



A PROSPECTIVE STUDY OF OUTCOME OF MULTIFOCAL INTRAOCULAR LENS (IOL) IMPLANTATION IN PATIENTS WITH CATARACT

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ABSTRACT

Purpose- A prospective study of outcome of multifocal intraocular lens (IOL) implantation in patients with cataract. **Methods-** The prospective study interventional non comparative study will enroll 50 cases of multifocal intra ocular lens implantations that reported to the Department of Ophthalmology at Maharani Laxmi Bai Medical College, Jhansi from July 2020- August 2021 (14 months duration) **Results:** The study included 27 males (56.25%) and 21 females (43.75%) i.e male preponderance. Cataract does not have predilection for sex. In our study age ranges from 40 years to 74 years, majority of the patients were found to be between the age of 50- 59 years . In this study the baseline BCVA in cataractous (operative) eye at the time of presentation were ranging from 6/12 to PL negative with most of the patients had BCVA-6\60 (11), 6/36 (09), FC 2mt (06). In the present study 71% patients was spectacles independence for distance and 92% patient did not require specs for near vision In the present study 28 (58%) patients experiences post op glare and 24 (42.00%) did not **Conclusion:** 1.In the present study 71% patients was spectacles independence for distance and 92% patient did not require specs for near vision 2.In the present study 28 (58%) patients experiences post op glare and 24 (42.00%) did not. 3.In this study out of 48 patients,19 patient developed complications 14 patients (29.00%) experience residual ametropia and 5 patients (10.00%) developed dry eye.

KEYWORDS : BCVA, NCT,UDVA

INTRODUCTION

An estimated 20.5 million Americans older than 40 years have cataract in at least one eye.^[1] While cataract is the leading cause of blindness worldwide ^[2,3] most populations in developed Western countries have access to cataract surgery (eg, 6.1 million [5.1%] of American citizens have pseudophakia/aphakia). The total number of Americans with cataract is predicted to increase to 30.1 million by 2020, of whom 9.5 million are expected to have pseudophakia. More than 80% of patients regain good best-corrected visual acuity (visual acuity ≥ 8/10) after cataract surgery, depending on other ocular pathology and duration of follow-up^[4-8].

Intraocular lens materials –

1. Polymethyl Methacrylate
2. Hydrophobic Foldable Acrylic
3. Silicone
4. Hydrophilic Foldable Acrylic

Types of intraocular lens –

MONOFOCAL	MULTIFOCAL	ACCOMMODATING	TORIC IOL
Provides good vision at one distance (typically far vision)	Correct vision for near, far and intermediate distances	Corrects vision for all ranges of vision using a hinged monofocal lens that moves within the eye like the natural lens of the eye	Corrects for astigmatism after cataract surgery.
Requires reading glasses after surgery	May substantially reduce the need for glasses*	May substantially reduce the need for glasses for distance and intermediate vision*	May substantially reduce astigmatism after cataract surgery
Covered by Medicare	Partial coverage by Medicare (consult our staff)	Partial coverage by Medicare (consult our staff)	Partial coverage by Medicare (consult our staff)

MATERIALS AND METHODS:

The proposed study will be carried out at the Department of Ophthalmology, MAHARANI LAXMI BAI MEDICAL COLLEGE, JHANSI, UTTAR PRADESH

Inclusion Criteria:

- Patients with age >35years and <75 years.
- Patients who agreed to participate in the study and willing to give the informed written consent.
- Patients diagnosed with unilateral or bilateral cataract and having impaired visual acuity in Snellen Chart of 6/12

or worse.

