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Original research article

Functional outcome in patients with age-related cataract managed using two different intraocular lenses

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Abstract

Aim: To study of visual functions with multifocal versus monofocal intraocular lenses after phacoemulsification in patients with age-related cataract.

Methods: A prospective observational study was conducted in the Department of Ophthalmology,Aiims,Patna, Bihar, India, for 18 months 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. Group A underwent phacoemulsification with multifocal [refractive-diffractive design] IOL implantation. Group B underwent phacoemulsification with monofocal IOL implantation

Results: The mean age of the study population in group 1 was 60.8±8.47 year and group 2 was 65.97±8.56 year. The majority of the patients in both the groups were between 55-65 years of age (group 1-42% and group 2-50%). On post-operative day 1, the UCVA was found to be 6/12 in 14 patients (28%), 6/9 in 11patients (22%), 6/18 in 10 patients (20%), 6/24 in 9 patients (18%) while 6/6 in 6 patients (12%) while in monofocal it was 6/9 in 21 patients (42%) and 6/12 in 16 patients (32%) while 6/18 in 7 patients (14%) and 6/6 in 6 patients (12%). At the last follow-up, there were 22 patients (44%) with 6/9 vision, 17 patients (34%) with 6/12, and 11 patients with 6/6 vision while in monofocal group 26 patients (52%) had 6/12 vision, 18 patients (36%) had 6/9 vision while only 6patients (12%) had 6/6 vision. There was no significant change in the near visual acuity in the monofocal group with 37 patients (74%) with N18 visual acuity, 8 patients (16%) with N12 and 2 patient (4%) with N24 visual acuity, thus showing there was paramount statistical significance between the groups with p-value higher than 0.05. In monofocal group at last follow-up 37 patients (74%) had N24 visual acuity, 11 patients (22%) had N18 visual acuity and only 2 patient with N10 visual acuity. Thus, showing there was paramount statistical significance between the groups with p-value higher than 0.05. In the multifocal group (Group 1), on day 1 the mean contrast sensitivity as assessed by the Pelli-robson chart was 1.31±0.39 which was lower as compared to the mean contrast sensitivity in the monofocal group (Group 2) which was 2.22±0.06, thus, the difference between the groups was statistically significant (p=0.001).

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

Introduction

Since the implantation of the first intraocular lens (IOL), attempts have been directed toward improvement of visual outcomes of cataract surgery. Loss of accommodation is inevitable with conventional monofocal IOLs and the first attempt to overcome this limitation was pseudophakic monovision.[1] Despite some reports of acceptable spectacle-free near and far visual acuity in more than half of the patients with monovision, this method may be

associated with problems in stereo acuity, contrast sensitivity and dominance.[2] Multifocal IOLs were designed to overcome the lack of accommodation in pseudophakic patients.[3] However, optical side effects, such as decreased contrast sensitivity, glare disability, and halos, have been reported in eyes with these IOLs.[4] In order to avoid the optical side effects of multifocal IOLs, accommodating IOLs were designed. The first developed and marketed accommodating IOLs were positional and had two main types; single optic and dual optic. Single optic IOLs are based on axial (backward and forward) movement of the optic resulting from contraction and relaxation of the ciliary muscle, increasing the effective power of the IOL and thereby providing near focus.[5] Several single-optic IOL models have been developed, such as the Crystalens (Bausch and Lomb, NY, USA), 1 CU (Human Optics AG, Erlangen, Germany) Tetraflex (Lenstec, FL, USA), and TekClear(Tekia, CA, USA). The plate style single optic accommodating IOL Crystalens HD is designed to be implanted within the capsular bag and is made from third generation silicone (Biosil) which unlike other IOL materials does not have internal reflectivity. It has a central bi-aspheric modification to increase depth of focus and provide better intermediate and near vision.[6] According to the manufacturer, the IOL has a double mechanism to improve near visual function; first, axial movement of the optic which occurs with ciliary muscle changes and second, the radius of curvature of the anterior surface (arching optic) which varies with accommodative effort. A number of studies have shown better visual and accommodative results with this lens as compared to standard monofocal IOLs.[7,8] Tekia TekClear is another single optic accommodating hydrophilic acrylic IOL with symmetric optic design, ultraviolet blocker and square edge design which has been approved for treatment of presbyopia by the European Commission since 2006. Near focus is achieved by anterior movement of the optic by ciliary muscle contraction during accommodative effort.[6]

Material and Methods

A prospective observational study was conducted in the Department of Ophthalmology, AIIMS, Patna, Bihar, India, for 18 months, after taking the approval of the protocol review committee and institutional ethics committee.

Inclusion criteria

The present prospective clinical study was conducted on 100 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.

