# A clinical study to assess feasibility, acceptance, and outcome of multifocal intraocular lens in patients with bilateral immature cataract at a tertiary eye care institute

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Purpose: To assess feasibility, acceptability, and outcome of multifocal intraocular lenses (IOL) in patients with bilateral immature cataract. Methods: 1691 patients with bilateral immature cataract were included in the study. The feasibility of these IOLs was calculated by studying ocular parameters using Visionix VX120 and subjective characteristics. A prospective study was then conducted in 148 eyes of 74 patients in which multifocal IOLs were implanted. Their visual outcome was assessed using LogMAR for distance and Snellen's chart for near vision, contrast sensitivity by Pelli-Robson chart, and satisfaction using visual function-7 questionnaire. Results: Considering ocular and subjective characteristics, it was feasible to implant the lens in 920 patients (54.40%) and the acceptability rate was 8.04%, most common reason for decreased acceptability was cost (85%) of IOL. The median distance uncorrected visual acuity (UCVA) at day 7 and at 30 days was LogMAR 0.2 (0.1–0.3) and 0.15 (0.1–0.2), respectively, which was statistically significant compared to preoperative distance UCVA (P < 0.001). The median near UCVA at day 7 and 30 days was N6 for both and statistically significant (P < 0.001) compared to preoperative near UCVA. 77.02% patients had distance UCVA of LogMAR (0.0-0.2) and 91.8% had near UCVA of N6-N8 at 30 days. The contrast sensitivity was decreased in all patients. Conclusion: Appropriately selected patients can achieve spectacle independence and good visual satisfaction which begins with proper patient education, lifestyle and personality dynamics, and individualized weighing of benefits and side effects of multifocal IOLs.



Key words: Acceptability, contrast sensitivity, feasibility, multifocal IOL, VF-7 satisfaction

Multifocal intraocular lenses (IOLs) provide good vision at a larger range of distances than standard IOLs, improving near and distance vision simultaneously.<sup>[1]</sup> They are a new alternative for appropriately selected patients who aspire to be spectacle-free after their cataract removal. Following bilateral multifocal IOLs implantation, rates of spectacle freedom are reported to be significantly higher (76% to 92% of patients) than with monofocal IOLs (8% to 12% of patients),<sup>[2]</sup> and achieve acceptable patient satisfaction.<sup>[3]</sup> But the visual disturbances like photic phenomena, waxy vision, dysphotopsia, blurred vision, and excessive expectations of patients have led to dissatisfaction among few patients sometimes even requiring IOL explantation.<sup>[4]</sup> Thus, proper selection of patients is necessary. Hence, the present study was planned to assess feasibility, acceptance, and outcome of multifocal IOL in patients with bilateral immature cataract.

# Methods

A prospective observational study was carried out during the period of January 2016–September 2017 in a comprehensive eye care center which acts as a tertiary unit for eye care in western Maharashtra. All patients with bilateral immature cataract coming to our eye care center willing to participate in the study

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Received: 29-Oct-2019 Accepted: 03-Jun-2020 Revision: 15-May-2020 Published: 26-Oct-2020 and were able to give informed consent were recruited. Neural adaptation ability was considered; thus, patients with bilateral cataracts and those willing to get operated for both eyes within a span of 90 days were included in the study. Feasibility rate was calculated after excluding nonfeasible population such as patients with posterior segment and optic nerve pathology, patients who are frequent night driver, and patients with type A personality. Ocular parameters considered for feasible population were such as pupil size of 3-4 mm, angle kappa 5-7 degrees, and astigmatism of less than 1 diopter. Approval from the Institutional Ethics Committee was obtained prior to initiation of the study. Acceptability rate was calculated after subtracting the number of patients from feasible population due to reasons such as cost issues, comfortability with near glasses, unwillingness for other eye surgery within a period of 90 days, and nonacceptable post-IOL implantation glare and halos.

### Sample size calculation

Prevalence (P) of multifocal IOL implantation, from October 2014 to October 2015 at our tertiary eye care institute was calculated as P = 38/750 = 0.05% = 5, where 38 patients

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**Cite this article as:** Deshpande R, Mangiraj V, Deshpande M, Dole K, Bharucha K, Sanghavi N. A clinical study to assess feasibility, acceptance, and outcome of multifocal intraocular lens in patients with bilateral immature cataract at a tertiary eye care institute. Indian J Ophthalmol 2020;68:2421-6.

