

A STUDY ON VISUAL ACUITY OUTCOME ANALYSIS OF PATIENTS WITH APODIZED DIFFRACTIVE MULTIFOCAL IOL IN TERTIARY CARE CENTRE

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ABSTRACT

BACKGROUND

The success of performing modern cataract surgery, where the technique and technology that goes hand in hand has increased, the expectation of patients towards spectacle independence has increased. In the earlier years, multifocal IOLs were used extensively. But the outcome was surprisingly suboptimal in the form of post-op refractive surprises, spectacle dependency, reduced reading speed, reduced level of contrast sensitivity and most alarmingly the photic phenomena (halos, glare, starburst etc.). Then started the evolution of various types of multifocal IOLs, i.e. Refractive IOLs, diffractive IOLs, diffractive-refractive IOLs, accommodative IOLs, IOLs with extended depth of focus etc.

Aim- To analyse the visual acuity outcome of apodized diffractive multifocal IOL of patients and their satisfaction level. Single surgeon retrospectively enrolled patients for bilateral implantation of apodized multifocal IOL.

MATERIALS AND METHODS

Casual acuity assessment in the post-operative period include distant vision and near vision. Patient's satisfaction was surveyed at the end of three months and one year after cataract surgery by means of a questionnaire. Two hundred and fifty patients of both sexes of age group 40 to 90 were enrolled. Their distant vision and near vision were assessed at one month, three months and one year post-operatively using Snellen visual acuity chart and document. The mean patient satisfaction in the form of reading speed, spectacle independence, to perform their hobbies etc. were assessed using a questionnaire called Response Rating Scale. Patients were highly satisfied with their vision and spectacle independence.

RESULTS

35.6 percent of patients had 6/6 nil glasses. 38.8 percentage of them had 6/9 vision and 2.8 percentage were unhappy patients. None of them needed their multifocal IOL explanted.

CONCLUSION

In summary, though most patients achieve spectacle independence with MF IOL, some have unsatisfactory visual outcome. If from day 1 to till 1-month post-operative period, patient is not happy with the visual outcome or experience, a very disturbing photic phenomenon IOL explanation is suggested.

KEY WORDS

Visual Acuity, Outcome Analysis, Apodized Diffractive, Multifocal IOL, Patient Satisfaction, Response Rating Scale, Unhappy Patients.

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BACKGROUND

The success of performing modern cataract surgery, where the technique and technology that goes hand in hand, has increased the expectation of patients towards spectacle independence. Initially, in the earlier years the multifocal IOL were used extensively.

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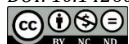
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But the outcome was surprisingly suboptimal in the form of post-op refractive surprises, spectacle dependency, reduced reading speed, reduced level of contrast sensitivity and most alarmingly the photic phenomena (Halos, Glare, Starburst etc.). Then started the evolution of various types of multifocal IOLs, i.e. Refractive IOLs, diffractive IOLs, diffractive-refractive IOLs, accommodative IOLs, IOLs with extended depth of focus etc. Satisfactory was the multifocal IOL with +4D add at the IOL plane, yielding +3.2D add at the spectacle plane which had apodized technology, asphericity and diffractive which gave spectacle independence in 70% of the patients.^{1,2,3,4,5} Then evolved the apodized multifocal IOL with +3D add at the spectacle plane yielding spectacle independence in 88% of patients.⁶ +3D add multifocal IOL has 9 diffractive steps. This aspheric IOL model has a 6.0 mm optic with a central zone of 3.6 mm apodization and outer refractive zone. The apodization technology means gradual decrease in the height in steps from center to periphery. This

claims to reduce the photic phenomenon and also results in smooth transition in distant vision from near as the pupil enlarges.⁷ The aspheric design constitute of negative spherical aberration to compensate for positive corneal spherical aberrations. The +3D add produced desired better intermediate vision. The near point was designed to improve intermediate vision. Careful patient selection, excellent history taking to assess the patient personality profile, subjecting every patient to detailed clinical evaluations using necessary diagnostic modalities, selecting appropriate IOL formulas and validating the IOL power could certainly increase the number of patients with spectacle independence and the happy patient profile also increases to be more than 90%.

Hence, the present study was designed in a single centre to evaluate the visual acuity and patient satisfaction levels after bilateral implantation of +3D aspheric apodized multifocal IOL.