- Surgeries performed by an experienced Ophthalmologist
- The patient should have a strong desire to be spectacle independent.
- Patient with preoperative good corneal endothelial cell counts, clear cornea, well dilated pupils under medication, intact zonular apparatus, and good ocular tone.
- Functional & Occupational Requirements (occupations involving intermediate reading e.g. clergy who read from a desk or stall, teachers and advocate who walk round the class/court inspecting/presenting)
- Patients who often complain of the difficulty in multi tasking post IOL surgery with monofocal lens implant. This category of patients are the ones to target for.
- Strong urge for near reading without glasses
- Patient with confirmed RTPCR negative report for covid -19 infection

Exclusion Criteria

- Age <35 years and >75 years
- Patients unwilling to give a written consent and routine follow up protocols will be excluded from the study
- Pregnant female and lactating mothers
- Tear film instability
- Neuro ophthalmic diseases
- Ophthalmic pathology that might affect postoperative visual function, such as macular degeneration, corneal diseases (corneal dystrophies 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.
- Ophthalmic Exclusion
 - Patients with more than 1.0D of corneal astigmatism
 - Individuals with a monofocal lens in one eye
 - History of previous Refractive Surgery
- Intra-operative Exclusion Criterias
 - Significant vitreous loss during surgery
 - Pupil trauma during surgery

- Zonular damage
- Capsulorrhexis tear
- Capsular rupture

Occupational exclusion:

occupations that require best possible distance vision at all times or excellent night vision i.e. pilot/drivers

Selection of cases:

The above mentioned prospective study was carried on 50 patients in 14 months time interval (July 2020 to August 2021)

Evaluation of patients:

A detailed history was taken from all patients. This included history of any ocular complaints, diminution of vision, duration of diminution, use of glasses, history of floaters, history of attacks of pain, redness, history of trauma to the eye, past ocular surgery, previous ocular medications, any systemic medication, history suggestive of any systemic complaints or diseases like of Diabetes Mellitus (DM), Hypertension (HTN) & family history of ocular or systemic diseases was elicited from the patients in the OPD.

Patients satisfying the inclusion criteria were selected and patient's particulars like **name, age, sex, address, socioeconomic status** and **occupation** was recorded.

Ocular examination:

Detailed ocular examination is done in all patients with special emphasis on:

Visual acuity:

Unaided visual acuity, visual acuity with pin hole & visual acuity with glasses in each eye were recorded using snellen's charts.

Slit lamp biomicroscopy:

Slit lamp biomicroscopy with diffuse illumination, focal illumination & retro-illumination were used & a careful assessment of corneal thickness & transparency, anterior chamber examination for any evidence of uveitis, the type of cataract & capsule.

Keratometry:

Keratometry of eye was done to measure corneal curvature by using manual keratometer

Axial length measurement:

Axial length measurement was done by ultrasound A Scan biometer (Biomedics model)

Calculation of iol power:

IOL power was calculated for operating eye by using the

Sanders Retzlaff-Kraff II (SRK II) Formula:

- $P = A - 2.5L - 0.9K$
- P=Implant power to produce emmetropia
- L=Axial length
- K=Average keratometer reading
- A=Specific constant for each lens type & manufacture

Biometry:

- An accurate biometry is a prerequisite for precise IOL power calculation The axial length may be estimated by either ultrasonic biometry or optical systems such as IOL Master (Carl Zeiss Meditec, Germany) and Lenstar (Haag Streit, Switzerland).
- Keratometry estimation is of paramount importance to determine the power as well as the axis of the Multi focal IOL. Various instruments based on different principles may be used for keratometry estimation, such as manual and automated

- Keratometers. Preoperative keratometry will be performed by the 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. The keratometry will be calculated by two methods to look for concordance and avoid great differences in preoperative keratometry values to avoid postoperative refractive surprise. It will be the values of optical keratometry that were relied upon. Axial length will be measured by optical coherence biometer. The axial length will be matched in both the groups as bag size tends to be larger in long eyes and this is an important factor in Multi focal IOL rotation. Four formulas will be used (SRK-T, Holladay, Hoffer Q, and Universal Barrett formula) to calculate standard error (SE) of Multi focal IOL. The four formulas will be employed just to look at concordance of calculated IOL power (spherical equivalent). We will use Universal Barrett formula for SE calculation as this is more accurate compared to other formulas for all axial lengths.
- The determination of model of Multi focal IOL to be implanted and the axis at which it should be placed with an aim of minimum residual cylinder will be performed using online calculator (www.acrysofMulti focal IOL calculator.com and www.zcalc. meditec.zeiss.com). We will not do any vector analysis.