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underwent multifocal IOL implantation among a total number of 750 patients with bilateral immature cataract who visited the hospital during the time period mentioned above. Using the prevalence, the sample size was calculated as 74 with the formula N =  $[(Z^2 \times P \times Q)/L^2]$ , where N = required sample size, Z = 1.96 at level of significance 5%, P = prevalence of cataract surgery with multifocal IOL implantation , Q = (100 – P), and L = experimental error (we assume error as 5%).

In addition, we assumed the power of the study to be 80% and the confidence interval to be 95%. Therefore,  $N = [(1.96)^2 \times 5 \times (100 - 5)]/(5)^2$ , N = 74 Patients.

Therefore, the total sample size = 74.

Written informed consent in an understandable language was obtained from patients before enrolling them in the study.

Ocular variables used for preoperative evaluation were visual acuity by logMAR visual acuity chart for distance vision at 6 m and Snelling's near acuity chart at 35 cm for near vision, slit lamp examination of anterior segment and grade of cataract, fundus examination, keratometry and optical biometry by Lenstar LS900 for axial length (AL), anterior chamber depth, lens thickness, IOL formulas (SRK/T for AL ≥22 mm, Hoffer Q <22 mm), corneal topography by Visionix VX120 machine [astigmatism <1.00 D for multifocal intraocular lens (MFIOL)], pupil size by Visionix VX 120 machine (3-4 mm for MFIOL), Angle kappa by Visionix VX120 machine (5°-7° for MFIOL), and intraocular pressure with Goldman's applanation tonometry. Phacoemulsification surgery was done either under topical or local anesthesia. Surgery was performed using standard operative techniques by different surgeons who specialized in performing phacoemulsification surgery with an experience of 15 years in the field. Size of capsulorrhexis is kept constant 5.5 mm. Different multifocal lenses used were Acrysof Alcon Restor: An apodized diffractive multifocal IOL, IDiff Plus: A diffractive-refractive multifocal IOL, Mflex Rayner: A refractive multifocal IOL, and Tecnis Symphony: A extended depth of focus (EDOF) IOL. Adequate care was taken to eliminate the effects of confounding variables. Near add was calculated as per patient's working distance requirement. Postoperative evaluation at 7 and 30 days was done using variables as uncorrected distance vision acuity and best-corrected distance vision acuity by logMAR visual acuity chart at 6 m, and uncorrected near vision acuity by Snellen's near vision chart at 35 cm. In addition, at day 30, visual satisfaction was assessed by visual function-7 (VF-7) questionnaire and contrast sensitivity by Pelli-Robson chart.

### Statistical analysis

Data was entered in a Microsoft Excel workbook and analyzed using Statistical Package for the Social Sciences 20.0 for Windows software package (SPSS Inc, Chicago, IL). Nonparametric data within the group at multiple intervals was assessed using Friedman's test followed by post hoc tests by Wilcoxon signed-rank test.

### **Definitions of outcomes**

1. Uncorrected distant visual acuity:

The preoperative and postoperative uncorrected distant visual acuities were classified using the World Health Organization (WHO) definitions of visual impairment and blindness Good [mild/no visual impairment-(LogMAR 0.0–0.2)] Borderline [moderate visual impairment-(LogMAR 0.3–1.0)] Poor [severe visual impairment-(LogMAR >1.0)].

2. Contrast sensitivity:

Contrast sensitivity measured using the Pelli-Robson chart was assessed at 1 m distance after giving best distance correction and with good illumination in the operated eye, 1 month after surgery. It was classified as follows: Good-(>1.20)

Borderline-(1.00-1.20)

Poor-(<1.00). 3. Quality of Vision:

Quality of vision was measured by administering a visual function questionnaire VF-7 and score was calculated The questionnaire was administered in English or Marathi. Patients were asked to rate their preoperative status, expected outcome, and postoperative status for each of the 7 items on the VF-7 scale on a scale of 4 to 0. The total score was calculated and classified as follows:

Good (>75)

Borderline (45–75)

Poor (<45).

The gain in visual function was calculated as the difference between the preoperative and postoperative scores and classified as follows:

Good (>/= 15) and poor (<15).

#### Feasibility

For the study, 1691 patients with bilateral immature cataract were screened.

