity, Pentacam based analysis of astigmatism, dry eye changes and IOP measurements at day 7, 1 month, 3 month and 6 month follow up visits were analysed.

**Results:** A total of 300 people were enrolled in the trial, 200 were randomly allocated to receive a hydrophilic foldable lens and 100 to receive a non foldable PMMA lens. At 6 months after surgery, 194 out of 200 patients (97%) had best corrected visual acuity of 6/9 or better in foldable group (group I) and 95 out of 100 (95%) in the non foldable group (Group II). Visual acuity of 6/12 - 6/18 was observed in 3% of foldable and 5% of non foldable group (p value - 0.385). None of the cases in both group I and II had best corrected visual acuity worse than 6/18 at the end of 1 month. Vision stabilized in both groups after first month postoperatively. Surgically induced astigmatism was 0.47 0.39 D in group I and 1.03 0.48 D in group 2 at the end of 6 months as compared to baseline. The difference in SIA between both groups was statistically significant (p value < 0.001). Dry eye changes were more in group 2 as compared to group 1 but the difference was not significant. As far as IOP changes were concerned, both the groups didn't have any significant difference, though the decrease in IOP was significant in each group after 6 months of cataract surgery (p value < 0.05).

**Conclusion:** Phacoemulsification with implantation of a foldable IOL through a 2.8mm incision leads to less post operative astigmatism as compared to phacoemulsification with implantation of a non foldable IOL through 5.25mm incision. The main concern of patients is final visual outcome, which remains the same with both foldable and non foldable IOLs. Therefore, phacoemulsification with either implantation of a foldable or an inexpensive rigid PMMA IOL gives excellent results in hands of experienced cataract surgeons.

**Keywords:** Cataract; Phacoemulsification; Intraocular lenses; Visual Acuity; Surgically Induced Astigmatism; Intraocular pressure

## Introduction

Cataract is one of the major Ophthalmological public health problem as it can significantly reduce patient's quality of life. It is one of the most common cause of visual impairment in the world [1]. India shares almost a quater of entire global burden of blindness with near about 8 million blind people [2].

Senile cataract is the most common form of visually significant cataract worldwide [3]. No medical treatment has been successful till date for treating cataract and there are no preventive strategies for cataract either [4]. The only treatment for a cataract is surgery. Although various safe and effective cataract surgeries are available in India that can restore vision, still the cataract burden continues to increase annually because of backlog of the patients to be operated upon besides increasing life expectancy of the populace [5].

Since the first intraocular lens (IOL) implantation surgery done by Harold Ridley in 1949, there have been many improvements in the procedure for cataract surgery [6]. Phacoemulsification, a commonly used technique for cataract extraction, has allowed dramatic reductions in the size of the incision. Earlier large, typically 10 - 12 mm, incision was given for crystalline lens extraction which required multiple sutures and frequently caused high levels of induced astigmatism and significant visual distortion. After introduction of phacoemulsification, the incision size became smaller leading to significant less complications besides rapid visual rehabilitation. The small incision surgery for a non foldable IOL, with typical incision of 5.0 - 5.5 mm, commonly requires a single suture. A foldable IOL allows "micro-incision" surgery, which snugly fits in 2.8 mm diameter phacoemulsification probe, the incision being small enough to be self healing and sutureless [7].

The outcomes of cataract surgery for an individual or a defined population is as important as measuring the quality of surgical operations that are performed [8]. Surgical induced astigmatism, dry eye changes after cataract surgery, IOP changes are some of the factors to be kept in mind while performing a cataract surgery.

Hence, the present study was conducted for comparing the visual outcomes of phacoemulsification with either a 2.8 - mm clear Corneal incision and a foldable intraocular lens (IOL) or a 5.25 - mm clear Corneal incision and a rigid Polymethyl Methacrylate (PMMA) IOL.

## Material and Methods

The comparative study was conducted on 300 patients (200 patients in group I and 100 patients in group II) aged between 35 - 85 years diagnosed with cataract that reduced vision to at least 6/18 in the eye to be operated upon, who visited the Outdoor Patient Department in Government Medical College, Patiala. All the patients were explained in detail about the Surgical procedures and were enrolled after obtaining written and informed consent, in accordance with declaration of Helsinki.

### Inclusion criteria included

1. Both males and females of age group 35-85 years, with cataract that reduced vision to at least 6/18 in the eye to be operated upon.
2. Patients who were willing and able to return for follow up at all subsequent study visits, and followed instructions from the study investigators.
3. All patients with preoperative Corneal astigmatism < 1D.

### Exclusion criteria included

1. Patients who had corneal diseases (Fuchs' endothelial dystrophy; Corneal stromal scarring) etc.
2. Patients who were suffering from chronic anterior uveitis.
3. Patients with Intraocular pressure > 21 mm Hg.
4. Patients who had high ametropia (Calculated IOL biometry for emmetropia: < 17.0 D, or > 26.0 D).
5. Patients who had diabetic retinopathy or hypertensive retinopathy.

### History

A detailed history was taken including gender, age at presentation, health, or chronic long term use of medication. Specifically, patients were questioned regarding history of any chronic disease such as hypertension,and diabetes mellitus to potentially exclude confounding variables in statistical analyses.