Exclusion criteria

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 Laumb keratometer, 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 50 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 1,10,40,70 and 100 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.[9,10]

Results

The mean age of the study population in group 1 was 60.8±8.47 year and group 2 was 65.97±8.56 year. The majority of the patients in both the groups were between 55-65 years of age (group 1-42% and group 2-50%). 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 0.131(>0.05). On post-operative day 1, the UCVA was found to be 6/12 in 14 patients (28%), 6/9 in 11patients (22%), 6/18 in 10 patients (20%), 6/24 in 9 patients (18%) while 6/6 in 6 patients (12%) while in monofocal it was 6/9 in 21 patients (42%) and 6/12 in 16 patients (32%) while 6/18 in 7 patients (14%) and 6/6 in 6 patients (12%). At the last follow-up, there were 22 patients (44%) with 6/9 vision, 17 patients (34%) with 6/12, and 11 patients with 6/6 vision while in monofocal group 26 patients (52%) had 6/12 vision, 18 patients (36%) had 6/9 vision while only 6patients (12%) 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, 12 patients (24%) had visual acuity of N10, also the same number had N18 visual acuity while 8 patients (16%) had N6 and N8 visual acuity, only 2 patients had N12 visual acuity while 2 patient (4%) had N24 and N36, but later at the last follow-up there were 17 patients (34%) with visual acuity N6, 17 patients (34%) with N8, 8 patients (16%) with N12, 6 patients (12%) with N10 and only 2 patient (4%) 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 37 patients (74%) with N18 visual acuity, 8 patients (16%) with N12 and 2 patient (4%) with N24 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 16patients (32%) with N18 intermediate visual acuity, 11 patients (22%) with N36 visual acuity, 7 patients (14%) with N24 visual acuity, 6 patients (12%) with N8 and N10 visual acuity and only 2 patient (4%) with N6 and N12 visual acuity but later at the last follow-up 12 patients (24%) had N6 and N18 visual acuity each while

11patients (22%) had visual acuity N8 and N12 and only 4 patients (8%) had N10 visual acuity, thus showing progressive improvement in visual acuity.(Table 3).
However, in monofocal group at last follow-up 37 patients (74%) had N24 visual acuity, 11 patients (22%) had N18 visual acuity and only 2 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 40 patients (80%) with no complaint of glare and haloes and only 10 patients (20%) 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 1.31±0.39 which was lower as compared to the mean contrast sensitivity in the monofocal group (Group 2) which was 2.22±0.06, thus, the difference between the groups was statistically significant (p=0.001). On further follow-up, there was a slight improvement in contrast sensitivity in the multifocal group, with mean contrast sensitivity being 1.71±0.40 on day 10, 1.98±0.47 on day 40, 2.05±0.33on day 70 and 2.17±0.24 on day 100. The mean contrast sensitivity in the multifocal group remained the same being 2.26±0.06 on day 100. (Table 5). On the last follow-up i.e. day 100, the difference among the two groups was statistically significant (p=0.006), 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.

Table 1: Distribution of subjects according to post-operative uncorrected distance visual acuity findings in Group 1 and 2 on variousfollow up visits (n=100)

UC VA	**Day 1**		**Day 10**		**Day 40**		**Day 70**		**Day 100**	
	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono
6/6	6	6	12	6	11	6	11	6	11	6
	(12%)	(12%)	(24%)	(12%)	(22%)	(12%)	(22%)	(12%)	(22%)	(12%)
6/9	11	21	17	21	22	18	22	18	22	18
	(22%)	(42%)	(34%)	42%	(44%)	(36%)	(44%)	(36%)	(44%)	(36%)
6/12	14	16	17	23	17	26	17	26	17	26
	(28%)	(32%)	(34%)	46%	(34%)	(52%)	(34%)	(52%)	(34%)	(52%)
6/18	10	7	2	0	0	0	0	0	0	0
	(20%)	(14%)	(4%)							
6/24	9	0	2	0	0	0	0	0	0	0
	(18%)		(4%)							
	p = 0.243		p= 0.515		p= 0.534		p = 0.534		p= 0.534	

Table 2: Distribution of subjects according to post-operative near visual acuity findings in Group 1 and 2 on various follow up visits(n=100)

	Day 1		**Day 10**		**Day 40**		**Day 70**		**Day 100**	
Near VA	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono
	8	0	16	0	16	0	16	0	17	0
N6	(16%)	(0%)	(32%)	(0%)	(32%)	(0%)	(32%)	(0%)	(34%)	(0%)
	8	0	0	0	16	0	17	0	17	0

N8	(16%)	(0%)	(0%)	(0%)	(32%)	(0%)	(34%)	(0%)	(34%)	(0%)
	12	3	16	3	8	3	8	3	6	3
N10	(24%)	(6%)	(32%)	(6%)	(16%)	(6%)	(16%)	(6%)	(12%)	(6%)
	4	8	8	8	8	8	7	8	8	8
N12	(8%)	(16%)	(16%)	(16%)	(16%)	(16%)	(14%)	(16%)	(16%)	(16%)
	12	37	7	37	0	37	2	37	2	37
N18	(24%)	(74%)	(14%)	(74%)	(0%)	(74%)	(4%)	(74%)	(4%)	(74%)
N24	3	2	3	2	2	2	0	2	0	2
	(6%)	(4%)	(6%)	(4%)	(4%)	(4%)	(0%)	(4%)	(0%)	(4%)
N36	3	0	0	0	0	0	0	0	0	0
	(6%)	(0%)	(0%)	(0%)	(0%)	(0%)	(0%)	(0%)	(0%)	(0%)
p-value	p= 0.021		p= 0.001		p= 0.000		p= 0.000		p= 0.000	