The most common reason for nonfeasibility in patients was retinal pathology in 273 (35.4%) patients [Graph 1 and Table 1].

### Acceptability

Among the 920 feasible patients, 846 patients did not accept multifocal IOL, while only 74 patients accepted implantation of multifocal IOL. Reasons are shown in Graph 2.

The most common reason for rejection of multifocal IOL was cost in 719 (85%) patients.

#### Mean age

The mean age of patients in the study was  $59.39 \pm 10.61$  years (35–79) as shown in Graph 3.

#### **Gender distribution**

In the present study, the majority of patients were females (62.2%) as shown in Graph 4.

Using Friedman test, there was a statistically significant difference in distant uncorrected visual acuity (UCVA) during the procedure of multifocal IOL implantation,  $\chi 2^{[2]} = 234.54$ , P < 0.001 [Table 2].

Using Friedman test, there was a statistically significant difference in near UCVA during the procedure of multifocal IOL implantation,  $\chi 2^{[2]} = 250.97$ , *P* < 0.001. [Table 3]

The distant best-corrected visual acuity (BCVA) was compared at preoperative and postoperatively at 30 days using Wilcoxon's signed-rank test. Median (interquartile range) distant BCVA at preoperative and at 30 days was 0.3 (0.2–0.58) and 0.1 (0–0.1), respectively. Compared to preoperative distant BCVA, there was a statistically significant improvement



Graph 1 : Reasons for nonfeasibility of multifocal IOL (n=771)



Graph 3: Age wise distribution of patients

in distant BCVA at 30 days (Z = -9.86, P < 0.001) [Table 4]. Compared to preoperative near BCVA, there was a statistically significant improvement in near BCVA at 30 days (Z=-7.77, p<0.001) [Table 5].

The VF7 score at day 30 was significantly higher in patients compared to baseline VF7 score. [Table 6]

The contrast sensitivity at day 30 in patients was significantly higher compared to baseline readings [Table 7].

## Results

1691 patients were screened for feasibility and acceptability. Feasibility was noted in 920 (54.4%) patients and the most common reason for nonfeasibility was retinal pathology in 275 (35.45%) patients. Among the 920 feasible patients, 846 patients did not accept multifocal IOL, while only 74 patients accepted implantation of multifocal IOL, with cost being the major reason for nonacceptability in 719 (85%) patients. Mean age of patients in the study was  $59.39 \pm 10.61$  years. Majority of patients were female 46 (62.2%) patients. The patients were implanted with four different type of multifocal IOL: diffractive-refractive in 51 (68.9%) patients, apodized diffractive in 36 (24.3%) patients, refractive in 4 (5.4%) patients, and EDOF IOLs in 2 (1.4%) patients. There was a statistically significant improvement in the uncorrected distant and near vision and corrected distant vision at 30 days compared to baseline (P < 0.001). 114 patients (77.02%) had distance UCVA of logMAR 0-0.2. 136 patients (91.89%) had UCVA near between N6 and N8. The postoperative vision gain was similar at day 30 according to grade of cataract and type of multifocal lens used.



Graph 2: Reasons for rejection of multifocal IOL (n=846)



Graph 4: Gender wise distribution of patients

VF7 score gain was noted in patients at day 30 of implantation. The contrast-sensitivity was found to decrease at day 30 of implantation.

# Discussion

Before 1980s, the aim of cataract surgeries was to prevent blindness, but now it has progressed to refractive procedure that aims for postoperative emmetropia,<sup>[5]</sup> with the best possible visual outcome and early functional recovery that is an improvement in visual function. Monofocal IOLs have a single focal point and provide better visual function for distance vision, but ultimately, such patients require glasses for compensation of loss of intermediate or near vision.<sup>[6]</sup> Bilateral multifocal IOLs have advantage of providing better vision and better patient satisfaction postoperatively. The multifocal IOLs include bifocal, trifocal, and EDOF IOLs. The EDOF lenses are found to offer better contrast sensitivity and decreased spectacle dependence for distance, intermediate, and near vision with lesser visual disturbances compared to bifocal IOLs.<sup>[7,8]</sup> There is a lack of literature regarding the feasibility and acceptability of the multifocal IOLs in patients, especially in Indian settings, thus there was a necessity to carry out research for the same. In the present study, out of 1691 patients with age-related senile cataract, only 920 (54.5%) were feasible. The causes for nonfeasibility were optic nerve pathology (19.4%), retinal pathology (35.4%), night driving (12.06%), type A personality (12.1%), and nonfeasible ocular parameters such as pupil size (6.4%), angle kappa (4.1%), and astigmatism (10.2%). Thus, the most common cause is retinal pathology. In India, cost of any medical intervention is an important issue, our institution being a charitable trust hospital, and the patient load visiting our hospital belonged to middle class so cost was the

