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Original Research Article

Study of visual functions with multifocal versus monofocal intraocular lenses after phacoemulsification in patients with age-related cataract

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ABSTRACT

Introduction: Early visual rehabilitation and targeting emmetropia using small incisions and foldable IOLs is the main objective of modern cataract surgery, the so termed 'refractive cataract surgery'. This current single-center prospective study assessed the clinical outcomes and thus patient satisfaction of multifocal IOLs over monofocal IOLs.

Objective: To study visual functions with a refractive –diffractive type multifocal versus monofocal intraocular lenses after phacoemulsification in patients with age related cataract.

Materials and Methods: 40 patients undergoing phacoemulsification for decreased vision due to age related cataract were randomly divided into 2 groups. Patients in group 1 underwent multifocal IOL [refractive –diffractive type] implantation and patients in group 2 underwent confocal IOL implantation. Postoperatively, patients were followed up for 90 days and assessed for unaided visual acuity for distance, intermediate and near vision, contrast sensitivity using Pelli-robson chart.

Results: At the end of the study, uncorrected visual acuity for distance (UDVA) was 6/9 in 65% patients in group 1 while 50% had uncorrected visual acuity of 6/9 in group 2. Uncorrected intermediate visual acuity (UIVA) in group 1 was N10 or better in 55% patients while in group 2, 75% patients had N24. Uncorrected near visual acuity (UNVA) in group 1 was N6 in 35% patients and N8 in 35% while in group 2, 75% patients had N18 vision, A paramount statistical difference was seen in the two groups.(p=0.001). The mean contrast sensitivity in group 1 was 2.04+/-0.23 and group 2 was 2.20+/-0.07(although statistically significant but within normal limits). None of the patients in any group had any significant complaint of glare or haloes.

Conclusion: Mutifocal IOLs decrease the spectacle dependence of patients without compromising the subjective visual functions.

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1. Introduction

Cataract has been documented to be the most significant cause of blindness in India, where visual acuity 3/60 or less in the better eye on presentation is defined as blindness.¹ The most recent estimates from the World Health Organisation (WHO) reveal that 35% of global blindness is due to un-operated cataract and 25% of moderate to severe vision impairment is due to un-operated cataract.^{2–4} In India, 62.6% of the blindness is attributed

to cataract.⁵ Cataract surgery has been viewed as one of the most cost effective health intervention with salvage of the disability-adjusted life years. Early visual rehabilitation and targeting emmetropia using small incisions and foldable IOLs is the main objective of modern cataract surgery, the so termed 'refractive cataract surgery'. Near vision and more recently, intermediate vision has been acknowledged by patients as reason for quality of life impairment. There have been studies reporting that the loss of reading ability can significantly reduce a patients' quality of life.^{5–7} Moreover, with the rise in computer use, there has

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been an increased emphasis on intermediate vision. Thus, there arose a need for evaluation of cataract surgery and intraocular lens.⁸ To achieve spectacle independence, when performing intermediate tasks, multifocal IOLs with lower addition powers ranging from +3.5 to +4.5D which provide excellent near visual acuity on the usual reading distance of 0.3m have been developed.

Numerous designs of multifocal IOLs have come up in recent years including refractive, diffractive, refractivediffractive and apodized-diffractive, with the aim to provide optimal visual function and spectacle independence at various distances.^{9,10} Previous multifocal IOLs are known to generate a decrease in contrast sensitivity as well as disabling photic phenomenon like halos and glare.¹¹ To overcome these limitations while maximizing visual outcomes, changes in angulation, addition of aspheric and apodized surfaces were done that have resulted in better contrast sensitivity and less visual disturbances.¹²

The new technologies emerging in recent years have been aimed at smoothening the changes in visual perception and making a much more physiological division of light. I diff plus (Care Group, India) is a new generation mutifocal IOL, which has a refractive-diffractive step design and an aspheric optic to minimize photic phenomenon and to provide optimal visual outcomes without impairing contrast sensitivity. The addition power (+4D, +3.5D, +3.0D) used in our study is +3.5D to achieve patient satisfaction in both intermediate and near tasks. The current single centre prospective study assessed the clinical outcome of this new multifocal IOL.