### Ocular examination

Visual acuity, Pentacam based analysis of astigmatism, dry eye tests (Schirmer's test, Tear film break up Time) and Intraocular pressure were noted before phacoemulsication and on postoperative Day 7, 1 month, 3 months and 6 months follow up visits.

### Surgical technique

### For foldable IOL implantation

1. Patient was made to lie on the operating table and Betadine painting and draping of eye to be operated upon was done. A peribulbar anesthesia was given.

2. Microscope was placed in position. The patient was protected by a sterile field but could breathe and speak normally.
3. Two side ports were made at the 12 o'clock and 6 o'clock position using a 24-gauge, 15-degree lancet tip blade.
4. A thick, dispersive ophthalmic viscoelastic device was injected into the anterior chamber to provide a working space and protect the inner surface (endothelial layer) of the cornea.
5. A clear corneal incision site (typically a tri-planar wound to promote self-seal) was created temporally with 2.8mm keratome.
6. A continuous curvilinear capsulorhexis was made after staining the capsule with trypan blue dye, using a cystotome or a rhexis forceps. Most of the capsule was left intact to provide a pouch for insertion of the IOL. This was a very important surgical step since mistakes could have made the removal of the natural lens and intraocular lens (IOL) insertion very difficult.
7. The cortex was dissociated from the overlying capsule by injecting a balanced salt solution (BSS) between the cortex and capsule (hydro dissection). The surgeon spinned or rotated the lens to ensure it was freely mobile.
8. Hydro delineation was similarly performed to separate the endonucleus from the epinucleus in required cases. The purpose was to leave the epinuclear shell to protect the posterior capsule during the initial stages of phacoemulsification and removal of the endonucleus.
9. A phacoemulsification probe used ultrasonic energy to break up the lens nucleus. A vacuum attached to the same probe removed the nucleus fragments that were generated. Several approaches were used, including a "divide and conquer" approach whereby the nucleus was first divided into two main pieces. Other techniques were also used to chop the nucleus
10. The cortex was aspirated and pulled away from the capsule. Care was taken to avoid tearing the capsule and allowing vitreous leakage into the anterior chamber. The capsular bag was filled with a cohesive OVD thus creating a space to inject the lens into it.
11. A foldable hydrophilic IOL (Aurolab, Madurai, TN, India) was then inserted into the capsular bag using a lens injector where it uncurled automatically. Both the haptics were placed in the capsular bag to maintain the optic within the center of the capsular bag.
12. The OVD was aspirated from the capsular bag and anterior chamber.
13. The corneal incision was hydrated with BSS, which caused local corneal epithelial cells to expand and compress each other and allowed for wound closure without sutures.
14. Topical antibiotic eye drops and a topical steroid were instilled immediate postoperatively.

### For Non foldable PMMA IOL implantation

1. Steps 1 - 10 as described previously under the surgical technique section was followed.
2. The incision was extended using a 5.25 keratome. A non foldable PMMA IOL (Appasamy Associates, Arumbakkam, Chennai, India) was inserted through a 5.25 mm incision. Then the corneal wound was closed by placing a single 10 - 0 nylon suture.
3. The OVD was aspirated from the capsular bag and anterior chamber.
4. The Corneal side ports were hydrated with BSS, which caused local corneal epithelial cells to expand and compress each other and allowed for wound closure without sutures.
5. Topical antibiotic eye drops and a topical steroid were instilled immediate postoperatively.

Postoperative Medications - Postoperatively the patients of both groups were put on following medications

1. Tablet Ofloxacin 200 mg BD for five days.
2. Tablet diclofenac 50mg BD for five days.
3. Antibiotic-steroid eyedrops [Moxifloxacin (0.5% w/v) + Prednisolone (1% w/v)]: one drop two hourly for two weeks, QID for one week then tapering, TID, BD and OD for each week.
4. Tear drops [Carboxymethylcellulose (0.5% w/v)] two hourly for two weeks then QID for 3 weeks.

POSTOPERATIVE FOLLOW UP – Post operative follow ups were done at day 7, 1 month, 3 months and 6 months in both the groups. The patients were subjected to same UCVA, BCVA, pentacam based analysis of astigmatism, TBUT, Schirmer's test and IOP evaluation at each visit.

## Statistical analysis

The data was collected from 300 patients divided, using random number tables, into 200 patients in group I and 100 patients in group II. All the cases were operated upon by a single surgeon (AA) who was blind towards the selection of the patient for a particular IOL, and randomization data was kept by single investigator (SG). The data was collected from the patients using case report form. The data was then entered in excel. The data obtained was statistically analyzed using SPSS version 20 (IBM Corp; SPSS Statistics for Windows, Version 27.0. Armonk, NY). Statistics were reported in terms of mean and percentages. The results were finally presented in tables and graphs. Chi-square test and Fisher's exact test were used for the assessment of level of significance. The p value of < 0.05 was considered statistically significant.

