Section: Ophthalmology

Original Research Article

EXPLORING ANALYSIS BETWEEN FOLDABLE & RIGID I.O.L (INTRA OCULAR LENS)

Soumya Shashi[1], Reena Kumari[2], Dinesh Kumar Bhagat[3]

[1]Final Year PGT, Department of Ophthalmology, MGM Medical College & LSK Hospital, Kishanganj, Bihar, India.
[2]Professor, Department of Ophthalmology, MGM Medical College & LSK Hospital, Kishanganj, Bihar, India.
[3]Associate Professor, Department of Ophthalmology, MGM Medical College & LSK Hospital, Kishanganj, Bihar, India.

Received : 17/06/2023
Received in revised form : 25/07/2023
Accepted : 06/08/2023

Keywords:
Foldable IOLs, Rigid IOLs, Visual rehabilitation, Cataract surgery.

Corresponding Author:
Dr. Dinesh Kumar Bhagat
Email: drdineshkrbhagat@yahoo.com

DOI: 10.47009/jamp.2023.5.4.275

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5(4); 1374-1378

Abstract

Background: The field of ophthalmology has seen remarkable advancements in recent years, particularly in the realm of intraocular lenses (IOLs). Intraocular lenses are vital components used in cataract surgery and other refractive eye procedures to replace the natural crystalline lens. With the advent of foldable and rigid IOLs, ophthalmologists are now presented with a plethora of options to cater to the diverse needs of patients. This study aims to explore and analyze the key differences between foldable and rigid IOLs in terms of their design, implantation techniques, post-operative outcomes, and patient satisfaction. **Materials and Methods:** This hospital based prospective study was conducted in the Department of Ophthalmology of M.G.M. Medical College & L.S.K. Hospital Kishanganj, Bihar during December 2020 to November 2022. A total of 200 patients were included in the present study by simple Randomization. Patients were divided in two groups; 100 patients underwent phacoemulsification with foldable intraocular lens (IOL) and remaining 100 underwent phacoemulsification rigid IOL. **Results:** The mean age in foldable IOL and Rigid IOL was 57.10 ±7.41 years and 56.70±9.43 years respectively. The visual outcome achieved on the 7thpostoperative day was also better in Foldable IOL in which the percentage of patients who achieved BCVA of 6/18 or better was 96%, whereas it was 92% in Rigid IOL group. The difference in BCVA between both groups was statistically insignificant (p value 0.23336) at postoperative day 7. The visual outcome achieved on the postoperative day at 6th week was also better in Foldable IOL in which the percentage of patients who achieved BCVA of 6/18 or better was 95%, whereas it was 90% in rigid IOL group. Post-operatively there was significant difference regarding astigmatism in Rigid IOL(P=0.0000053) as compared to Foldable IOL (P=0.0000012). **Conclusion:** Foldable IOLs offer early visual rehabilitation due to smaller incisions. Both techniques achieve excellent visual outcomes, with Foldable IOLs showing slightly less induced astigmatism. Foldable IOLs are preferred due to smaller incisions and reduced risk of wound-related complications. Visual acuity at different post-operative stages is better with Foldable IOLs. Foldable IOLs allow early return to work and do not require hospital stay. Despite their advantages, Foldable IOLs are expensive, making Rigid IOLs a more affordable option, especially in developing nations like India.

INTRODUCTION

Cataract remains the leading cause of global blindness, despite increased cataract surgeries due to initiatives like Vision 2020. Poor visual outcomes affect a significant proportion of operated cataract patients in Asia, Africa, and Latin America. Developing nations, home to 87% of the world's blind, face specific challenges in accessing effective cataract surgeries.[1,2]

Phacoemulsification, a popular method, involves a foldable IOL implantation through a small incision, providing rapid wound healing, less astigmatism, and early visual rehabilitation. In higher-income countries, this procedure is preferred due to its superior visual outcomes. However, in low- and middle-income countries (LMICs), access to

ISSN(O): 2687-5365; ISSN(P):2753-6556

phacoemulsification is limited by the high cost of equipment and foldable IOLs.[3-5]

This study compares the outcomes of inexpensive rigid IOLs with more expensive foldable IOLs after phacoemulsification. The aim is to determine if rigid IOLs can provide comparable safety and efficacy, potentially making phacoemulsification more accessible to LMIC patients.

