INDEX OF CONTENTS

ACRONYMS AND ABBREVIATIONS

ABBREVIATION	MEANING
IOL	Intraocular Lens
MFIOL	Multifocal Intraocular Lens
BCVA	Best Corrected Visual Acuity
IOP	Intra Ocular Pressure

INTRODUCTION

The loss of eyesight as a result of cataract can seriously impair a person's quality of life. In fact, cataract is the leading cause of blindness in the world. Unlike in the past, advances in the field of IOL technology have significantly improved the results of cataract surgery.

The human lens has the ability to change its focal length which enables us to see both – distant as well as near objects with relative ease. However, the traditionally used IOLs consist of monofocal lenses whose focal length is fixed. This enables the patients to see distant objects clearly. However, the patient is forced to use spectacles for near vision. This dependence on spectacle use may impair one's quality of life.

The objective of cataract surgery should not be only to remove the opacified lens, but also to improve the quality of life. Subjects who do not wish to use spectacles after cataract surgery need an IOL that enables them to see both distant as well as nearby objects clearly. This can be achieved by using multifocal IOLs. A multifocal IOL is similar in design to bifocal spectacles – different regions of the IOL are used for different distances. Therefore, the main aim of using multifocal IOLs is to liberate the patients from having to use spectacles post cataract surgery.

The initial designs of multifocal IOLs were associated with poor functional outcomes. Patients often complained of halos, poor accommodation, reduced contrast sensitivity, and glare. With the latest improvements in intraocular lens technology, newer multifocal IOLs have been developed which aim to reduce these drawbacks and can produce acceptable functional outcomes in patients. However, multifocal IOLs are costlier as compared to their traditional monofocal counterparts. Not only that, many patients continue to complain of halos and glare.

Our study aims to evaluate the clinical and functional outcomes achieved in patients after multifocal IOL implantation.

REVIEW OF LITERATURE

There are several studies which have described the postoperative outcomes of visual acuity for far and near distance following implantation of multifocal IOLs. Most of these studies have focussed on comparison between Multifocal and Monofocal IOLs. However, the following points need to be kept in mind when reviewing the literature:

- The type as well as the manufacturer of the IOL can significantly affect the visual outcomes. We have restricted our review of literature to the studies which implanted a multifocal IOL which was of similar design as one proposed to be used in our study (Tecnis ZMB00 by Abott Medical Optics Inc.).
- One general problem with collecting visual acuity data from different publications is the variation in the presentation of outcomes. Some give Jaeger optotypes whereas others give mean logMAR values with or without standard deviation.
- With respect to measuring techniques, thus far there has been no standardized way of testing near visual acuity.

1) Study for evaluating patient outcomes following MFIOL implantation by Lane et al[1]

A study was conducted in the US by Lane et al to evaluate the improvements in patient outcomes after multifocal IOL implantation. The study consisted of a total of 147 patients. They found that

- The mean UDVA was 20/56 Snellen (0.45 ± 0.25 logMAR; 95% CI, 0.41-0.49) at baseline and 20/22 Snellen (mean 0.04 ± 0.13 logMAR; 95% CI, 0.02-0.06) at 6 months, p value <0.001.
- The mean UNVA was 20/83 Snellen (0.62 ± 0.31 log-MAR; 95% CI, 0.57-0.67) at baseline and 20/25 Snellen (0.10 ± 0.16 logMAR, 95% CI, 0.08-0.13) at 6 months, p value <0.001.
- More patients (n = 98, 66.6%) reported halos after surgery than before surgery (n = 87, 59.2%); the difference was not statistically significant (p value 0.14).
- At baseline, 102 patients (69.4%) said they were not at all satisfied with their vision, 21 (14.3%) were a little satisfied, 17 (11. 6%) were moderately satisfied, and 7 (4.7%) were mostly satisfied. At

6 months, 76 patients (51.7%) were completely satisfied, 52 (35.4%) were mostly satisfied, 9 (6.1%) were moderately satisfied, 5 (3.4%) were a little satisfied, and 5 (3.4%) were not at all satisfied.

- The mean score for patient-rated quality of vision was 6.0 ± 2.4 at baseline with glasses, 4.2 ± 2.5 at baseline without glasses, and 8.5 ± 1.6 at 6 months without glasses; the improvement after surgery was statistically significant (p value <.0001).

2) Prospective Observational study by Lubinski et al[2]

This was a prospective observational study comparing the visual outcomes as well as patient satisfaction in patients undergoing cataract surgery with bilateral implantation of the Tecnis ZMB00 diffractive IOL.

40 eyes from 20 patients were evaluated both before as well as after surgery.

They found that

- UNVA and UIVA improved significantly in patients following the surgery.
- 85% of patients no longer needed to wear corrective lenses.
- Mean overall patient satisfaction was 9.39±1.06 and 9.19±1.20 at 3 and 6 months, respectively.
- Low level of halo perception was reported in 75% of patients.
- No significant changes were observed in the general vision satisfaction score between 3 and 6 months after surgery (9.39±1.06 vs. 9.19±1.20, p=NS, scale ranging from 0 [not satisfied at all] to 10 [completely satisfied]). Furthermore, no significant changes between 3 and 6 months postoperatively were detected in the scores for the different aspects of visual function evaluated with the VF-14 test.