## Results and Observations

Among patients undergoing phacoemulsification with implantation of foldable IOL (Group I), mean age of the patients was 61.75 years. 15.5 percent of the patients belonged to the age group of 35 to 50 years, 33.5 percent of the patients belonged to the age group of 51 to 60 years. 34.5 percent and 16.5 percent of the patients belonged to the age group of 61 to 70 years and 71 to 85 years respectively. Similarly, among patients undergoing phacoemulsification with implantation of non foldable IOL (Group II), mean age was 60.06 years. 24 percent of the patients belonged to the age group of 35 to 50 years, 30 percent of the patients belonged to the age group of 51 to 60 years. 31 percent and 15 percent of the patients belonged to the age group of 61 to 70 years and 71 to 85 years respectively. There was no significant difference between both groups in regard to age as shown in table 1. In Group I (Foldable IOL), 104 patients out of 200 (52%) were males rest were females whereas in Group 2 (Non Foldable IOL), 54 patients out of 100 (54%) were males while the remaining were females (Table 2).

In group I, 55% of patients had Uncorrected Visual Acuity (UCVA) between 6/24 - 6/60 preoperatively and 45% patients had UCVA < 6/60. At post operative day 7, 99% of patients had UCVA better than 6/18. Only 1% of patients had UCVA between 6/24 - 6/60 at postoperative day 7. At 1 month visit, 100% of patients had UCVA better than 6/18. None of the patients had UCVA < 6/18 at the end of one month in group I which included patients with foldable IOL implantation.

| Age Group (In Years) | Group 1 (Foldable Iol) | | Group 2 (Non Foldable Iol) | |
|---|---|---|---|---|
| | Number Of Patients | Percentage | Number Of Patients | Percentage |
| 35-50 | 31 | 15.5 | 24 | 24.0 |
| 51-60 | 67 | 33.5 | 30 | 30.0 |
| 61-70 | 69 | 34.5 | 31 | 31.0 |
| 71-85 | 33 | 16.5 | 15 | 15.0 |
| Mean + SD | 61.75 ± 9.49 | | 60.06 ± 10.99 | p-value = 0.359 |

**Table 1:** Age Distribution Among The Patients.

| Gender Distribution | Group 1 (Foldable Iol) | | Group 2 (Non Foldable Iol) | |
|---|---|---|---|---|
| | Number Of Patients | Percentage | Number Of Patients | Percentage |
| Male | 104 | 52.0 | 54 | 54.0 |
| Female | 96 | 48.0 | 46 | 46.0 |
| Total | 200 | 100 | 100 | 100 |
| p-value = 0.744 Significance = NS | | | | |

**Table 2:** Gender Distribution Among Patients.

*p-value <0.05 is taken as significant

In group II, 64% of patients had UCVA between 6/24 - 6/60 preoperatively and 36% patients had UCVA < 6/60. At post operative day 7, 98% of patients had UCVA better than 6/18. Only 2% of patients had UCVA between 6/24 - 6/60 at postoperative day 7. At 1 month visit, 99% of patients had UCVA better than 6/18. 1% of patients had UCVA < 6/18 at the end of 1 month in group II which included patients with non-foldable IOL implantation. Visual acuity stabilised at the end of 1 month in both the groups with no statistically significant difference in both groups.

In group I, 10.5% patients had preoperative Best Corrected Visual Acuity (BCVA) between 6/12 - 6/18, 67% patients had preoperative BCVA between 6/24 - 6/60 and 22.5% patients had preoperative BCVA less than 6/60. 90.5 percent patients had BCVA between 6/6 - 6/9 and 9.5 percent patients had BCVA between 6/12 - 6/18 at postoperative Day 7. In group I, 97 percent patients had BCVA between 6/6 - 6/9 and 3 percent patients had BCVA between 6/12 - 6/18 at 1 month post operative visit. Vision stabilized at the end of 1 month and remained same at post operative 3 month and 6 month visit (Table 3 and 4).

| Uncorrected visual acuity | Preoperative Foldable IOL | Preoperative Non Foldable IOL | Postoperative Day 7 Foldable IOL | Postoperative Day 7 Non Foldable IOL | 1 month Postoperative Foldable IOL | 1 month Postoperative Non Foldable IOL |
|---|---|---|---|---|---|---|
| 6/6 – 6/18 | 0 (0.0%) | 0 (0.0%) | 198 (99%) | 98 (98%) | 200 (100%) | 99 (99%) |
| 6/24 – 6/60 | 110 (55%) | 64 (64%) | 2 (1%) | 2 (2%) | 0 (0.0%) | 1 (1%) |
| < 6/60 | 90 (45%) | 36 (36%) | 0 | 0 | 0 | 0 |
| | p value = 0.137 | | p value = 0.603 | | p value = 0.333 | |
| Best corrected visual acuity | | | | | | |
| 6/6 – 6/9 | 0 (0.0%) | 0 (0.0%) | 181 (90.5%) | 88 (88%) | 194 (97%) | 95 (95%) |
| 6/12 – 6/18 | 21 (10.5%) | 11 (11%) | 19 (9.5%) | 12 (12%) | 6 (3%) | 5 (5%) |
| 6/24 – 6/60 | 134 (67%) | 69 (69%) | 0 (0.0%) | | 0 (0.0%) | |
| < 6/60 | 45 (22.5%) | 20 (20%) | | | 0 | |
| | p value = 0.884 | | p value = 0.502 | | p value = 0.385 | |

