

Binocular Visual Function With Staged Implantation of Diffractive Multifocal Intraocular Lenses With Three Add Powers



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- **PURPOSE:** To evaluate the binocular visual function and depth of focus after staged implantation of diffractive multifocal intraocular lenses (MIOLs) with 3 different add powers following cataract removal.
- **DESIGN:** Prospective comparative case series.
- **METHODS:** Setting: Institutional. Study Population: Both eyes of 56 patients that underwent staged implantation of bifocal IOLs. Intervention: In the first eye, MIOLs with a +4.0-diopter (D) add power were implanted. Based on outcomes at 1 week postoperatively and patient preference for near vision, 1 of 3 near add powers—+4.0 D (group MM), +3.25 D (group ML), or +2.75 D (group MK)—was implanted in the fellow eye. Main Outcome Measure(s): Three months postoperatively, the binocular uncorrected and distance-corrected visual acuities (BUCVA and BDCVA, respectively) at 5.0, 1.0, 0.5, 0.4, and 0.3 meters; binocular defocus curves; contrast sensitivity; and near stereopsis were measured.
- **RESULTS:** The MM, ML, and MK groups included 21, 18, and 17 patients, respectively. The mean BUCVA in the MM group was significantly ($P = .003$) worse than that in the MK group at 0.5 meter. The BDCVAs at 0.5 meter in the ML and MK groups were significantly ($P < .02$) better than that in the MM group. The defocus curves with the -2.0 D refraction differed significantly ($P < .001$) between the MM and MK groups. The binocular contrast sensitivity and stereopsis values did not differ significantly.
- **CONCLUSIONS:** Staged implantation of different add powers obtained better binocular intermediate visual acuity without degradation of visual function. (Am J Ophthalmol 2019;199:223–229. © 2018 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>)).

MULTIFOCAL INTRAOCULAR LENSES (MIOLS) WITH various add powers are commercially available, so suitable add powers can be selected based on patient preference. The bifocality property of conventional MIOLs inherently induces degraded visual acuity (VA) between the designated distance and near focus points.^{1–3} The intermediate VA can be improved using trifocal or extended depth of focus (EDOF) IOLs,⁴ monovision techniques, or mix-and-match implantation of different add powers. Retrospective assessments of contralateral implantation of diffractive MIOLs with +3.0- and +4.0-diopter (D) add powers have reported improved binocular intermediate VAs.⁵ Implantation of different add powers is one method to extend the depth of focus in binocular vision.^{5,6} The Tecnis MIOLs (ZMB00, ZLM00, ZKM00; Johnson & Johnson Surgical Vision, Santa Ana, California, USA) have add powers of +4.0, +3.25, and +2.75 D to provide near vision at about 30, 42, and 50 cm, respectively.⁷ It has been anticipated that combining different add powers might facilitate various depths of focus in the postoperative binocular vision. However, the binocular VA after contralateral implantation of different add powers has not been assessed often.^{5,8,9} The current study evaluated the binocular visual function after staged implantation of MIOLs with different add powers.

METHODS

THE INSTITUTIONAL REVIEW BOARD OF TOKYO DENTAL Collage approved the prospective comparative study protocol (No. 680), which adhered to the Declaration of Helsinki. All patients provided written informed consent after they received an explanation of the study protocol. The study included patients who planned cataract surgery with bilateral MIOL implantation and who had no history of corneal surgery. Although the implanted MIOLs were not toric, eyes with substantial corneal astigmatism were included when patients agreed to an enhancement procedure such as laser in situ keratomileusis (LASIK) postoperatively.

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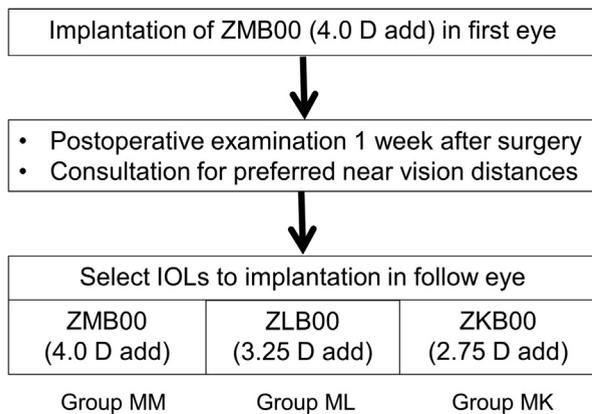


FIGURE 1. Staged implantation of multifocal intraocular lenses (IOLs) with three different add powers of +2.75, +3.25, and +4.0 diopter (D). The patients were divided into three groups based on the choice of +4.0-D add power IOLs only (group MM), +4.0-D and +3.25-D add power IOLs (group ML), and +4.0-D and +2.75 add power IOLs (group MK).