Table 1: Feasibility of patients			
Feasibility	Frequency	Percentage	
Feasible	920	54.4	
Not Feasible	771	45.6	
Total	1691	100	

Table 2: Distance UCVA			
Value (LogMAR)	Preoperative (%)	Day 7 postoperative	Day 30 postoperative
0	-	11 (7.4%)	16 (10.8%)
0.1	1 (0.7%)	40 (27%)	58 (39.2%)
0.2	9 (6.1%)	44 (29.7%)	40 (27%)
0.3	9 (6.1%)	32 (21.6%)	24 (16.2%)
0.4	8 (5.4%)	11 (7.4%)	4 (2.7%)
0.5	19 (12.8%)	9 (6.1%)	5 (3.4%)
0.6	30 (20.3%)	1 (0.7%)	1 (0.7%)
0.7	23 (15.5%)	-	-
0.8	2 (1.4%)	-	-
0.9	8 (5.4%)	-	-
1.0	21 (14.2%)	-	-
1.1	1 (0.7%)	-	-
1.2	6 (4.1%)	-	-
1.3	10 (6.8%)	-	-
1.8	1 (0.7%)	-	-

#### **Table 3: Near UCVA**

Value ( <i>n</i> )	Preoperative (%)	Day 7 postoperative	Day 30 postoperative
6	3 (2%)	82 (55.4%)	109 (73.6%)
8	16 (10.8%)	47 (31.8%)	27 (18.2%)
10	12 (8.1%)	11 (7.4%)	5 (3.4%)
12	22 (14.9%)	4 (2.7%)	3 (2%)
18	26 (17.6%)	2 (1.4%)	1 (0.7%)
24	23 (15.5%)	1 (0.7%)	3 (2%)
36	46 (31.1%)	1 (0.7%)	-

most common reason for rejection. Thus, multifocal IOLs being expensive, it limits its acceptability. In present study, among the patients rejecting multifocal IOLs, cost was a hindrance in 85% patients, decreasing the acceptability rate to 8.04%. Thus, after a screening of 1691 patients, only 74 (4.4%) patients with bilateral immature cataract could be implanted with multifocal IOLs. Hence, from our study, we found that before implanting multifocal IOL, it is very necessary to evaluate for feasibility and acceptability of patients, which had been carried out in the present study, and those patients with chances of good visual outcome should be counselled for multifocal IOL. Maxwell et al. implanted 274 patients of bilateral cataract with multifocal IOLs.<sup>[9]</sup> Cionni et al. implanted multifocal in bilateral eyes in 15 patients.<sup>[10]</sup> Medeiros et al. implanted bilateral multifocal IOLs in 20 patients.[11] Gundersen and potvin enrolled 65 patients for implanting the bilateral multifocal IOL.<sup>[12]</sup> In a large trial by Javitt and Steinert across 8 sites in USA, 7 sites in Germany, and 1 site in Austria, 124 patients

Table 4: Distance BCVA			
Value (LogMAR)	Preoperative (%)	Day 30 postoperative	
0	6 (4.1%)	68 (45.9%)	
0.1	8 (5.4%)	58 (39.2%)	
0.2	41 (27.7%)	16 (10.8%)	
0.3	28 (18.9%)	4 (2.7%)	
0.4	14 (9.5%)	2 (1.4%)	
0.5	14 (9.5%)	-	
0.6	7 (4.7%)	-	
0.7	4 (2.7%)	-	
0.9	1 (0.7%)	-	
1.0	10 (6.8%)	-	
1.1	2 (1.4%)	-	
1.2	7 (4.7%)	-	
1.3	5 (3.4%)	-	
1.8	1 (0.7%)	-	