**Table 3:** Visual Outcomes In Both Group 1 And 2.

| Uncorrected visual acuity | 3 months postoperative Foldable IOL | 3 months postoperative Non Foldable IOL | 6 months postoperative Foldable IOL | 6 months postoperative Non Foldable IOL |
|---|---|---|---|---|
| 6/6 – 6/18 | 200 (100%) | 99 (99%) | 200 (100%) | 99 (99%) |
| 6/24 – 6/60 | 0 (0.0%) | 1 (1%) | 0 (0.0%) | 1 (1%) |
| < 6/60 | | | | |
| | p value = 0.333 | | p value = 0.333 | |
| Best corrected visual acuity | | | | |
| 6/6 – 6/9 | 194 (97%) | 95 (95%) | 194 (97%) | 95 (95%) |
| 6/12 – 6/18 | 6 (3%) | 5 (5%) | 6 (3%) | 5 (5%) |
| 6/24 – 6/60 | 0 (0.0%) | | 0 (0.0%) | 0 (0.0%) |
| < 6/60 | 0 | | | |
| | p value = 0.385 | | p value = 0.385 | |

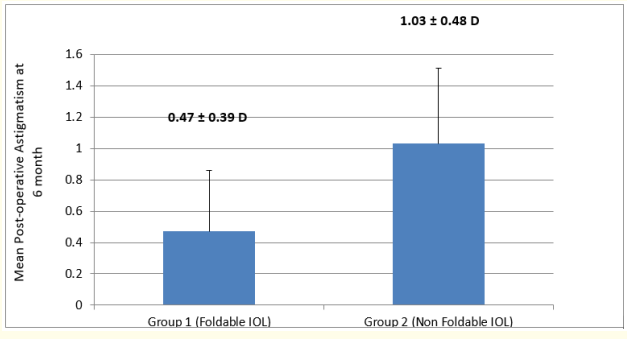
**Table 4:** Visual Outcomes in Both Group 1 and 2.

In group II, 11% patients had preoperative BCVA between 6/12 - 6/18, 69% patients had preoperative BCVA between 6/24 - 6/60 and 20% patients had preoperative BCVA less than 6/60. In group II, 88 percent patients had BCVA between 6/6 - 6/9 and 12 percent patients had BCVA between 6/12 - 6/18 at postoperative Day 7. In group II, 95 percent patients had BCVA between 6/6 - 6/9 and 5 percent patients had BCVA between 6/12 - 6/18 at 1 month post operative visit. Visual acuity stabilized at the end of 1 month and remained same at post operative 3rd month and 6th month visit (Table 3 and 4).

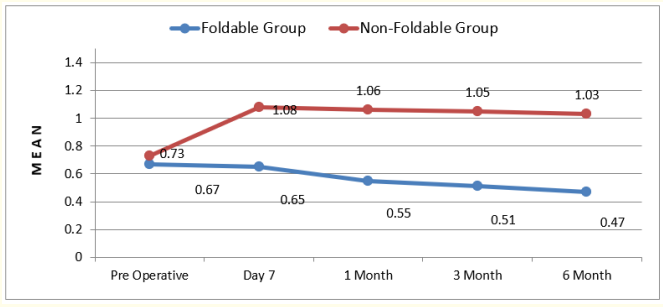
Mean preoperative astigmatism was 0.67 0.22 D in group I. Surgically induced astigmatism values were, 0.65 0.40 D, 0.55 0.43 D, 0.51 0.44 D and 0.47 0.39 D at, postoperative day 7, 1 month, 3 months and 6 months visit respectively in group 1. In group 2, mean preoperative astigmatism was 0.73 0.24 D. Surgically induced astigmatism values were, 1.08 0.39 D, 1.06 0.46 D, 1.05 0.48 D and 1.03 0.48 D at postoperative day 7, 1 month, 3 months and 6 months visit respectively. The difference between two groups at each visit was statistically significant with p value < 0.001 (Table 5 and Graph 1 and 2).

| Sia | Group I (Foldable Iol) | | Group Ii (Non Foldable Iol) | | P Value |
|---|---|---|---|---|---|
| | MEAN | SD | MEAN | SD | |
| Pre Operative | 0.67 | 0.22 | 0.73 | 0.24 | 0.032 |
| Day 7 | 0.65 | 0.40 | 1.08 | 0.39 | < 0.001 |
| 1 Month | 0.55 | 0.43 | 1.06 | 0.46 | < 0.001 |
| 3 Month | 0.51 | 0.44 | 1.05 | 0.48 | < 0.001 |
| 6 Month | 0.47 | 0.39 | 1.03 | 0.48 | < 0.001 |