Rigid IOL implantation has several drawbacks, such as larger incisions, induced astigmatism, and increased risk of complications like endophthalmitis and secondary glaucoma. Foldable IOLs have become the preferred choice in both Western countries and India due to their benefits, allowing patients to resume normal activities sooner.

MATERIALS AND METHODS

This hospital based prospective study was conducted in the Department of Ophthalmology of M.G.M. Medical College & L.S.K. Hospital Kishanganj, Bihar during December 2020 to November 2022. A total of 200 patients were included in the present study by simple Randomization. Patients were divided in two groups; 100 patients underwent phacoemulsification with foldable intraocular lens (IOL) and remaining 100 underwent phacoemulsification rigid IOL.

Surgical Technique: An automated keratometer was used for the purpose of keratometry and an A-Scan ultrasound for the purpose of axial length measurement. The power of the intra-ocular lens was calculated with the modified SRK/T formula.

After pupil dilatation with tropicamide and phenylephrine eye drops, a peribulbar injection was given in supine position and the patient eyeball is pressed with the palm of the hand over a piece of a cotton gauge to soften the eyeball. Preoperative povidone iodine 5% solution was used for disinfection of the periocular skin area. The surgeon performed the operations in sitting position on two alternate tables using separate microscope.

All the surgeries were done via the temporal approach by the same surgeon. Phacoemulsification technique was used for performing cataract surgery in this study. Procedure done was phacoemulsification with 2.8mm port. After nucleus and epinucleus management, foldable intra ocular lens was implanted under viscoelasitcs in the capsular bag with IOL injector. For all rigid IOL cases, a large incision was made of 5.2mm by keratome and lens was implanted in the capsular bag with the help of Kelman Mcphersonforcep. All wounds were closed by wound hydration with 27 G cannula and injection Gentamycin and Dexamethasone was injected subconjunctivally.

Types of outcome measures

Primary outcomes

Postoperative visual acuity: Proportion of people achieving good functional vision, defined as presenting visual acuity better than or equal to 6/12 in the operated eye and proportion of people with a poor outcome after surgery, defined as best corrected visual acuity (BCVA) worse than 6/60 in the operated eye.

Secondary outcomes

Intra-operative complications

capsular rupture with or without vitreous loss
iris prolapse
postoperative inflammation
other complications as reported

Statistical Analysis

All recorded data was analyzed with suitable diagrams, figures, tables and findings were discussed in details to draw appropriate conclusions using standard statistical analysis. Data were analyzed using Statistical Package for the Social Sciences (SPSS) Inc, Chicago, USA; Version 19.0. Continuous variables were expressed in mean and standard deviations (SD). Categorical variables were expressed as number and percentages. Proportional Z test was used to compare categorical variable. A value of $p < 0.05$ was considered to indicate statistical significance.

RESULTS

Table 1: Age Distribution

Age Group	GROUP A (n=100)		GROUP B (n=100)	
	Frequency	Percentage	Frequency	Percentage
40-50 years	18	18.0	14	14.0
51-60 years	44	44.0	52	50.0
61-70 years	26	22.0	28	26.0
>70 years	12	10.0	6	6.0
Total	100	100.0	100	100.0
Mean Age	56.70 ±9.43		57.10 ±7.41	
Statistical Analysis	Z value- 0.334, p value: 0.7387> 0.05, not significant, accept null hypothesis.			

The mean age in foldable IOL and Rigid IOL was 57.10 ±7.41 years and 56.70±9.43 years respectively. There was no significant difference regarding age between two groups (p value = 0.7387).

ISSN(O): 2687-5365; ISSN(P):2753-6556

Table 2: Sex Distribution

Sex	GROUP A (n=100)		GROUP B (n=100)	
	Frequency	Percentage	Frequency	Percentage
Male	48	48.0	44	44.0
Female	52	52.0	56	56.0
Total	100	100.0	100	100.0
Statistical Analysis	Chi-square-0.3211 P Value- 0.57322, not significant p<0.05			

With respect to the sex, there were more female patients in both Rigid IOL (52%) and Foldable IOL (56%) group. In above analysis both the groups were comparable and there was no significant difference between two groups (p value =0.57322).

Table 3: Economical feasibility

Price of rigid IOL	Price of foldable IOL
X	3X

This table simply represents the price difference between foldable and rigid IOL showing 3 times difference of price between the two IOL types, where the rigid IOL is more economic than foldable IOL.