2. Materials and Methods

The present prospective clinical study was conducted on 40 eyes of patients reporting to outpatient services of our tertiary eye care health institute in North India, with decreased vision due to age related cataract for cataract surgery and intraocular lens implantation. Patients between 40-80 years reporting with cataract (less than grade 3), managed by phacoemulsification and willing for implantation of multifocal IOLs and having astigmatism less than 1.5D cylinder were included in the study. The other inclusion criteria was that they should have the ability to understand the typE questionnaire.

Patients with age less than 40 years, professional drivers or mentally retarded, having a pre-cataract myopia or hyperopia of 3D or more, history of amblyopia, fundus abnormalities that could cause significant vision impairment, previous surgical intraocular procedures and ocular co- morbidities, such as previous trauma, glaucoma, diabetic retinopathy, pseudoexfoliation syndrome, chronic uveitis and corneal opacities, were all excluded from the study.

Intra operative exclusion criteria included iris pupillary trauma, vitreous loss and inability to place the IOL in the capsular bag. Post-operative exclusion criteria included persistent corneal oedema, excessive post operative inflammation and absent fundal glow.

Detailed pre operative history regarding age, sex, type of cataract, history of trauma and any associated ocular or systemic diseases having effect on vision was recorded.

Patients were subjected to complete ocular examination which included visual acuity on Snellen's chart for distant, intermediate and near vision, refraction for recording BCVA, applanation tonometry, slit lamp examination with both dilated and undilated pupil, fundus examination using indirect ophthalmoscopy and slit lamp biomicrocopy, keratometry using Bausch and Laumbkeratometer, biometry and lens power calculation using SRK-T and SRK-II formula was done.

Informed and written consent was taken and patients were divided into two groups of 20 each.

Group A underwent phacoemulsification with multifocal [refractive-diffractive design] IOL implantation. Group B underwent phacoemulsification with monofocal IOL implantation

All patients underwent phacoemulsification with IOL implantation performed by a single surgeon and only aspheric of IOLs were implanted in both groups to ensure proper matching of the groups.

Patients were followed up on post-operative days 1,7,30,60 and 90 and evaluated for unaided distance, intermediate and near visual acuity. Contrast sensitivity was recorded on the Pelli robson chart. Glare/haloes were reported using the typE questionnaire. The 'glare, haloes and rings around lights' were quantified into 0-4 as per the typE questionnaire, where 'not at all' scores 0, 'a little bit' scores 1, 'moderately' scores 2, 'quite a bit' scores 3 and extremely scores 4.^{13,14}

3. Observation and Results

The mean age of the study population in group 1 was 59.6±8.39year and group 2 was 64.75±8.39 year. The majority of the patients in both the groups were between 56-65 years of age (group 1-40.0% and group 2-48.0%). In multifocal group (group -1), the number of female patients were more as compared to male patients, thus difference among the two groups was not statistically significant, the p-value being 0.114(>0.05). On post-operative day 1, the UCVA was found to be 6/12 in 6 patients (30%), 6/9 in 4 patients (20%), 6/18 in 4 patients (20%), 6/24 in 4 patients (20%) while 6/6 in 2 patients (10%) while in monofocal it was 6/9 in 8 patients (40%) and 6/12 in 7 patients (35%) while 6/18 in 3 patients (15%) and 6/6 in 2 patients (10%). At the last follow-up, there were 9 patients (45%) with 6/9 vision, 7 patients (35%) with 6/12, and 4 patients with 6/6 vision while in monofocal group 10 patients (50%) had 6/12 vision, 8 patients (40%) had 6/9 vision while only 2 patients (10%) had 6/6 vision (Table 1). However, both at first post-operative day and last follow-up the two group's visual acuity was found to be statistically insignificant with p-value less than 0.05.

Post-operatively at day 1, 5 patients (25%) had visual acuity of N10, also the same number had N18 visual acuity while 3 patients (15%) had N6 and N8 visual acuity, only 2 patients had N12 visual acuity while 1 patient (5%) had N24 and N36, but later at the last follow-up there were 7 patients (35%) with visual acuity N6, 7 patients (35%) with N8, 3 patients (15%) with N12, 2 patients (10%) with N10 and only 1 patient (5%) with N18 visual acuity, thus signifying an overall improvement in visual acuity with the course of time. (Table 2). However, there was no significant change in the near visual acuity in the monofocal group with 15 patients (75%) with N18 visual acuity, 3 patients (15%) with N12 and 1 patient (5%) with N18 visual acuity, thus showing there was paramount statistical significance between the groups with p-value higher than 0.05.