MATERIALS AND METHODS

This is a retrospective cohort study. This study involves patients ranging from 40 years of age to 80 years of age of both sexes. The sample size was 250 patients who underwent bilateral multifocal IOL with aspheric design using apodized technology with +3D add. Very careful selection of the patients were done. A detailed questionnaire was given to the patients including the nature of work and type of hobbies, ex: cooking, knitting bags, tailoring, swimming, walking, playing video games, playing golf, painting, gardening, watching TV, the time spent on social media etc. was interacted with the patients in a detailed fashion. The reading desire of the patient or his necessity to read is assessed. The type of reading material and the duration of reading hours, the time duration spent with spectacles for near vision task were analysed. Their necessity/ desire to drive two-wheeler or four wheelers was also analysed. The duration of driving and whether it is day time or night time driving were studied.

The personality profile of the patients was understood by a prolonged chair time. The prior information was given to the patients about the photic phenomenon and the possibility of minimal dependency of glasses and their expressions observed. All patients with type A personality having over expectation were deleted for MF IOL implantations. Patients with more than 0.75D to 1.0D are excluded for MF IOL. Patients with corneal degenerative changes and corneal

dystrophies, any form of pupillary abnormalities, any fundus, macular or optic nerve head pathologies were not offered MF technology. Patients who had undergone retinal surgeries, monofocal IOL in one eye were not offered MF IOL. Patients who had undergone surgeries for strabismus or with history of amblyopia were also not taken up.

All the patients were subjected to diagnostic evaluation tool like OCT for any subtle macular/ foveal pathologies like IS/ OL junction disruption wherever visual acuity assessment cannot be done Retina Acuity Metre was used to predict the visual outcome. Aberrometry was performed in all the patients willing for MF IOL. Patients having higher order aberrations - coma more than 33 were not taken up for MF IOL. Angle kappa was evaluated using a synoptophore or optical biometry. Patients with more than 5° angle kappa were not taken up for MF IOL surgery.

Visual acuity outcome analysis was done using Snellen's visual acuity chart- One month, three months and one-year post-op and documented. Patient's satisfaction in one month, three months and 1-year post-operative period were assessed using response rating scale. Surgical technique aiming precision in post-operative visual acuity. All the patients were operated with limbal corneal 2.2 mm main incision and 1 mm sideports. The incision side was temporarily located unless the steep meridian was found elsewhere, especially when the patient selected had an astigmatism of 0.75D or 1.0D. Patients with all grades of cataract were involved in the study. In all the patients, a rhexis marker of 5.5 mm diameter was used to impress upon the clear cornea. Continuous curvilinear capsulorhexis of 5 mm was performed with the rhexis marker of 5.5 mm as a guiding tool. In most of the cases, this was achieved with the exception of few cataracts like mature and hypermature cataracts. This 5 mm rhexis ensured 1 mm overlap of the 6 mm optic. All the cataracts were emulsified using gravity-based fluid system and OZil technology using Kelman Mini-Flared 45° angled phaco needle.

Statistical Analysis

The data was analysed using SPSS (version 17.0) software. The frequency (no. of respondents) and percentage (%) of respondents selected for the study were analysed through the software.

Questionnaire Section	Response Rating Scale
Visual Disturbance Items	
<p style="text-align: center;"><i>How much difficulty do you have with each of the following?</i></p> <p>Glare/ Flare (trouble seeing street signs due to bright light or oncoming headlights) Night vision Colour perception (trouble recognising specific colours) Depth perception (trouble lining things up, pouring liquids or going down stairs) Halos (rings around lights) Distorted near vision (straight lines look crooked close-up) Distorted far vision (straight lines look crooked at distance) Blurred near vision Blurred far vision Double vision</p>	<p style="text-align: center;">0 = no difficulty 1= minimal difficulty 2 or 3 = moderate difficulty 4 or 5 = severe difficulty</p>
Visual Lifestyle Activities	

<p><i>How much difficulty do you have with each activity due to your vision? (without glasses or contact lenses)</i></p> <p>Watching TV or movies Playing or working outside Caring for/ playing with children Reading the time on an alarm clock Performing your job/ hobbies Participating in sports/ recreation Participating in social events Reading and near work/ activities Driving at night Driving when it is raining Using a computer Cooking Shopping Using a cell phone Shaving or putting on makeup</p>	<p>0 = no difficulty 1 = minimal difficulty 2 or 3 = moderate difficulty 4 or 5 = severe difficulty Or Not applicable</p>
Spectacle Use	
<p><i>How often do you wear glasses or contacts? How often do you wear glasses or contacts.....</i></p> <p>.....for distance visionfor intermediate vision?for near vision?</p>	<p>Always, sometimes, never Never, rarely, occasionally, often, always</p>
Satisfaction	
<p><i>On a scale of 1 to 10, how satisfied are you with your vision?</i></p>	<p>1 = least, 0 = most</p>
Response Rating Scale	

RESULTS

In the present investigation, a sample of 250 individuals of both male and female were taken. Among 250 patients, 123 were males and 127 were females, which revealed that both males and females had equal desire and opportunities for advanced technology IOL, namely Multifocal IOL. The results were tabulated in Table 1.