**Table 5:** Analysis of Surgically Induced Astigmatism over a period of 6 months.




**Graph 1**: Mean Postoperative Astigmatism Analysis At 6 Month.

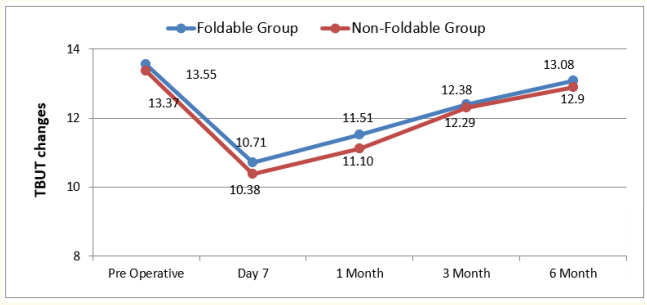



**Graph 2**: Analysis of Surgically Induced Astigmatism over a period of 6 months.

Mean Tear Film Breakup Time (TBUT) at preoperative, post operative day 7, 1 month, 3 months and 6 months in group I were 13.55 1.83, 10.71 2.07, 11.51 1.95, 12.38 1.92, 13.08 1.77 seconds respectively. In group II, these were 13.37 1.54, 10.38 1.93, 11.10 1.94, 12.29 1.82, 12.90 1.73 seconds at preoperative, post operative day 7, 1 month, 3 months and 6 months visits. We found no statistical differences in mean TBUT at each visit between both groups. Though the mean TBUT decreased significantly at day 7 as compared to preoperative values in each group (p value < 0.05) (Table 6 and Graph 3).

| TBUT (At Visit) | Group I (Foldable IOL) | Group II (Non Foldable IOL) | P Value |
|---|---|---|---|
| Pre Operative | 13.55 ± 1.83 | 13.37 ± 1.54 | 0.400 |
| Day 7 | 10.71 ± 2.07 | 10.38 ± 1.93 | 0.191 |
| 1 month | 11.51 ± 1.95 | 11.10 ± 1.94 | 0.086 |
| 3 month | 12.38 ± 1.92 | 12.29 ± 1.82 | 0.714 |
| 6 month | 13.08 ± 1.77 | 12.90 ± 1.73 | 0.404 |

**Table 6:** TBUT changes over the period of 6 months.

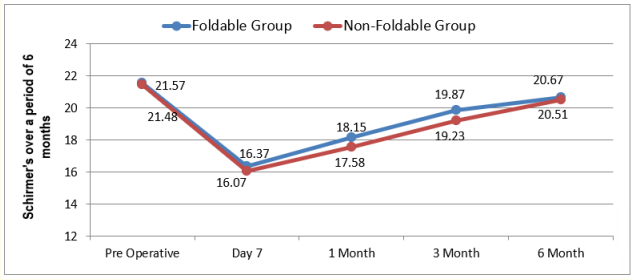



**Graph 3**: TBUT changes over the period of 6 months.

Similarly mean Schirmer's value decreased at postoperative day 7 in each group as compared to their preoperative values and then started reaching near normal value gradually upto 6 months of follow up period. (Table 6). Preoperative, post operative day 7, 1 month, 3 months and 6 months values of Schirmer's Test in group I were 21.57 3.33, 16.37 3.53, 18.15 3.63, 19.87 3.11 and 20.67 2.81 mm. The mean Schirmer's Test values in group II were 21.48 3.00 (preoperative), and 16.07 2.90, 17.58 2.87, 19.23 2.95 and 20.51 2.60 mm at their respective follow up visits. Comparison between two groups showed non-significant Schirmer's changes over a period of 6 months (Table 7 and Graph 4).

| Schirmer's Test (At Visit) | Group I (Foldable IOL) | Group II (Non Foldable IOL) | P Value |
|---|---|---|---|
| Pre Operative | 21.57 ± 3.33 | 21.48 ± 3.00 | 0.830 |
| Day 7 | 16.37 ± 3.53 | 16.07 ± 2.90 | 0.035 |
| 1 month | 18.15 ± 3.63 | 17.58 ± 2.87 | 0.175 |
| 3 month | 19.87 ± 3.11 | 19.23 ± 2.95 | 0.088 |
| 6 month | 20.67 ± 2.81 | 20.51 ± 2.60 | 0.634 |

**Table 7:** Schirmer's Test over period of 6 months.

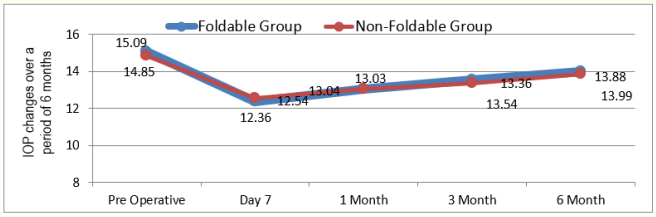



**Graph 4**: Schirmer's test over period of 6 months.

IOP changes over a period of 6 months showed no significant differences between both groups. Mean IOP values at preoperative, post operative day 7, 1 month, 3 months and 6 months were 15.09 1.76, 12.36 1.38, 13.03 1.38, 13.54 1.59 and 13.99 1.66 mm Hg respectively, in group I. Mean IOP values in group II, respectively, were 14.85 1.58, 12.54 1.54, 13.04 1.44, 13.36 1.57 and 13.88 1.63 mmHg preoperative and respective follow up visits. Maximum decrease was found on post operative day 7 in both groups after which IOP started reaching near baseline (Table 8 and Graph 5).