Table 4: Visual Outcome at Postoperative Day 1

Visual Outcome	GROUP A (n=100)		GROUP B (n=100)	
	Frequency	Percentage	Frequency	Percentage
Good (6/6-6/18)	72	72.0	76	76.0
Borderline (6/24-6/60)	20	20.0	22	22.0
Poor (<6/60)	8	8.0	2	2.0
Total	100	100.0	100	100.0
Statistical Analysis	Chi-square-3.8033, p Value- 0.1493, not significant at p<0.05			

With respect to the preoperative visual acuity in this study, it was almost similar in both groups. The visual outcome achieved on the first postoperative day was better in group Bin which the percentage of patients who achieved BCVA of 6/18 or better was 76%, whereas it was 72%in group A. The difference in BCVA between both groups was statistically insignificant (p value = 0.1493) postoperative day 1. Data is provided in Table 4.

Table 5: Visual Outcome at Postoperative Day 7

Visual Outcome	GROUP A (n=100)		GROUP B (n=100)	
	Frequency	Percentage	Frequency	Percentage
Good (6/6-6/18)	92	92.0	96	96.0
Borderline (6/24-6/60)	8	8.0	4	4.0
Poor (<6/60)	0	0.0	0	0.0
Total	100	100.0	100	100.0
Statistical Analysis	Chi-square-1.4184, p Value- 0.23336, not significant at p<0.05			

The visual outcome achieved on the 7thpostoperative day was a better in group B in which the percentage of patients who achieved BCVA of 6/18 or better was 96%, whereas it was 92% in group A. The difference in BCVA between both groups was statistically insignificant (p value 0.23336) at postoperative day 7. Data is provided in Table 5.

Table 6: Visual Outcome at Postoperative Day 6th week

Visual Outcome	GROUP A (n=100)		GROUP B (n=100)	
	Frequency	Percentage	Frequency	Percentage
Good (6/6-6/18)	90	90.0	95	95.0
Borderline (6/24-6/60)	10	10.0	5	5.0
Poor (<6/60)	0	0.0	0	0.0
Total	100	100.0	100	100.0
Statistical Analysis	Z = 1.3423 Chi-square-1.8018, p Value- 0.1794,			

The visual outcome achieved on the 6th postoperative week was a better in group B in which the percentage of patients who achieved BCVA of 6/18 or better was 95%, whereas it was 90% in group A. The difference in BCVA between both groups was statistically insignificant (p value 0.1794) at postoperative day 7. Data is provided in Table 6.

ISSN(O): 2687-5365; ISSN(P):2753-6556

Table 7: Comparison between the mean preoperative and postoperative Astigmatism

Astigmatism	Preoperative		Postoperative		p value
	Mean	±SD	Mean	±SD	
Group A	0.94	±0.35	1.22	±0.35	Z = 5.6569 P=0.0000053 < 0.05, Highly significant
Group B	0.79	±0.33	1.05	±0.34	Z = 5.4874 P=0.0000012 < 0.05, Highly significant

Table 7. Presents the data regarding the mean preoperative and postoperative astigmatism in both the groups. There was a significant difference in group A and group B pre and postoperatively regarding the astigmatism. Moreover, we found less astigmatism in group Bas compare to preoperative and postoperative patients with groupA.

Table 8: Early Postoperative Complications

Postoperative Complications	GROUP A (n=100)		GROUP B (n=100)	
	Frequency	Percentage	Frequency	Percentage
Corneal Edema	10	10.0	10	10.0
Anterior Chamber reaction	14	14.0	12	12.0
Hyphema	2	2.0	0	0.0
Iris Prolapse	2	2.0	0	0.0
Wound Leak	2	2.0	0	0.0
None	70	70.0	78	78.0
Total	100	100.0	100	100.0
Statistical Analysis	Chi-square-2.4837 p Value- 0.6475 >0.05, not significant			

Postoperatively, 10 patients in group A and 10 patients in group B had corneal edema; and 14patient in Group A and 12 patients in Group B had increased anterior chamber reactions due to postoperative uveitis and 2 patient each had Hyphema, Iris Prolapse, Wound Leak in group A.70 patients in group A and 78 patients in group B had no complications. In Above analysis the group Awere having less postoperative complications. Data is shown in Table 8.

DISCUSSION

Hence the present study was aimed to find out the effectiveness of Foldable IOL in comparison to Rigid IOL.