The different age group of patients from 30 to 90 years old were selected for the present study. This includes both the gender to study the visual acuity outcome in multifocal IOLs. Of the different age group of patients studied, the highly productive age of less than 40 years were heavily committed professionally and economically. This age group is highly committed to near vision task and to outdoor activities, which involved driving either during the day time or night time. Hence, those who opted/ selected for multifocal technology were minimum (0.8%). Followed by the age group of more than 80 years of patients who were least (2.4%) motivated for premium IOL technology. The age of 60 to 69 years old patients was observed as the most motivated age group for spectacle independence for distance, near and intermediate, in which 38% was noticed followed by the age group of 50 to 59 years old patients (32%) (Table 2). These results indicate that the middle-aged patients had more expectation towards spectacle independence and were willing to tolerate minimal visual disturbances encountered after multifocal IOL implantation as a trade-off for spectacle independence.

The frequency distribution of the respondents with uncorrected visual acuity during one week and one month post-op were documented. The results revealed that 38.8% of the patients had uncorrected visual acuity after 1-week treatment for distant vision acuity at the level of 6/9, followed with 35.6% of patients had normalisation upto 6/6 of vision after 1-week treatment, 18% had corrected vision upto 6/18 level and to the least 0.4% of patients had treatment upto 6/36 level. The results were depicted in

Table 3. The results in Table 4 showed out of 250 patients, 35.6% of them had unaided vision of 6/6. 38.8% of them improved from 6/9 to 6/6 with minimal correction of 0.25D to 0.50D. 18% of them improved from 6/12 to 6/6 with correction of less than 0.75D. 1.6% of the patients who did not improve were diagnosed with PCO. One patient who had 6/36 nig, nip had diabetic macular oedema, which was missed preoperatively. Frequency distribution of the respondents with near vision acuity was given in Table 5 and the results showed that after 1-week treatment for near vision acuity, out of 250 patients 94.4% had normalisation of vision upto level of N6 and followed by 2.4% were treated upto level of N8 and to the least 0.4% were treated upto N24 level. Based on the present study, it is inferred that out of 250 patients 243 (97.2%) were satisfied with the vision after multifocal IOL implantation, while 7 (2.8) respondents were not satisfied with the visual outcome because four of them had PCO, one had diabetic maculopathy and the other two had photic phenomena (Table 6).

In the postop, it is inferred that 93.2% of 250 patients had good reading ability and speed after the treatment with multifocal IOL implantation, but 6.8% (Table 7) of them did not have good vision for reading. They were advised to read under good illumination.

The frequency distribution of patients based on their IOL power of the eye, for which they had treatment were analysed and tabulated in Table 8. Among 250 patients 60.4% had 21 - 25D of IOL power, 30.8% had 16 - 20D power and showed low myopes, 5.6% had 11 - 15D power and were high myopes and only 3.2% had more than 25D power and small eyes. At the end of one month, the questionnaire was given to patient for assessing the satisfaction level on visual performance on day-to-day life. The results showed that under the Response Rating Scale, there was no difficulty or minimum difficulty with 25 - 27 items. The patients related to

the items pertaining to driving showed no difficulty or minimal-to-moderate difficulty.

Gender	Frequency	Percent (%)
Male	123	49.2
Female	127	50.8
Total	250	100.0

Table 1. Frequency distribution of the Respondents based on their Gender

Age	Frequency	Percent (%)
<40 yrs.	2	0.8
40-49 yrs.	41	16.4
50-59 yrs.	80	32.0
60-69 yrs.	96	38.4
70-79 yrs.	25	10.0
>80 yrs.	6	2.4
Total	250	100.0

Table 2. Frequency distribution of the Respondents based on their Age

UCVA (1 st Postop)	Frequency	Percent
6/6	89	35.6
6/9	97	38.8
6/12	45	18.0
6/18	14	5.6
6/24	4	1.6
6/36	1	0.4
Total	250	100.0

Table 3. Frequency distribution of the Respondents with Uncorrected Visual Acuity during 1 week and 1 month Postop

BCVA (1 st Post OP)	Frequency	Percent
6/6	89	35.6
6/9 - 6/6	97	38.8
6/12 - 6/6	45	18.0
6/18 - 6/6	14	5.6
6/24 - nig, nip	4	1.6
6/36	1	0.4
Total	250	100.0