Post-operatively at day 1, there were 6 patients (30%) with N18 intermediate visual acuity, 5 patients (25%) with N36 visual acuity, 3 patients (15%) with N24 visual acuity, 2 patients (10%) with N8 and N10 visual acuity and only 1 patient (5%) with N6 and N12 visual acuity but later at the last follow-up 5 patients (25%) had N6 and N18 visual acuity each while 4 patients (20%) had visual acuity N8 and N12 and only 2 patients (10%) had N10 visual acuity, thus showing progressive improvement in visual acuity.(Table 3). However, in monofocal group at last follow-up 15 patients (75%) had N24 visual acuity, 4 patients (20%) had N18 visual acuity and only 1 patient with N10 visual acuity. Thus, showing there was paramount statistical significance between the groups with p-value higher than 0.05.

Post-operatively at day 1, there were 16 patients (75%) with no complaint of glare and haloes and only 4 patients (25%) with little complaint of glare and haloes while in the monofocal group there were no patients with any complaint of glare and haloes and at the last follow-up there were no patients in any group with the complaint of glare and haloes.(Table 4)

In the multifocal group (Group 1), on day 1 the mean contrast sensitivity as assessed by the Pelli-robson chart was 1.29 ± 0.41 which was lower as compared to the mean contrast sensitivity in the monofocal group (Group 2) which was 2.20 ± 0.07 , thus, the difference between the groups was statistically significant (p=0.001). On further followup, there was a slight improvement in contrast sensitivity in the multifocal group, with mean contrast sensitivity being 1.59 ± 0.38 on day 7, 1.92 ± 0.36 on day 30, 1.99 ± 0.27 on day 60 and 2.04 ± 0.23 on day 90. The mean contrast sensitivity in the multifocal group remained the same being 2.20 ± 0.07 on day 90. (Table 5). On the last follow-up i.e. day 90, the difference among the two groups was statistically significant (p=0.007), thus, the two groups were different in terms of contrast sensitivity but the mean of contrast sensitivity in the multifocal group were in the normal range of contrast sensitivity as measured by the Pelli-robson chart.

4. Discussion

In our study, on last day of follow up(day 90), in the multifocal group 65% patients had uncorrected distance visual acuity(UCDVA) of 6/9 or better while 35% had 6/12, while in the monofocal group 50% had UCDVA 6/9 or better while 50% had 6/12.

In 2015, a similar study was conducted in India by Kumare and colleague's. They also found no statistical difference between two groups.¹⁵ Study conducted by Yamauchi and colleagues who compared Tecnis monofocal and multifocal IOLs also found no difference in UCDVA of two groups.¹⁶ Cionni et al. in 2009 also observed similar results.¹⁷

At the end of our study, multifocal group had 35% patients with near vision N6 and 35% with N8 near visual acuity while in monofocal group 75% patients had N18 and 15% had N12. Thus, difference in uncorrected near visual acuity between the two groups was found to be statistically significant (p=0.001) at the end of 3 months.

Harman et al. in 2006 concluded that UNVA in multifocal in 1CU and Array groups (N6) was better than monofocal(N10). It was found to be statistically significant (p<0.001).¹⁸ Alio et al. also concluded that multifocal IOL group had significantly better uncorrected near acuity and DCNVA (Jaeger [J] 5 versus J2) (both P<.01).¹⁹ Also a clinical trial by Cillino et al. observed similar resuts, UCNVA was 20/50 in the monofocal IOL groups (P<0.0005).²⁰

At the last follow-up, i.e., day 90, the multifocal group had 25% (5 patients) with N6 and 20% (4 patients) with N8 un-corrected intermediate visual acuity (UIVA), the rest 55% (11 patients) with N18 or better UIVA 75% (15 patients) had N24 and 20% (4UIVAThe difference in the groups was statistically significant (p= 0.001). Our results are well comparable to the results of Yamauchi et al, Cillino et al. and Cionni et al. who also observed that statistically significant differences were found favouring the multifocal group for uncorrected intermediate visual acuity. ^{16,17,20}