The present study was conducted in the Department of Ophthalmology of M.G.M. Medical College & L.S.K. Hospital. A total of 200 patients were included in the present study. Patients were divided in two groups; 100 patients underwent Phacoemulsification with Rigid IOL and remaining 100 underwent Phacoemulsification with Foldable IOL.

With respect to the preoperative visual acuity in this study, it was almost similar in both groups. The visual outcome achieved on the first postoperative day was better in Foldable IOL in which the percentage of patients who achieved BCVA of 6/18 or better was 78%, whereas it was 70% in Rigid IOL group. The difference in BCVA between both groups was statistically insignificant (p value = 0.1493) postoperative day 1.

The visual outcome achieved on the 7th postoperative day was better in foldable IOL in which the percentage of patients who achieved BCVA of 6/18 or better was 96%, whereas it was 92% in Rigid IOL. The difference in BCVA between both groups was statistically insignificant (p value 0.23336) at postoperative day 7.

The visual outcome achieved at 6th week postoperative was better in foldable IOL in which the percentage of patients who achieved BCVA of 6/18 or better was 95%, whereas it was 90% in Rigid IOL. The difference in BCVA between both groups was statistically insignificant (p Value-0.1794) at postoperative 6th week.

We found significant difference regarding preoperative and postoperative astigmatism between groups. Postoperatively, 10 patients in each group A & group B had corneal edema; and 14 patients had increased anterior chamber reactions due to postoperative uveitis in Rigid IOL. Above analysis both the groups were comparable in terms of postoperative complications.

In the present study there was a significant difference in group A(P=0.0000053) and group B (P=0.0000012) postoperatively regarding the astigmatism. Moreover, we found less astigmatism in group B as compare to postoperative patients with group A. This is consistent with the study of Anand Aggarwal. et al.(2022)where 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.[6]and also consistent with the study of Dr RupaliTyagi, Dr Tarannum Shakeel, Dr Manisha Gupta (2018)which showed that though there was a statistically significant difference in terms of surgically induced astigmatism, the final visual outcome was comparable in the two groups.[7]

With respect to surgically induce astigmatism less astigmatism was found in 2.8mm incision than 5.2 mm incision which is constant with the study

ISSN(O): 2687-5365; ISSN(P):2753-6556

ofSweta Ambadkar, Archana Thool (2021) showed SIA is less in 3.2 mm incision as compared to 5.5 mm incision with increase in against the rule astigmatism postoperatively.[8]

Amarnath V Awargaonkar, Archana A Vare, Varsha S Nandedkar, Amruta Jiwane, Sagar Janrao. (2019) concluded that there were similar results with regard to surgical induced astigmatism and corrected visual acuity after Phacoemulsification cataract surgery using foldable PCIOL and rigid PCIOL implantation and the present study also showed no significant difference in the visual acuity between the two groups.[9]

However, the present study is not consistent with the study of Dr. Mona Liza Mahesar, Dr. Azfar Ahmed Mirza, Dr. Noman Ahmed, Dr. Sameen Afzal Junejo & Dr. Asif Mashood Qazi (2017)which showed significant difference found in visual outcome between rigid and foldable IOL implantation.[10]

The present study showed similar results with AHennig et al (2014) which showed in the hands of experienced cataract surgeons, phacoemulsification with implantation of a foldable or a rigid IOL gives excellent results. Using an inexpensive rigid PMMA IOL will make phacoemulsification more affordable for poor patients in low- and middle-income countries.[11]

Afsar A., Patel S., Woods R. et al.(1999) showed that implanting a foldable acrylic IOL gave no post-operative benefit in visual acuity and contrast sensitivity to pseudophakes over a less expensive rigid PMMA IOL, within 2 months of post-operative period and this is consistent with the present study.[12]

Hence, based on the observation of the present study and other previous studies we can suggest that although Rigid IOL is the preferred technique among most of the eye surgeons all over the world, another alternative to Rigid IOL–Foldable IOL – was shown to get popularity because of its comparable surgical and postoperatively good visual outcomes to Rigid IOL. Furthermore, Rigid IOL is cheap and affordable; hence, it can be implanted in overcrowded poor communities in which large number of cataract surgeries are needed to be performed to overcome the increasing incidence of blindness in those communities. In this study, the two IOL's used for cataract surgery were compared from the aspect of finding out the effectiveness of rigidas an alternative to foldable IOLs surgery. Hence, Rigid IOL is a good alternative to Foldable IOL.