Table 5: Near BCVA			
Value ( <i>n</i> )	Preoperative (%)	Day 30 postoperative	
6	68 (45.9%)	143 (96.6%)	
8	32 (21.6%)	4 (2.7%)	
10	6 (4.1%)	1 (0.7%)	
12	6 (4.1%)	-	
18	4 (2.7%)	-	
24	10 (6.8%)	-	
36	22 (14.9%)	-	

received bilateral multifocal IOLs and completed the study.<sup>[13]</sup> In a study by Bi *et al.*, all 20 patients were implanted with ReSTOR multifocal implants.<sup>[14]</sup> Chiam *et al.* implanted bilateral multifocals in 100 patients.<sup>[15]</sup> Cillino *et al.* implanted multifocals bilaterally in 47 patients.<sup>[16]</sup> In the present study, also bilateral IOLs were implanted in 74 patients. In most of the studies, multifocal IOL was implanted without checking feasibility and acceptability, but we carried out study for the same and found that acceptability was low mostly due to cost issue.

The mean age of patients in Maxwell et al.'s study was 68.9 years.<sup>[9]</sup> Mean age of patients with multifocal IOLs in study by Liang et al. was 69.7 ± 9.6 years.<sup>[17]</sup> The mean age of patients in the study by Medeiros et al. was  $64.2 \pm 8.3$  and  $64.4 \pm 7.7$  years in the two groups with multifocal IOLs.[11] In Gundersen and potvin study, the mean age of patients was  $59 \pm 9$  and  $58 \pm 10$  years in the two groups with multifocal IOLs.<sup>[12]</sup> In Bi *et al.* study, the mean age of patients with multifocals was  $53 \pm 4.5$  years.<sup>[14]</sup> The mean age of patients was  $67.8 \pm 8.1$  and  $69 \pm 7$  years in the two groups with multifocal IOLs in Chiam et al. study.<sup>[15]</sup> In the present study, we found similar results, i.e., the mean age of patients in current study was  $59.4 \pm 10.6$  years. In the present study, females were 62.2%, while males were 37.8%. In Maxwell et al. study, 68.5% were women.<sup>[9]</sup> In the study by Medeiros et al., males and females constituted 30% and 70% of study sample.<sup>[11]</sup> In Javitt and Steinert study, females and males were 61.3% and 38.7%, respectively.<sup>[13]</sup> In Bi et al.'s study, males and females were equal in proportion.<sup>[14]</sup> It can be observed that in almost all studies, including the present

Table 6: Assessmen	t VF7 score at baseline a	and 30 days		
Baseline VF7 score	Day 30 VF7 score	Statistical test	t <b>P</b>	Interpretation
51.33±7.87	88.02±7.86	Paired t-test	<i>P</i> <0.00	The VF7 score at day 30 was significantly higher compared to preoperative scores.
Paired <i>t</i> test; *** <i>P</i> <0.001				
Table 7: Contrast se	nsitivity at day 30			
Baseline contrast sensitivity	Day 30 contrast sensitivity	Statistical test	Р	Interpretation
1.18±0.23	1.45±0.3	Paired <i>t</i> -test	<i>P</i> <0.001	The contrast sensitivity at day 30 was significantly higher compared to preoperative scores.

one, females were more implanted with multifocal IOLs than male. The reasons for such distribution can be females being less frequent night drivers, wanting to be more spectacle independent (cosmetic), and readily accepting glare and halos because of more hours spent indoors.