• **IMPLANTED MULTIFOCAL INTRAOCULAR LENSES:** The implanted ZMB00, ZLB00, and ZKM00 MIOLs were 1-piece, hydrophobic acrylic, diffractive MIOLs with add powers of +4.0, +3.25, and +2.75 D, respectively. The physical sizes, such as the 6.0-mm optics diameter, aspherical optics on the front surface, continuous sharp edges of the optics, and anteriorly shifted haptic designs of the MIOLs, were identical, except for the number of rings in the diffractive optics. The MIOL power was determined using the SRK/T formula. The axial length and keratometry were measured using the IOLMaster 700 (Carl Zeiss Meditec, Inc, Dublin, California, USA). Emmetropia was the goal for all eyes.

• **STAGED IMPLANTATION:** After the cataracts were removed by a phacoemulsification and aspiration technique using a LenSx Laser System (Version 2.23) and/or a Centurion Vision System (Alcon Laboratories, Fort Worth, Texas, USA),¹⁰ the MIOLs were implanted completely within the capsules using an IOL inserter system. In the first eyes of 56 patients with cataracts, the ZMB00 IOL with +4.0-D add power was implanted into either the dominant or nondominant eye. After routine examinations 1 week postoperatively, patients were asked for their preference for the near VA in the fellow eye (Figure 1). Based on the patient preference and outcomes of the first eye, the MIOL for the fellow eye was chosen from among the ZMB00 (+4.0-D add power), ZLM00 (+3.25-D add power), and ZKB00 (+2.75-D add power) MIOLs. The patients then were divided into 3 groups based on the choice of the ZMB00 MIOL only (group MM), the ZMB00 and ZLM00 MIOLs (group ML), and the ZMB00 and ZKB00 MIOLs (group MK). A LASIK enhancement was planned 1 month postoperatively if necessary.

• **EXAMINATIONS:** Three months after the MIOL implantations, the binocular uncorrected and distance-corrected VAs (BUCVA and BDCVA, respectively) were measured at the distances of 5.0, 1.0, 0.7, 0.5, and 0.3 meters. The VAs were converted to the logarithm of the minimum angle of resolution (logMAR) for analysis. Binocular defocus curves from -5.0 D to +2.0 D in increments of 0.5 D also were obtained under distance correction. Patients were asked about their use of spectacles.

The binocular contrast sensitivity was measured using the CSV-1000 instrument (Vector Vision Inc, Fairfield, Connecticut, USA) under illumination of 85 cd/m².

The near stereopsis was measured at 16 inches using the Titmus stereoscopic test under photopic illumination. The numbers of answers for the 3 targets (fly, animal, and circle) without refractive correction were converted to seconds of arc for analysis, with 100 seconds of arc considered as the maximal limit of normal stereopsis.¹¹

Patient satisfaction and symptoms of undesirable optical phenomena were recorded. The overall satisfaction level and satisfaction levels for distance, intermediate, and near vision were graded as very satisfied, satisfied, neither satisfied nor dissatisfied, unsatisfied, and very unsatisfied. The percentages of patients who were very satisfied and satisfied and the percentages of patients with moderate to severe glare, halo, and low-contrast sensitivity also were determined.

• **STATISTICAL ANALYSIS:** The clinical outcomes including the logMAR VAs, defocus curve, contrast sensitivity, and near stereopsis were compared among the 3 groups using the Kruskal-Wallis test following Steel-Dwass multiple comparison. The influence of IOLs in the dominant eyes on BDCVA were evaluated in the ML and MK groups. The difference in BDCVA was examined using the Mann-Whitney test. Use of spectacles, patient satisfaction, and symptoms of undesirable optical phenomena were evaluated using the χ^2 test. $P < .05$ was considered significant.