CONCLUSION

Foldable IOLs offer early visual rehabilitation due to smaller incisions. Both techniques achieve excellent visual outcomes, with Foldable IOLs showing slightly less induced astigmatism. Foldable IOLs are preferred due to smaller incisions and reduced risk of wound-related complications. Visual acuity at different post-operative stages is better with Foldable IOLs. Foldable IOLs allow early return to work and do not require hospital stay. Despite their advantages, Foldable IOLs are expensive, making Rigid IOLs a more affordable option, especially in developing nations like India.

REFERENCES

1. Pascolini D, Mariotti SP. Global estimates of visual impairment: 2010. Br J Ophthalmol. 2012;96 (5:614–618. [PubMed] [Google Scholar]
2. Lindfield R, Vishwanath K, Ngounou F, Khanna RC. The challenges in improving outcome of cataract surgery in low and middle income countries. Indian J Ophthalmol. 2012;60 (5:464–469. [PMC free article] [PubMed] [Google Scholar]
3. Riaz Y, Mehta JS, Wormald R, Evans JR, Foster A, Ravilla T, et al. Surgical interventions for age-related cataract Cochrane Database Syst Rev 2006(4CD001323doi:10.1002/14651858.CD001323.pub2 [PMC free article] [PubMed] [CrossRef]
4. Gogate PM, Kulkarni SR, Krishnaiah S, Deshpande RD, Joshi SA, Palimkar A, et al. Safety and efficacy of Foldable IOL compared with Rigid IOL cataract surgery by a randomized controlled clinical trial: six-week results. Ophthalmology. 2005;112 (5:869–874. [PubMed] [Google Scholar]
5. Cook C, Carrara H,Myer L. Phaco-emulsification versus Rigid IOL cataract surgery in South Africa. S Afr Med J. 2012;102 (6:537–540. [PubMed] [Google Scholar].
6. Anand Aggarwal., et al. "A Prospective Study on Visual Outcomes of Cataract Surgery after Foldable IOL with Foldable vs Non Foldable Intraocular Lenses". Acta Scientific Ophthalmology 5.3 (2022): 48-59.
7. Dr Rupali Tyagi1, Dr Tarannum Shakeel2, Dr Manisha Gupta3 "Comparative Analysis of Foldable IOL Cataract Surgery with Rigid and S in Terms of Safety, Efficacy and final Visual outcome – A Retrospective Study at a State Hospital" JMSCR Volume 06 Issue 11 November 2018.
8. SwetaAmbadkar, ArchanaThool "Comparative Study of Postoperative Astigmatism Following Foldable IOL with Scleral Incision and Posterior Chamber Foldable and Rigid (Nonfoldable) Intraocular Lens Implantation" Journal of DattaMeghe Institute of Medical Sciences University ¦ Volume 16 ¦ Issue 4 ¦ October-December 2021.
9. Amarnath V Awargaonkar, Archana A Vare, Varsha S Nandedkar, AmrutaJiwane, SagarJanrao. Assessment of surgical induced astigmatism with foldable and non-foldable intraocular lens implantation after Foldable IOL cataract surgery. MedPulse International Journal of Ophthalmology. June 2019; 10(3): 60-63.
10. Dr.Mona Liza Mahesar1, Dr.Azfar Ahmed Mirza2, Dr.Noman Ahmed3, Dr.Sameen Afzal Junejo4&Dr. Asif Mashood Qazi5 "The Visual Outcome between Foldable and Rigid Intraocular Lens Implantation in Foldable IOL – A Hospital Based Study" IOSR Journal of Dental and Medical Sciences (IOSR-JDMS) e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 16, Issue 10 Ver. XIII (Oct. 2017), PP 74-80.
11. Hennig A, Puri LR, Sharma H, Evans JR, Yorston D. Foldable vs rigid lenses after Foldable IOL for cataract surgery: a randomised controlled trial. Eye (Lond). 2014 May;28(5):567-75. doi: 10.1038/eye.2014.26. Epub 2014 Feb 21. PMID: 24556879; PMCID: PMC4017108.
12. Afsar, A., Patel, S., Woods, R. et al. A comparison of visual performance between a rigid PMMA and a foldable acrylic intraocular lens. Eye 13, 329–335 (1999). https://doi.org/10.1038/eye.1999.84.

ISSN(O): 2687-5365; ISSN(P):2753-6556