The preoperative distance BCVA of patients in the present study was logMAR 0.45 ± 0.36, while that in the study by Liang et al. was  $0.28 \pm 0.12$ .<sup>[17]</sup> The preoperative distance BCVA in the two groups of patients with multifocal IOLs was  $0.24 \pm 0.18$ and  $0.16 \pm 0.19$  in the study by Medeiros *et al.*<sup>[11]</sup> The median BCVA in patients in Chiam et al. study was 20/40.[15] Better the preoperative visual acuity, probability of good visual outcome increases in the postoperative period. In the present study, apodized diffractive lens was used in 24.3% eyes, diffractive-refractive lens in 68.9% eyes, refractive lens in 5.4% eyes, and EDOF IOLs in 1.4% eyes. The multifocal IOLs were implanted according to patient's choice. In the study by Maxwell et al., patients were implanted with apodized diffractive ReSTOR lens. Apodized diffractive lens was used in all bilateral patients by Cionni et al.<sup>[10]</sup> Study by Mesci et al. demonstrated better visual acuities and higher contrast sensitivity when a diffractive multifocal IOL was used compared to refractive multifocal IOLs.<sup>[18]</sup> Hence, diffractive multifocal IOLs are more commonly preferred over other types. The ReSTOR diffractive lens has a central diffractive zone with a refractive only zone peripherally, which directs relatively less light to the near focus in large pupils.<sup>[19]</sup> In an extensive meta-analysis of monofocal versus multifocal IOL implantation in 46 bilateral cataract patients, 76.1% were implanted with multifocals, of which 41.3% used diffractive lens, 30.4% used refractive lens, and 4.3% used accommodative lens. Of 46 bilateral cataract patients, ReSTOR was used in 34.3%.<sup>[20]</sup> The mean power of mutifocal IOLs in present study was  $21.4 \pm 2.55$  D. Liang et al. implanted multifocal IOLs with a mean power of 20.13 ± 2.38 D.<sup>[17]</sup> Medeiros et al. implanted TNFT100 and ZXR00/ZMB00 lens with mean power of  $22.2 \pm 1.5$  and  $21 \pm 2.7$ D, respectively.<sup>[11]</sup> Thus, the most common multifocal lens in the present study implanted was a diffractive-refractive IOL due to its lower cost and good visual outcome compared to others. The EDOF IOLs being newer in market and due to its high cost had least implantation percentage in our study. Following implantation, the mean distance BCVA in present study at 30 days was  $0.08 \pm 0.09$ , and all the visual acuities improved at 30 days compared to 7 days and this gradual improvement in vision was attributed to the presence of inflammation immediately after surgery which eventually subsides over few days. In Maxwell et al. study, improvement with distance and near UCVA and BCVA was noted at 6 months in both groups with multifocal IOLs.<sup>[9]</sup> Postoperative improvement in UCVA and BCVA at 6 months was noted by Cionni et al.[10] Liang *et al.* observed mean distance BCVA of  $0.05 \pm 0.05$  at 6 months postoperatively.[17] The contrast-sensitivity score in multifocal IOLs implantation in present study was  $1.45 \pm 0.3$ postoperatively, which was increased compared to the preoperative levels, and this was an apparent increase in CS due to removal of cataractous lens. Liang et al. observed a small loss of contrast sensitivity with multifocal IOLs, while another study by Mesci et al. demonstrated increase with multifocal IOLs.[17,18] Cionni et al. noted improvement in contrast sensitivity at 6 months of bilateral multifocal implantation.<sup>[10]</sup> In Yamauchi et al. study, contrast sensitivity was found to be better in the monofocal group compared to the multifocal group.<sup>[21]</sup> In Ye et al. study, patients with multifocal IOL showed less contrast sensitivity compared to monofocal IOL implanted patients.<sup>[22]</sup> The decreased contrast sensitivity with Multifocal IOLs is explained by the division of the light rays into two or more foci by the lens.

In the present study, VF7 score was used to assess the quality of life and satisfaction. VF7 showed a significant improvement at 30 days postoperatively. In a 28-question patient satisfaction survey, the mean patient satisfaction score at 6 months was  $8.9 \pm 1$ , which was higher than the patients implanted with multifocal mixed IOL.[10] The quality of vision questionnaire scores for multifocal IOLs in the study by Gundersen and potvin were higher compared to those with monofocal IOLs.<sup>[12,22]</sup> VF7 score similar to that in the present study was used by Cillino et al. The mean preoperative VF7 scores were  $76.9 \pm 3.2$ ,  $77 \pm 2.1$ , and  $76.7 \pm 3.2$  in the Array, ReZOOM, and TecnisZM900 multifocal lens groups, respectively. The postoperative VF7 scores were 93.8 ± 9.9, 94.6 ± 5.8, and 99.1 ± 1.9 in the three groups, respectively.<sup>[16]</sup> Improvement in quality of life noted in the present study was in accordance with the other studies.

## Conclusion

On the basis of the results of the current study, it is important to note that counselling should be done after initially checking patient's feasibility. Preoperative evaluation of all factors that can influence postoperative outcome of multifocal IOL is necessary. Multifocal IOL's cost is major issue in reducing acceptability rate. Appropriately selected patients can achieve spectacle independence and good visual satisfaction which begins with proper patient education, consideration of lifestyle and personality dynamics, and individualized weighing of benefits and side effects of multifocal IOLs.

Financial support and sponsorship Nil.

### **Conflicts of interest**

There are no conflicts of interest.

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