Table 3: Distribution of subjects according to post-operative intermediate visual acuity findings in Group 1 and 2 on various follow up visits (n=100)

	Day 1		**Day 10**		**Day 40**		**Day 70**		**Day 100**	
Near VA	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono
	2	0	9	0	11	0	11	0	12	0
N6	(4%)	(0%)	(18%)	(0%)	(22%)	(0%)	(22%)	(0%)	(24%)	(0%)
	6	0	9	0	6	0	8	0	11	0
N8	(12%)	(0%)	(18%)	(0%)	(12%)	(0%)	(16%)	(0%)	(22%)	(0%)
	6	2	0	3	11	2	8	2	4	2
N10	(12%)	(4%)	(0%)	(6%)	(22%)	(4%)	(16%)	(4%)	(8%)	(4%)
	2	0	5	0	9	0	12	0	11	0
N12	(4%)	(0%)	(10%)	(0%)	(18%)	(0%)	(24%)	(0%)	(22%)	(0%)
	16	11	20	11	6	11	8	11	12	11
N18	(32%)	(22%)	(40%)	(22%)	(12%)	(22%)	(16%)	(22%)	(24%)	(22%)
N24	7	37	0	3	5	37	3	37	0	37
	(14%)	(74%)	(0%)	(6%)	(10%)	(74%)	(6%)	(74%)	(0%)	(74%)
N36	11	0	7	0	2	0	0	0	0	0
	(22%)	(0%)	(14%)	(0%)	(4%)	(0%)	(0%)	(0%)	(0%)	(0%)
Significance	p= 0.027		p= 0.001		p= 0.000		p= 0.000		p= 0.000	

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=100)

Glare	**Day 1**		**Day 10**		**Day 40**		**Day 70**		**Day 100**	
	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono	Multi	Mono
0	41	50	46	0	49	50	50	50	50	50
	(82%)	(100%)	(92%)		(98%)					
1	9	0	4	0	1	0	0	0	0	0
	(18%)		(8%)		(2%)					
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
p-value	p = 0.136		p= 0.449		p= 0.001		-	-	

Discussion

In our study, on last day of follow up(day 100), in the multifocal group 56% patients had uncorrected distance visual acuity(UCDVA) of 6/9 or better while 34%had 6/12, while in the monofocal group 52%had UCDVA 6/9 or better while 52% 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.[11] Study conducted by Yamauchi and colleagues who compared Tecnis monofocal and multifocal IOLs also found no difference in UCDVA of two groups.[12] Cionni et al. in 2009 also observed similar results.[13]

At the end of our study, multifocal group had 34% patients with near vision N6 and 34% with N8 near visual acuity while in monofocal group 74% patients had N18 and 22% had N12. Thus, difference in uncorrected near visual acuity between the two groups was found to be statisticallysignificant (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 ($p<0.001$).[14] Alio et al. also concluded that multifocal IOL group had significantly better uncorrected near acuity and DCNVA (Jaeger [J] 5 versus J2) (both $P<.01$).[15] Also a clinical trial by Cillino et al. observed similar results, UCNVA was 20/50 in the monofocal IOL group, compared with 20/32 or better in the multifocal IOL groups($P<0.0005$).[16]

At the last follow-up, i.e., day 100, the multifocal group had 24% (12 patients) with N6 and 22% (11 patients) with N8 un-corrected intermediate visual acuity (UIVA), the rest 55% (11 patients) with N18 or better UIVA 74% (37 patients) had N24 and 22% (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.[12,13,16] In our study, the mean contrast sensitivity as assessed by the Pelli-robson chart was 1.31±0.39 which was lower as compared to the mean contrast sensitivity in the monofocal group (Group 2) which was 2.22±0.06, thus, the difference between the groups was statistically significant (p=0.001),But nevertheless the values of contrast sensitivity were well within normal range as assessed by Mantyjarvi et al. in 2009.[17] 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 no significant difference in mean contrast sensitivity ($p<0.05$).[14] In 2005, Alio and colleagues compared multifocal and monofocal IOLs and found no significant difference in contrast sensitivity.[15]

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($p=0.038$).[16] 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.[13]

In our study, on the first day of follow up, on assessing glare and haloes using typE questionnaire, there were 17 patients (74%)with a score of 0 while 12 patients (24%) with a score of 1, signifying very little bother from glare and haloes and the p value being 0.111. 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 ($p<0.05$).[18] 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.[11]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.

Conclusion

The present study concluded that Mutifocal IOLs decrease the spectacle dependence of patients without compromising the subjective visual functions**.**

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