In our study, the contrast sensitivity log values as measured by the Pelli-robson chart were 2.04+/-0.23 in the multifocal group and 2.20+/-0.07 in the monofocal group, the difference in two groups being statistically significant(p=0.007).But nevertheless the values of contrast sensitivity were well within normal range as assessed by Mantyjarvi et al. in 2009.²¹

In 2006, Harman et al. conducted a study to compare the binocular near vision performance in patients implanted with the 1CU accommodating intraocular lens(IOL) with a multifocal and monofocal IOL. They observed

UCVA	CVA Day 1		Da	Day 7		Day 30		Day 60		
	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono
616	2	2	4	2	4	2	4	2	4	2
0/0	(10%)	(10%)	(20%)	(10%)	(20%)	(10%)	(20%)	(10%)	(20%)	(10%)
6/0	4	8	7	8	9	8	9	8	9	8
0/9	(20%)	(40%)	(35%)	40	(45%)	(40%)	(45%)	(40%)	(45%)	(40%)
(11)	6	7	7	10	7	10	7	10	7	10
0/12	(30%)	(35%)	(35%)	50	(35%)	(50%)	(35%)	(50%)	(35%)	(50%)
6/10	4	3	1	0	0	0	0	0	0	0
0/18	(20%)	(15%)	(5%)							
6/24	4	0	1	0	0	0	0	0	0	0
	(20%)		(5%)							
Significance	e p = 0	0.235	p= 0	0.515	p=0	0.534	p=0	0.534	p= 0	.534

Table 1: Distribution of subjects according to post-operative uncorrected distance visual acuity findings in Group 1 and 2 on various follow up visits (n=40)

Table 2: Distribution of subjects according to post-operative near visual acuity findings in Group 1 and 2 on various follow up visits (n=40)

Near VA	Da	y 1	Day 7 Day 30 Day 60		y 60	Day 90				
	Multi n=20	Mono	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono
N6	3 (15%)	0 (0%)	6 (30%)	0	6 (30%)	0	6 (30%)	0	7 (35%)	0
N8	3 (15%)	0 (0%)	0	0	6 (30%)	0	7 (35%)	0	7 (35%)	0
N10	5 (25%)	1 (5%)	6 (30%)	1 (5%)	3 (15%)	1 (5%)	3 (15%)	1 (5%)	2 (10%)	1 (5%)
N12	2 (10%)	3 (15%)	4 (20%)	3 (15%)	4 (20%)	3 (15%)	3 (15%)	3 (15%)	3 (15%)	3 (15%)
N18	5 (25%)	15 (75%)	3 (15%)	15 (75%)	0 (0%)	15 (75%)	1 (5%)	15 (75%)	1 (5%)	15 (75%)
N24	1 (5%)	1 (5%)	1 (5%)	1 (5%)	1 (5%)	1 (5%)	0	1 (5%)	0	1 (5%)
N36	1 (5%)	0 (0%)	0	0	0	0	0	0	0	0
Significance	p = 0	.021	P=	0.001	p= 0	.000	p= 0	.000	p= 0	.000

no significant difference in mean contrast sensitivity (p<0.05).¹⁸ In 2005, Alio and colleagues compared multifocal and monofocal IOLs and found no significant difference in contrast sensitivity.¹⁹

In a randomised control trial by Cilino et al. in 2008, it was concluded that new generation, diffractive, pupil independent multifocal IOLs provide better near vision, equivalent intermediate vision, less unwanted photic phenomenon and greater spectacle independence than either monofocal or refractive multifocal IOL thus refractive multifocal IOL group exhibited lower contrast sensitivities at 3 cycles/degree(p=0.038).²⁰ In study by Cionni et al. in 2009, even though it was observed that contrast sensitivity was significantly better in monofocal patients yet they concluded that multifocal IOLs provide high patient satisfaction, excellent functional vision and high rates of

spectacle freedom.¹⁷

In our study, on the first day of follow up, on assessing glare and haloes using typE questionnaire, there were 16 patients (75%) with a score of 0 while 4 patients (25%) with a score of 1, signifying very little bother from glare and haloes and the p value being 0.106. At the last follow up there were no patients with complaints of glare and haloes in either group. This observation in our study varied from the scores observed by Leyland et al., who conducted a study in 2002, to evaluate the functional effect of bilateral implantation of two different IOLs compared with the standard monofocal IOL and found that monofocal and bifocal scores were 0(0-2) and 0(0-3) respectively, while the multifocal group scored slightly worse, with 1(0-4) equating to a median score of a 'a little bit bothered'(p=0.01) at a follow up of 2 months, which was statistically significant