Table 4. Frequency distribution of the Respondents with Best Corrected Visual Acuity during 1 week and 1 month Postop

Near Vision (1 st Postop)	Frequency	Percent
N6	236	94.4
N8	6	2.4
N10	4	1.6
N12	3	1.2
N24	1	0.4
Total	250	100.0

Table 5. Frequency distribution of the Respondents with Near Vision Acuity during 1 week and 1 month Postop

Patient Satisfaction	Frequency	Percent
No	7	2.8
Yes	243	97.2
Total	250	100.0

Table 6. Frequency distribution of the Respondents based on their Satisfaction about the Spectacle Independence

Reading Ability	Frequency	Percent
Good	233	93.2
Not Good	17	6.8
Total	250	100.0

Table 7. Frequency distribution of the Respondent's Reading Ability after the Vision Treatment

IOL Power	Frequency	Percent
11-15 D	14	5.6
16-20 D	77	30.8
21-25 D	151	60.4
>25 D	8	3.2
Total	250	100.0

Table 8. Frequency distribution of the Respondents based on their IOL Power after the Treatment for Vision

DISCUSSION

Post-Op Assessment

Post-op slit lamp examination, visual acuity assessment refraction was alone in 1 week/ 1-month postoperative period. No significant difference in the visual acuity was noted at 3 months, 1-year postoperative period. Visual acuity one-month post-op was taken for the study purpose. Fundus evaluation was done at 1 month postoperative, then onwards every visit. 4 patients were noted to have PCO. One patient had fundus pathology, for whom there was moderate visual loss.

The UCVA and BCVA for both near and distance in the patients after implantation of bilateral aspheric apodized MFIOL +3D add was assessed one week and one-month post-op.

From the present study it was observed that near, intermediate and distant vision was better in 97.3% of patients using +3D add. In contrast to the present study, 75% reported that the +4D add gives better visual acuity for distance intermediate using the same technology.

At the end of one month, the questionnaire finds under the Response Rating Scale there was no difficulty or minimum difficulty with 25 - 27 items. The patients related to the items pertaining to driving as no difficulty or minimal-to-moderate difficulty. In the present study, the high expectation of spectacle independence was a noticeable outcome and spectacle independence was attributed to the apodized diffractive optics, which could be the reason for the reduction in the photic phenomenon. Another equally important reason is strictly adhering to the patient selection criteria. Apart from the optic design, visual disturbances could be resulting from ocular straylight due to PCO. In our study 4 patients who developed significant PCO, YAG capsulotomy was done following which patients had considerable relief from photic experience and visual acuity also improved. After successful bilateral implantation of the +3D add aspheric apodized diffractive IOL implantations, 97.2% of our patients had complete spectacle independence for vision for various distance namely near, intermediate and infinity which is more than the FDA clinical trials in which they find 88% of positive results.

High level of spectacle independence, minimal or no visual disturbances in the form of photic phenomenon, absence of PCO are all co-related with patient's satisfaction. Unhappy patients have been attributed to those who do not achieve visual goals, have compromises in the quality and sharpness of vision or with newer aberrations.⁸⁻¹⁷

In a study by Chiasmet, 21.3% of patients with apodized IOL had moderate glare as compared to 7.5% of patients with Monofocal IOLs. Pieh et al claimed that halos can appear under high contrast conditions.¹⁸ Visual complaints in the postoperative period has to be managed after a systematic

approach. In patients who had residual astigmatism of pre-existing 0.75 to 1.0 D cylindrical power or a new spherical error, they can be counselled and prescribed for spectacle correction. Patients who are not able to read under dim lighting conditions were advised to read under bright illuminations or natural lighting.

CONCLUSION

Minimal visual disturbances involved in the multifocal IOL in the form of photic phenomenon, blurred vision etc., are considered as a trade-off for spectacle independence. Understanding the technology in the multifocal IOL being used, strictly adhering to the patient selection criteria, sticking onto the relative and absolute contraindications, subjecting the patients to all the necessary preoperative assessment tools, helps in reducing the number of unhappy patients in the post-op period. Rejecting the one-eyed patients, patients with higher order aberrations more than 33 μm , angle kappa more than 5° gives good number of happy patients.

In summary, though most patients achieve spectacle independence with MF IOL, some have unsatisfactory visual outcome. If from day 1 to till 1-month postoperative period patient is not happy with the visual outcome or experience very disturbing photic phenomenon, IOL explanation is suggested.

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