3) Randomized Clinical Trial comparing outcomes following Monofocal and Multifocal IOL implantation by Javitt et al[3]

Javitt et al conducted a multicentric, prospective, randomized, double-masked, clinical trial involving more than 250 patients. It was a comparative study in which patients were assigned to either Monofocal IOL or Multifocal IOL. Their outcomes were compared both before as well as 3 and 6 months after surgery. They found that

- Combined distance and near VA of 20/40 or better and J3 or better were achieved by 96% of the patients who had received multifocal IOL.
- Cataract patients who received multifocal IOLs obtained better uncorrected and distance corrected near VA and reported better overall vision
- 75% of the subjects who had undergone Multifocal IOL did not wear spectacles after surgery.
- Patients with multifocal IOL complained of more glare or halo as compared to the subjects who had undergone monofocal IOL implantation.

4) A Retrospective analysis comparing patient outcomes following Monofocal and Multifocal IOL implantation by de Asis et al[4]

This was a retrospective analysis comparing the differences in quality of life following implantation of Tecnis ZCB00 monofocal and Tecnis ZMB00 multifocal IOL. The quality of life was assessed using the NEI-RQL-42 quality of life questionnaire.

They found that the multifocal group obtained better results in

- Near vision
- Dependence on correction

However, they were also more likely to complain of glare and halos, as compared to the monofocal cohort.

5) A meta-analysis comparing outcomes with Multifocal IOL implantation by Cochener et al[5]

Cochener et a conducted a meta-analysis of comparative clinical trials published between 2000 and 2009 that included bilateral MFIOL implantations and control groups with monofocal IOLs. The meta analysis included various types of multifocal IOLs such as Diffractive IOLs, Refractive IOLs.

They found that

- MFIOLs offered patients significantly better UNVA than monofocal IOLs. The corresponding mean values were 0.14 logarithm of the minimum angle of resolution (logMAR) and 0.47 logMAR, respectively
- Halo incidence rates with different types of multifocal implants did not differ significantly

LACUNAE IN KNOWLEDGE

There is a paucity of Indian literature for clinical and functional outcomes following multifocal IOL implantation.

RESEARCH HYPOTHESIS & QUESTION

Research Hypothesis

The multifocal IOLs are associated with good clinical as well as functional outcomes.

Research Question

What are the clinical and functional outcomes following implantation of multifocal IOLs?

AIMS AND OBJECTIVES

AIM:

To determine the clinical and functional outcomes in patients undergoing multifocal IOL implantation.

OBJECTIVE:

To determine the following outcomes in patients undergoing multifocal IOL implantation -

- Clinical outcomes will be assessed using the following parameters
    - Change in Binocular Uncorrected Near Visual Acuity before and after surgery
    - Change in Binocular Uncorrected Distant Visual Acuity before and after surgery
    - Change in Binocular Best Corrected Visual Acuity before and after surgery
- Functional outcomes will be assessed using the following parameters
    - Proportion of subjects reporting persistent glare or halos after surgery
    - Proportion of subjects who no longer require spectacles for activities of daily living
    - Change in the Patient satisfaction as measured by the Visual Function questionnaire

MATERIALS AND METHODS

Place of study - Mohan Eye Institute, 11-B, Sir Gangaram Hospital Marg, New Delhi- 110060

Study Duration: 1st January 2022- 31st may 2023

Type of study: Prospective Observational cross-section study

Subjects: Patients undergoing multifocal IOL implantation in our institute

Sample size:

Formula for calculating sample size based on difference in means (based on power) in a paired study design is as follows-

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 S_p^2}{\delta^2}$$

Where-

n = Number of subjects

α = Probability of Type 1 error

β = Probability of Type 2 error

$Z_{1-\alpha/2}$ = Standard normal deviate for given value of α

$Z_{1-\beta}$ = Standard normal deviate for given value of β

S_p^2 = Standard Deviation of variable of interest based on previous studies

δ = Smallest difference in means that we regard as being important to be able to detect

The following assumptions have been used for our study:

α = 5%

β = 20%

Power = 1-β= 80%

$Z_{1-\alpha/2} = 1.96$

$Z_{1-\beta} = 0.841$

The sample size has been calculated based on various values of S_p and δ for different parameters from the study by Lane et al.

PARAMETER	MEAN (PRE-OPERATIVE)	MEAN (POST-OPERATIVE)	CHANGE IN MEAN VALUE	POOLED STANDARD DEVIATION	CALCULATED SAMPLE SIZE
UNVA(logMAR)	0.62±0.31	0.10±0.16	0.52	0.24	6.56
UDVA(logMAR)	0.45±0.25	0.04±0.13	0.41	0.19	6.6
Patient Satisfaction Score	6±2.5	8.5±1.6	1.5	2.09	15.2

Keeping in view the small sample sizes achieved using UNVA and UDVA, we have decided to use the patient satisfaction score for calculating our sample size

$$n = \frac{(1.96 + 0.84)^2 \, 2.09^2}{1.5^2}$$

$$n = 15.2$$

However, considering the low sample size obtained and the number of patients attending our center, a convenient sample size of 40 eyes shall be used for the study.