RESULTS

THE MM, ML, AND MK GROUPS, RESPECTIVELY, WERE composed of 21, 18, and 17 patients. Table 1 shows the patient demographic data. No differences in age ($P = .074$, Kruskal-Wallis test) were seen among the groups, while the axial length in the MM group was significantly ($P < .012$, Steel-Dwass multiple comparison) shorter than the other groups. Ocular dominances were identified in 20, 16, and 16 eyes in the MM, ML, and MK groups, respectively. With the sample sizes ($n = 17$) and significance level of .05, the detection power in detecting large variances in BDCVAs between 3 add powers was

TABLE 1. Preoperative Demographic Data of the Study Patients

Characteristic	Group		
	MM	ML	MK
Implanted IOL	ZMB00 x2	ZMB00, ZLB00	ZMB00, ZKB00
Patients, n	21	18	17
Age (years), mean ± SD, range	73.0 ± 7.4, 60–87	69.4 ± 3.8, 61–75	68.5 ± 6.3, 58–83
Axial length (mm), mean ± SD, range	23.5 ± 1.4, 21.5–27.1	24.6 ± 1.7, 22.0–27.8	24.9 ± 1.4, 22.5–27.5
IOL power (D), mean ± SD, range	21.6 ± 3.8, 13.0–27.5	17.1 ± 5.5, 5.0–26.0	17.6 ± 4.8, 7.0–25.0
Corneal astigmatism (D), mean ± SD, range	0.70 ± 0.57, 0.05–2.96	0.66 ± 0.44, 0.00–2.12	0.52 ± 0.49, 0.00–2.55

D = diopter; IOL = intraocular lens; MK = +4.0-D and +2.75-D add power IOLs; ML = +4.0-D and +3.25-D add power IOLs; MM = +4.0-D add power IOLs.

TABLE 2. Postoperative Binocular Uncorrected Visual Acuity

	Group		
	MM	ML	MK
MRSE (D)	-0.04 ± 0.36	-0.22 ± 0.35	-0.03 ± 0.31
LogMAR BUCVA			
5.0 m	-0.08 ± 0.07	-0.11 ± 0.13	-0.14 ± 0.05
1.0 m	0.06 ± 0.12	0.02 ± 0.14	0.01 ± 0.14
0.5 m	0.08 ± 0.06	0.02 ± 0.10	-0.03 ± 0.09
0.4 m	0.08 ± 0.09	0.03 ± 0.10	0.02 ± 0.08
0.3 m	0.12 ± 0.11	0.08 ± 0.14	0.09 ± 0.12
% 1.0 logMAR or better			
5.0 m	100%	94%	100%
1.0 m	81%	83%	82%
0.5 m	81%	89%	94%
0.4 m	81%	89%	94%
0.3 m	62%	67%	65%

BUCVA = binocular uncorrected visual acuity; D = diopter; logMAR = logarithm of the minimum angle of resolution; MK = +4.0-D and +2.75 add power intraocular lenses (IOLs); ML = +4.0-D and +3.25-D add power IOLs; MM = +4.0-D add power IOLs; MRSE = manifest refraction spherical equivalent.

Data are expressed as the mean ± standard deviation unless otherwise indicated.

anticipated as 0.70 when the effect size was 0.4 (corresponded to large in Cohen’s classification).

Preoperative stereopsis was measured in 20, 17, and 16 patients; 1 patient in the MM group with marked preoperative stereopsis (3000 seconds of arc) was excluded from the analysis. The mean stereopsis values were 66 ± 40, 87 ± 84, and 78 ± 53 seconds of arc in the MM, ML, and MK groups, respectively.

Table 2 shows the mean manifest refraction spherical equivalent (MRSE) and BUCVA. Although there was no significant ($P = .09$, Kruskal-Wallis test) difference in the MRSE, a significant ($P = .003$, Steel-Dwass multiple