| Mean IOP (At Visit) | Group I (Foldable IOL) | Group II (Non Foldable IOL) | P Value |
|---|---|---|---|
| Pre Operative | 15.09 ± 1.76 | 14.85 ± 1.58 | 0.260 |
| Day 7 | 12.36 ± 1.38 | 12.54 ± 1.54 | 0.294 |
| 1 month | 13.03 ± 1.38 | 13.04 ± 1.44 | 0.954 |
| 3 month | 13.54 ± 1.59 | 13.36 ± 1.57 | 0.367 |
| 6 month | 13.99 ± 1.66 | 13.88 ± 1.63 | 0.587 |

**Table 8:** IOP changes over period of 6 Months.




**Graph 5**: IOP changes over period of 6 Months.

## Discussion

Cataract is the most important and significant cause of blindness in senile age group globally. Modern cataract surgeries with intraocular lens implantation have become the safest, successful, simple, consistent and the most frequently performed surgeries [9].

Cataract surgery has undergone various advances since it was evolved. It started from ancient couching and then transformed to ICCE, ECCE and finally evolved to the modern phacoemulsification technique. "One of the most fascinating developments in the history of cataract surgery is the Kelman technique of reducing a cataract to minute particles by ultrasonic vibration and aspirating them by controlled suction." [10] Good optical properties, dimensional and material stability and a few post-operative complications are desirable properties of any Intraocular Lens (IOL). Since foldable IOLs are usually more expensive than rigid IOLs, we compared the visual acuity, residual refractive error, dry eye and IOP changes with a foldable acrylic lOL and rigid PMMA lOL implanted using phacoemulsification.

In the present study, a total of 300 patients with cataract were examined for UCVA, BCVA, surgically induced astigmatism, IOP and

dry eye changes both preoperatively and postoperatively. 200 patients were included in group I with foldable IOL and 100 patients were included in group II with non foldable IOL insertion. Mean age of the patients was 61.75 years in group I and 60.06 years in group II. There was no significant difference in both the groups in regard of age distribution. Similarly, in a study conducted by Hennig A., *et al.* [11] comparing foldable and rigid lenses after phacoemulsification for a cataract surgery, mean age of the patients in foldable lens group and non foldable lens group was 57.4 and 56.9 years respectively. Mean age of the patients of the foldable and non-foldable group in the study conducted by Tyagi R., *et al.* [12] was 60.16 years and 63.73 years respectively. Our study participants had relatively higher age of undergoing cataract surgery as compared to western population. Expectedly, the mean age in our study was similar to other reported Indian studies.52 percent of the patients of foldable group and 54 percent of the patients of the non-foldable group were males in our study. Both the groups were comparable in terms of gender wise distribution. Our results were in concordance with the results obtained by previous authors. In a study conducted by Prasad., *et al.* [13] comparing the visual outcome in patients who underwent cataract surgery with PMMA IOL or foldable acrylic IOL in phacoemulsification 26 out of 50 were males in PMMA group and and 24 out of 50 were males in acrylic lenses group. Their study did not show any significant difference in gender wise distribution among both the groups. Therefore, our study allowed for age and gender matched statistical comparison for visual outcomes in both the groups.

55% patients had preoperative UCVA between 6/24 - 6/60 and 45% patients had preoperative UCVA < 6/60 in group I. In group II, 64% patients had preoperative UCVA between 6/24 - 6/60 and 36% patients had preoperative UCVA < 6/60. UCVA at postoperative day 7, 1 month, 3 months and 6 months was mostly between 6/6 - 6/18 in both the groups. Non-significant results were obtained while comparing the distribution of patients according to UCVA at pre-operative, postoperative day 7, 1 month, 3 months and 6 months in between the two study groups. A randomized controlled trial conducted by Hennig A., *et al.* [11] on a large sample size of 1200 patients at Lahan eye hospital, Nepal with a longer follow up of 12 months reported that the number of patients with UCVA < 6/18 was similar in the two groups at 1 year and did not show any significant difference. Another study conducted by Tyagi R [12] showed UCVA better than 6/18 in 69.2% patients with rigid IOL and 76% patients with foldable IOL on day 1. It was statistically non significant. Our study similarly showed no significant difference in UCVA on post operative follow ups between both the groups.

In our study, 97% patients had BCVA better than 6/9 at 6 months postoperative visit in group I and 95% patients had BCVA better than 6/9 in group II. No patient had BCVA worse than 6/18 in both the groups at the end of 6 months. Non-significant results were obtained while comparing the distribution of patients according to BCVA at pre-operative, postoperative day 7, 1 month, 3 months and 6 months in between the two study groups. In a study conducted by Afsar., *et al* [14], all subjects had a best corrected Snellen visual acuity of 6/9 or better, a result similar to previous reports. Prasad., *et al.* [13] conducted a study to compare the visual outcome in patients who underwent cataract surgery with PMMA IOL or foldable acrylic IOL in phacoemulsification. The post- operative refraction was stabilised at the end of 4 weeks in both the groups. The best corrected visual outcome in phacoemulsification with PMMA IOL and Acrylic foldable IOL showed no significance in terms of the type of IOL. Other studies conducted by Alam., *et al*. [15] and Raiyawa., *et al.* [16] showed similar results in terms of BCVA. Our results were in concordance with their studies.