The study was followed in accordance with **Ethical Standards Committee** on human experimentation (institutional or regional) and abides by tenets of **Declaration of Helsinki (1975 and 2000 revision)**. Necessary permission from **Institutional Ethical and Research Committee** was obtained thereby.

Statistics:

Data will be analysed by the Statistical Package for the Social Sciences (SPSS for windows, version 25.0). Descriptive statistics included mean and standard deviation for numerical variables, and the percentage of different categories for categorical variables

RESULT

A total of 50 patients who fulfilled the inclusion criteria were selected for this study, out of which 2 patients were excluded (drop out) at initial Stage of study due to reasons mentioned below Finally 48 patients were included in this study. In total 48 eyes of 48 patient were included in this study

Age:

In our study age ranges from **40 years to 74 years**, majority of the patients were found to be between the age of 50- 59 years

Gender:

The study included 27 **males (56.25%)** and 21 **females (43.75%)** i.e male preponderance.

Table 1: Bcva In Cataractous (operative) Eye Of The Patients At The Time Of Persentation

Baseline UDVA/log MAR (in operative eye)	No. of cases	Percentage (%)
6/6(0)	0	0%
6/9(0.176)	0	0%
6/12(0.301)	05	10%
6/18(0.4771)	04	8%
6/24(0.602)	05	10%
6/36(0.78)	09	18%
6/60(1)	15	31.00%
FC 3mt(1.301)	01	2%
FC 2mt(1.477)	06	12%
FC 1mt(1.778)	03	6%
Total	48	100%

UDVA (uncorrected distance visual acuity), FC (finger counting)

Table 2: Socio-economic Status Of The Patients (according To The Modified Kuppaswami Scale)

Socioeconomic status	Number of patients	Percentage
High	31	65.00%
Medium	12	25.00%
Low	05	10.41%
Total	48	100%

Table 3: Vision At 1 Week Of Follow Up

UDVA(LogMAR)	Preoperative vision	1 week	p value
Mean±SD	0.95±0.351	0.53±0.153	0.001

Table 4: UdvA At 6 Months Of Follow Up

UDVA(logMAR)	Preoperative vision	6 months	p value
Mean±SD	0.95±0.351	0.12±0.173	0.001

Table 5: Bcva At The 1 Month Of Follow Up

BCVA(logMAR)	Preoperative BCVA	1 month	p value
Mean±SD	0.86±0.252	0.12±0.154	0.001 (S)

Table 6: Bcva At The 6 Months Of Follow Up

BCVA (logMAR)	Preoperative BCVA	6month	p value
Mean±SD	0.86±0.252	0.16±1.173	0.001 (S)

In this study 44 patients (92.00%) have N\6 near vision and 4 patients (8.00%) have N\9 near vision.

In this study 28 (58.00%) patient experience glare and 20 (42.00%) patient did not.

Table 7: Patients With Spectacles Independence At 1 Month

1 MONTH FOLLOW UP	Patients specs independence	Percentage
YES	28	58.00%
NO	20	42.00%
TOTAL	48	100%

In this study at 6 month out of 48 patients 34 (71.00%) patients was spectacles independence and 14 patients (29%) was not

DISCUSSION:

In our study cataract was proportionately higher in male (56.25%) compared to females (43.75%) In the present study maximum number of 36.00% cases belonged to age group 50-59 yrs Kazuno nagishi et al^[9] study the intermediate and near VAs varied with the IOL models; 68.4% of patients were almost or totally spectacle-independent; 3.9% of patients reported surgical dissatisfaction. In patients implanted bilaterally with the same mIOLs, postoperative blurred vision and/or decreased contrast was the most important factor in the overall surgical satisfaction.in our study 71% patients was spectacle independence and few of them having halos 58%.

J,Javitt et al^[10] –A higher proportion in the multifocal group achieved both 0.5 (20/40) and J3 or better uncorrected binocular distance and near visual acuities (97% with P < .001). our study is consistent with other study

S.Cillino et al^[11] study Night halos were more common in the refractive groups (P<0.01). Spectacle independence was 20% in the monofocal IOL group, 43.7% and 53.3% in the refractive multifocal IOL groups, and 87.5% in the diffractive multifocal IOL group (P<0.05). Our study is consistent with this study .night halos in our study is 58% and spectacle independency is 71%.