Intermedia	Da te	Day 1 e		Day 7		Day 30		Day 60		y 90
va	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono
N6	1 (5%)	0	3 (15%)	0	4 (20%)	0	4 (20%)	0	5 (25%)	0
N8	2 (10%)	0	3 (15%)	0	2 (10%)	0	3 (15%)	0	4 (20%)	0
N10	2 (10%)	1 (5%)	0	1 (5%)	4 (20%)	1 (5%)	3 (15%)	1 (5%)	2 (10%)	1 (5%)
N12	1 (5%)	0	2 (10%)	0	4 (20%)	0	5 (25%)	0	4 (20%)	0
N18	6 (30%)	4 (20%)	6 (30%)	4 (20%)	3 (15%)	4 (20%)	3 (15%)	4 (20%)	5 (25%)	4 (20%)
N24	3 (15%)	15 (75%)	0	1 (5%)	2 (10%)	15 (75%)	2 (10%)	15 (75%)	0	15 (75%)
N36	5 (25%)	0	2 (10%)	0	1 (5%)	0	0	0	0	0
Significance	p= 0	.007	P= 0	0.012	p= 0	.001	p= 0	.000	p= 0	.000

Table 3: Distribution of subjects according to post-operative intermediate visual acuity findings in Group 1 and 2 onvarious follow up visits (n=40)

Table 4: Distribution of subjects according to post-operative bother due to glare/halo score in Group 1 and 2 on various follow up visits (n=40)

Glare/ haloes score	Day 1		Day 7		Day 30		Day 60		Day 90	
	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono
0	16 (80%)	20 (100%)	18 (90%)	0	19 (95%)	20	20	20	20	20
1	4 (20%)	0	2 (10%)	0	1 (5%)	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0
Significance	p= (0.106	p= 0	.487	p= 0	.001		-	-	

Table 5: Post-operative mean contrast sensitivity findings in Group 1 and 2 on various follow up visits(n=40)

Creare	Der. 1	Der: 7	Der: 20	 Day (0	Der: 00
Group	Day 1	Day /	Day 50	Day ou	Day 90
3.6.1.1	1.00	1.50	1.00	1.00	2.04
Multi	1.29	1.59	1.92	1.99	2.04
(n=20)	(± 0.41)	(± 0.38)	(±0.36)	(± 0.27)	(±0.23)
MONO	2.20	2.20	2.20	2.20	2.20
(n=20)	(± 0.07)				
Significance	p = 0.001	P = 0.001	p = 0.002	p = 0.002	p = 0.007

(p < 0.05).²²

In our study, on initial follow ups, few patients reported bother from glare and haloes but on subsequent visits they reported improvement. This might be explained as most patients being housewives adapted well to discomfort, since they had no cumbersome work, like driving, to perform. In 2015, a similar study was conducted in India by Kumare and colleagues who observed that in the multifocal IOL group 10% reported of halos as compared to 7.5% by monofocal IOL group. The chi square value comes out to be 0.0611 and p value is 0.8048(not significant). In the multifocal IOL and monofocal IOL group the complaint of glare was reported by 12.5% and 10% patients respectively(p=0.6445). Thus, there was no significant difference in terms of haloes and glare.¹⁵

In the present study, the visual performance of multifocal IOLs and monofocal IOLs composed of the same optic material and design was compared. The mean un-corrected distance visual acuity (UDVA) was almost similar in both the groups. (UNVA) and uncorrected intermediate visual acuity (UIVA) was significantly better and the rate of spectacle dependence was significantly lower in the multifocal group. The contrast sensitivity was better in the monofocal group, however, both groups had values of contrast sensitivity lying in t'glare, haloes and rings around lights' quantified into 0-4 as per the typE questionnaire, exhibited no significant differences between the two groups.

5. Conclusion

Thus, our results demonstrate that a new generation, refractive-diffractive design, mutifocal IOL decreases the spectacle dependence of patients without compromising the subjective visual functions.

6. Conflicts of Interest

Nil

7. Source of Funding

Nil.

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