Patients undergoing cataract surgery, presently, expect clear vision and less dependence on spectacles. Surgical Induced Astigmatism (SIA) needs to be reduced in order to accomplish this goal. Our study showed significant difference in SIA at the end of 6 months with mean SIA of 0.47  0.39 D in group I with temporal 2.8 mm incision and foldable IOL insertion and mean SIA of 1.03  0.48 D in group 2 with temporal 5.25 mm incision and non foldable IOL insertion. A single suture was applied to group II to close the main wound. SIA was statistically significant ($p < 0.001$).A study conducted by Tyagi R., *et al.* [12] in 2018 showed that the mean SIA at 6 weeks in group A (PMMA IOL) was 1.100.51 D and 0.71  0.32 D in group B (Foldable IO). It was statistically significant ($p < 0.001$). A randomised controlled trial conducted by Hennig A., *et al.* [11] showed no difference in the average astigmatism at 6 weeks or 1 year. A study conducted by Nikose AS., *et al*. [17] showed that the mean SIA in group A (temporal 2.8 mm clear Corneal incision) was 0.98 D on the 30th day, which reduced to 0.768 D after 90 days. In group B (Superior 2.8 mm clear corneal incision), the mean SIA was 1.651 D after 30 days, whereas it reduced to 1.293 D after 90 days. These observations proved that the SIA reduced after 90 days and that there was a significant difference between 30th

and 90th day SIA. Some more studies reported in literature showed varying results where author did not find significant difference in surgically induced astigmatism between foldable and non foldable IOL insertion after phacoemulsification. In our study, SIA is significant in both the groups as compared to the preoperative values ($p < 0.001$). SIA is higher in non foldable IOL insertion after phacoemulsification as compared to foldable IOL insertion ($p < 0.001$). Though SIA is significantly higher in group 2 in our study, the final BCVA is similar in both the groups, thus not affecting the final visual outcome of cataract surgery in the patients.

The mean  SD of preoperative tear breakup time (TBUT) in eyes with cataract was 13.55  1.83 seconds among patients who underwent phacoemulsification with foldable IOL insertion (Group I) which was lowered significantly to 10.71 ± 2.07 seconds on Day 7 after the cataract surgery ($p < 0.001$). In group 2 the mean ± standard deviation TBUT preoperatively was 13.37 ± 1.54 seconds which was also significantly reduced to 10.38 ± 1.93 seconds on Day 7 after cataract surgery by phacoemulsification technique with non foldable IOL insertion ($p < 0.001$). The decrease of Tear Breakup Time was slightly more among patients in Group 2 as compared to the patients in group 1 but the decrease was statistically insignificant. So, non-significant results were obtained while comparing the distribution of patients according to TBUT at pre-operative, postoperative day 7, 1 month, 3 months and 6 months in between the two study groups. Within each group, irrespective of the Group 1 or 2 at 1 week, 1 month, 3 months or 6 months postoperatively, our study showed statistically significant deterioration of tear stability proven by TBUT as compared to their preoperative values. Our results were in concordance with similar studies by Gupta M., *et al* [18], Sinha M., *et al.* [19] which also reported similar results where all dry eye parameters showed worsening after 1 week followed by gradual trend of recovery, which despite of showing initial trend of recovery did not return completely to their preoperative values by the end of 3 months. Rapid deterioration of all the tear film parameters was observed in our study in the initial first week postoperatively in both the groups, which was consistent with findings by various authors. This can be explained because of the liberation of intense inflammatory mediators which desensitize the corneal sub-epithelial axons which results in tear film disturbance. At 4 weeks, 12 weeks and 24 weeks, gradually there occurs release of nerve growth factor (NGF) which causes nerves to regenerate slowly at par with the healing process, which explains why tear film parameters tend to stabilize to near the baseline value at 6 months.

When compared between the groups, the changes in dry eye parameters were found to be almost similar at any point of follow-up time. Sinha M., *et al*. [19] however found that while comparing between the groups, phacoemulsification showed marginally better tear film parameters. Contrary to our speculation at the beginning of the study that group 2 (non foldable IOL) might result in significant tear film changes as compared to group 1 (phacoemulsification with foldable IOL) because of longer Corneal incision resulting in more reduction in corneal sensitivity, our hypothesis did not work here, as in our study no significant difference was found in tear film parameters between the two groups. This is in concordance with similar studies by Gupta M., *et al* [18], Cetinkaya S., *et al* [20], Kasetsuwan N., *et al.* [21] which also did not report any significant differences in dry eye parameters following each procedure whether at day 7,1 month, 3 months or 6 months between both the groups.

Non-significant results were obtained while comparing the distribution of patients according to Schirmer's results at pre-operative, postoperative day 7, 1 month, 3 months and 6 months in between the two study groups. In regard to Schirmer's test, in both the groups 1 and 2, it reduced upto 1 week following cataract surgery and then returned to near baseline value at 6 months. Cho and Kim [22] also observed that dry eye symptoms and tear parameters results aggravated after cataract surgery as compared to the preoperative values. They concluded that TBUT and barrier function of corneal epithelium got affected in the early postoperative period after cataract surgery which is consistent with the present study. As the corneal epithelium progresses towards normalization so does the tear film parameters, which also normalizes near baseline values at the end of 6 months. The results of this study suggests that the removal of cataract is associated with worsening of TBUT and Schirmer's test values upto 1 week but revert back near the preoperative values at 6 months. Studies by Kasetsuwan N., *et al*. [21] and Dhawan M., *et al*. [23] also showed decreased test scores on immediate postoperative period followed by improvement at 1 month and 3 month postoperative period.