CONCLUSION

- Over all more than a quarter of the world's population around 2.2 billion people suffer from vision impairment, out of which one billion cases could have been prevented or have been left unaddressed, according to the first *World Vision Report* released by the World Health Organization

(WHO) on October 8, 2019. Cataract are responsible for 65.2 million cases globally^[137].In India cataract is the leading cause of blindness in people above 50 years, according to the *National Blindness and Visual Impairment Survey India 2015-19*. The condition is behind 66.2 % blindness cases, 80.7 % severe visual impairment cases and 70.2 % moderate visual impairment cases. And around 93% of blindness cases and 96.2 % of visual impairment cases in this age group were avoidable. In the South East Asia region Cataract is the most common cause of blindness and is responsible for 50-80% of all blindness. Accordingly, control of blindness and visual impairment due to cataract is a priority in the World Health Organization's (WHO) current "Universal Eye Health: a global action plan 2014–2019" which was endorsed at the 66th World Health Assembly".

- Multifocal IOLs are good options to correct pseudophakic presbyopia as they achieve spectacle independence in the majority of the cases with high levels of patient satisfaction. The visual needs of each patient should be carefully analyzed to choose the multifocal model that best fits their lifestyle.
- To obtain success after surgery, it is crucial to adequately select the patient, include an extensive preoperative evaluation of ocular surface and macula, as well as determine the correct IOL and surgical technique, because the several models have different visual performances. It is also very important to spend some chair time with the patient to explain all factors involved in the outcomes of the surgery and possible complications management.
- However, some patients may be dissatisfied and the most common complaints are blurred vision and photopic phenomena, usually due to residual refractive errors, PCO, dry eye, inadequate pupil size, wavefront abnormalities, and IOL decentration. Thus, most of these complications if managed properly may not affect the visual outcomes and the patient's satisfaction and quality of life.

REFERENCES:

1. [Thylefors BNegrel ADPararajasegaram RDadzie KY Global data on blindness [review]. Bull World Health Organ. 1995;73115- 121
2. Rahmani BTielsch JMKatz JGottsch JQuigley HJavitt JSommer Afor the Baltimore Eye Survey, The cause-specific prevalence of visual impairment in an urban population. Ophthalmology. 1996;1031721 1726
3. Ellwein LBurato CJ Use of eye care and associated charges among the Medicare population:1991-1998. ArchOphthalmol. 2002;120804- 811 US Census, 2000 Population Tables:
4. US Census 2000 Summary File 1 (SF 1) 100-Percent Data.
5. Writing Group for the Eye Diseases Prevalence Research Group, Causes and prevalence of visual impairment among adults in the UnitedStates. Arch Ophthalmol. 2004;122477- 485
6. Mitchell PCummings RGAttebo KPanchapakesan J Prevalence of cataract in Australia: the Blue Mountains Eye Study. Ophthalmology. 1997;104581- 588
7. Klein BEKlein RLinton KLP Prevalence of age-related lens opacities in a population: the BeaverDam Eye Study. Ophthalmology. 1992;- 99546- 552.
8. Leske MCCConnell AMWu SYHyman LSchachat A Prevalence of lens opacities in the Barbados Eye Study. Arch Ophthalmol. 1997;115105- 111.
9. Negishi K, Hayashi K, Kamiya K, Sato M, Bissen-Miyajima H; Survey Working Group of the Japanese Society of Cataract and Refractive Surgery. Nationwide Prospective Cohort Study on Cataract Surgery With Multifocal Intraocular Lens Implantation in Japan. Am J Ophthalmol. 2019 Dec;208:133-144.
10. Javitt JC, Steinert RF. Cataract extraction with multifocal intraocular lens implantation: A multinational clinical trial evaluating clinical, functional, and quality-of-life outcomes. Ophthalmology. 2000;107:2040- 2048.
11. Cillino S, Casuccio A, Di Pace F, Morreale R, Pillitteri F, Cillino G, Lodato G. One-year outcomes with new-generation multifocal intraocular lenses. Ophthalmology. 2008 Sep;115(9):1508-16.