Inclusion Criteria:

- Subjects between the ages 45 and 75 years
- Bilateral cataracts
- Pre-operative corneal astigmatism of less than 1.0 D
- Strong motivation for independence from wearing corrective lenses
- Fundus should be normal

Exclusion Criteria:

- < 45 or > 75 years of age
- Subjects with unrealistic visual outcome expectations
- Subjects employed in a profession demanding high visual precision (e.g., an architect)
- Psychiatric diseases, stroke, dyslexia
- Dissatisfaction with progressive glasses
- Need for an IOL power beyond the available dioptre range
- Presence of retinal abnormalities which predispose to a grave visual prognosis
- Other conditions which preclude a cataract surgery such as uncontrolled systemic diseases, cardiac illness, uncontrolled hypertension or diabetes, high IOP etc.

Methodology:

Patients undergoing cataract surgeries in Mohan Eye Institute, New Delhi, shall be included in the study. The aims and objectives as well procedure shall be explained to the subjects in a language they understand. After explaining all the risks and benefits of enrolling in the study and taking signed consent, subjects shall be recruited in the study.

After performing a comprehensive ophthalmological and systemic examination as well as applying the appropriate Inclusion and Exclusion criteria and after taking due consent, a minimum of 40 eyes will be recruited in the study.

All surgeries shall be performed by the same surgeon under local anaesthesia through standard operative techniques. The Tecnis ZMB00 (Abott Medical Optics Inc.) IOL shall be used in all the cases.

All subjects will be evaluated at 3 points of time -

- Baseline i.e. Pre-operatively
- After 3 months of surgery
- After 6 months of surgery

The following parameters will be recorded for each subject at each time point

- Binocular Uncorrected Near Visual Acuity (Snellen’s chart at 35 cm)
- Binocular Uncorrected Distant Visual Acuity (Snellen’s chart at 6 m)
- Binocular Best corrected Visual Acuity
- Refraction
- Presence of glare
- Presence of halos
- Patient satisfaction as measured by the Visual Function questionnaire
- Independence from spectacles

STATISTICAL ANALYSIS

The data will be entered in Microsoft Excel spreadsheet and analysis will be done using Statistical Package for Social Sciences (SPSS) version 20.0. Continuous variables will be represented as mean ± SD or medians with Inter-quartile range. Categorical variables will be represented as number and percentage (%). McNemar test will be used to evaluate the difference in the frequency distributions of categorical variables. The quantitative variables will be tested for normality with the Shapiro Wilk test for normality, Q-Q plots and visual inspection of the histograms. The quantitative variables will be tested for difference in means using appropriate tests. All tests of significance will be two-tailed and statistical significance shall be defined as $P < 0.05$. Appropriate graphs such as pie charts, bar diagrams and histograms will be constructed.

ETHICAL CONSIDERATIONS

There are no ethical issues to consider for the purpose of the study.

- This is only an observational study and does not subject the patients to any additional intervention or investigation.
- All the investigations that are needed for the purpose of the study are routinely performed for any subject who undergoes cataract surgery. Therefore, subjects shall not be subjected to any undue and additional financial burden.
- The procedure shall be explained in the local language to all the subjects before enrolling in the study.
- Written informed consent shall be taken in all cases.
- Patients shall be informed that they reserve the right to quit from the study at any point of time and that it shall have no bearing on the quality of care offered to them.

REFERENCES

1. Lane SS, Javitt JC, Nethery DA, Waycaster C. Improvements in patient-reported outcomes and visual acuity after bilateral implantation of multifocal intraocular lenses with+ 3.0 dioptre addition: multicentre clinical trial. Journal of Cataract & Refractive Surgery. 2010 Nov 1;36(11):1887-96.
2. Lubiński W, Gronkowska-Serafin J, Podborączyńska-Jodko K. Clinical outcomes after cataract surgery with implantation of the Tecnis ZMB00 multifocal intraocular lens. Medical science monitor: international medical journal of experimental and clinical research. 2014;20:1220.
3. 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 Nov 1;107(11):2040-8.
4. de Asís Bartol-Puyal F, Talavero P, Giménez G, Altemir I, Larrosa JM, Polo V, Pablo LE. Reading and quality of life differences between Tecnis ZCB00 monofocal and Tecnis ZMB00 multifocal intraocular lenses. European Journal of Ophthalmology. 2017 Jun 26;27(4):443-53.
5. Cochener B, Lafuma A, Khoshnood B, Courouve L, Berdeaux G. Comparison of outcomes with multifocal intraocular lenses: a meta-analysis. Clinical Ophthalmology (Auckland, NZ). 2011;5:45.