Non-significant results were obtained while comparing the mean IOP at pre-operative, postoperative day 7, 1 month, 3 months and 6 months in between the two study groups. Mean IOP was 15.09, 12.36, 13.03, 13.54 and 13.09 mmHg at pre-operative, postoperative day 7, postoperative 1 month, postoperative 3 months and postoperative 6 months in group I and 14.85, 12.54, 13.04,

13.36 and 13.88 mm Hg at pre-operative, postoperative day 7, 1 month, 3 months and 6 months in group II. There was no significant difference in mean IOP both the groups on each follow up visit. IOP started decreasing gradually up to day 7 postoperatively after that it again started normalizing to near baseline up to 6 months. A possible explanation for the decrease in IOP after cataract surgery with PCIOL implantation is increased anterior chamber depth (reduction in lens volume) resulting in decreased resistance to aqueous outflow [24]. Additionally, higher levels of prostaglandins (F2) in aqueous humor [25] may also reduce the IOP. Reduced IOP may also be associated with a hyposecretion of aqueous humor resulting from traction on the ciliary body due to fibrosis and contraction of the posterior lens capsule. Baek SU., *et al*. [26] conducted a study in 2019 which showed similar results. According to them, phacoemulsification resulted in IOP reduction, which effect regressed in healthy subjects and glaucoma patients over the course of long-term follow up. The phacoemulsification effected a reduction of IOP: 1.03 ± 3.72 mmHg in healthy subjects at the end of 6 months of follow up period in their study. Our results are in concordance with other studies which showed similar results by Lv., *et al* [27], Baek SU., *et al* [26].

Thus in our study we compared the visual outcomes of cataract surgery with foldable vs non foldable IOLs. The outcome of a cataract surgery depends on various factors like incision, approach, type of surgery, mode of intraocular lens insertion, and type of IOL.

The introduction of self-sealing clear corneal incision has gained popularity worldwide as it offers several benefits over the traditional sutured limbal incisions and scleral tunnel. In our study, UCVA and BCVA did not show significant difference in both the groups although a lesser number of patients had UCVA between 6/6 - 6/9 in group II as compared to group I.

Postoperative SIA depends on location, size, and architecture of the wound, and also the surgeons position and comfort during the procedure. The small size incision gives a rapid and a stable optical recovery, and thus a lesser SIA. Many studies were done to compare the astigmatism with different types of small incisions at different locations like superior, super nasal, supertemporal, and temporal. Regarding the architecture of the cornea, giving phacoemulsification incision on the steepest corneal axis at the time of cataract surgery can correct a small amount of astigmatism. We conducted the surgeries by temporal approach with different incision sizes in both the groups and found a significant difference in SIA comparing both the groups ($p < 0.05$). More SIA was found in patients operated with 5.25 mm clear corneal incision showing that larger the size of incision, larger is the post operative astigmatism.

Patients can complain of dryness postoperatively at any time starting from immediate first postoperative day, however the highest incidence is on the seventh postoperative day. The signs and symptoms associated with dry eye improve gradually. The tear breakup time and Schirmer's test also showed consistent results in evaluating dry eye postoperatively. In addition, no significant difference was observed between both the groups regarding dry eye parameters contrasting our expectations that group II might be associated with greater tear film changes as compared to group I. All the dry eye tests conducted on eyes undergoing cataract surgery showed initial deterioration following cataract surgery. The mean values of TBUT and Schirmer's showed initial reduction at postoperative at day 7. Thus cataract surgery affects both tear quantity and tear quality as after cataract surgery the corneal epithelium remains unstable due to altered corneal sensation and dynamics of tear film.

The IOP-lowering effect of cataract surgery has long been known in both glaucoma and non-glaucoma patients ranging from 3 to 60 months in previous studies which was consistent with our study as both the groups showed a significant reduction in IOP at 6 months compared with that before surgery ($p < 0.001$). It is probably the result of the thin inserted IOL compared with the thickness of natural crystalline lens and that lens exchange deepens the anterior chamber.

## Limitations of the Study

There are some limitations of our study. Firstly, the sample size is relatively small in both the groups. In our hospital, we perform phacoemulsification with implantation of foldable IOL more as compared to non foldable IOL, so we could enroll less number of patients in group II. Another limitation is that patients were followed up for only 6 months and future studies are warranted for studying long term effects.

## Conclusion

Phacoemulsification with implantation of a foldable IOL through a 2.8mm incision leads to less post operative astigmatism as compared to phacoemulsification with implantation of a non foldable IOL through 5.25 mm incision. The main concern of patients is final

visual outcome, which remains the same with both foldable and non foldable IOLs. Therefore, phacoemulsification with implantation of a foldable or an inexpensive rigid PMMA IOL gives excellent visual outcomes in hands of experienced cataract surgeons.

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