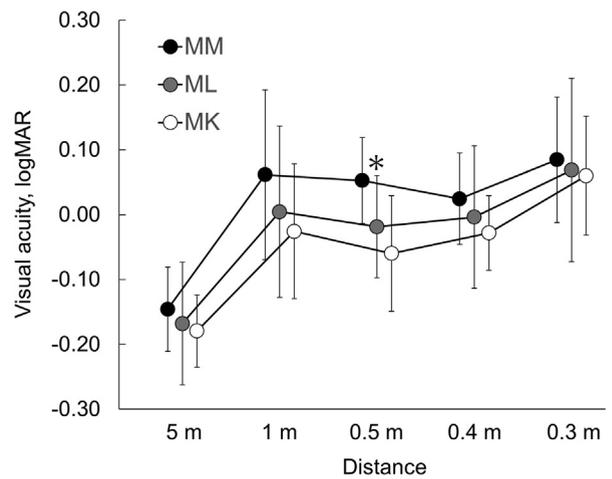


FIGURE 2. Binocular distance-corrected visual acuities (BDCVAs) after implantations of in +4.0 D add power IOLs only (group MM), +4.0 D and +3.25 D add power IOLs (group ML), and +4.0 D and +2.75 D add power IOLs (group MK). The BDCVA at 0.5 meter in the MM group is significantly ($*P < .02$) worse than in the other groups. logMAR = logarithm of the minimum angle of resolution; m = meters.

comparison) difference was found between the MM and MK groups at 0.5 meter. Table 2 also shows the percentages of eyes with a BUCVA of 1.0 logMAR (20/25 or J2).

Figure 2 shows the mean BDCVAs from 0.3 to 5.0 meters. The mean BDCVA in the MM group was significantly worse at 0.5 meter than those of the ML and MK groups ($P = .02$ and $P = .001$, respectively, Steel-Dwass multiple comparison). One patient in the MM group used spectacles for distance vision and underwent LASIK to correct the refractive error 6 months postoperatively; no patients in the ML and MK groups used spectacle correction.

In the ML and MK groups, the ZMB00 MIOLs were implanted in 9 and 6 dominant eyes, respectively. Table 3 shows the mean BDCVAs when the ZMB00 or ZLB00/ZKB00 MIOLs were implanted in dominant eyes.

TABLE 3. Effect of Multifocal Intraocular Lens in Dominant Eyes on Postoperative Binocular Corrected Visual Acuity

MIOL in dominant eye	Group			
	ML		MK	
	ZMB00 (N = 9)	ZLM00 (N = 7)	ZMB00 (N = 6)	ZKM00 (N = 10)
LogMAR BDCVA				
5.0 m	-0.21 ± 0.09	-0.14 ± 0.07	-0.16 ± 0.04	-0.19 ± 0.07
1.0 m	-0.07 ± 0.06 ^a	0.06 ± 0.17 ^a	0.00 ± 0.12	-0.05 ± 0.10
0.5 m	-0.02 ± 0.07	-0.02 ± 0.10	-0.07 ± 0.11	-0.05 ± 0.09
0.4 m	-0.03 ± 0.08	0.01 ± 0.15	-0.04 ± 0.07	-0.02 ± 0.05
0.3 m	0.02 ± 0.11	0.12 ± 0.17	0.07 ± 0.10	0.06 ± 0.10

BDCVA = binocular distance-corrected visual acuity; logMAR = logarithm of the minimum angle of resolution; MIOL = multifocal intraocular lens; MK = +4.0-diopter (D) and +2.75-D add power IOLs; ML = +4.0-D and +3.25-D add power IOLs; MM = +4.0-D add power IOLs. Data are expressed as the mean ± standard deviation. ^aP = .017, Mann-Whitney test.

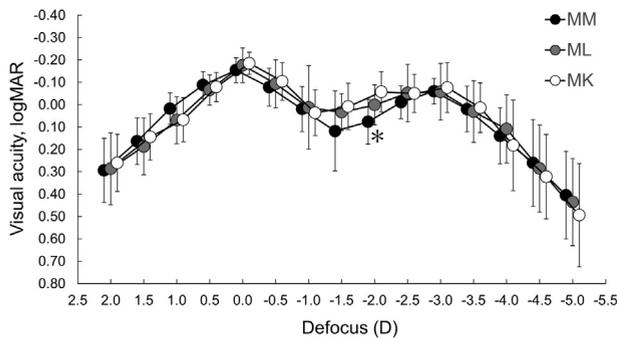


FIGURE 3. Binocular defocus curves after implantations of in +4.0 D add power IOLs only (group MM), +4.0 D and +3.25 D add power IOLs (group ML), and +4.0 D and +2.75 D add power IOLs (group MK). logMAR = logarithm of the minimum angle of resolution. *Significant ($P < .001$, Steel-Dwass multiple comparison) difference between the MM and MK groups.

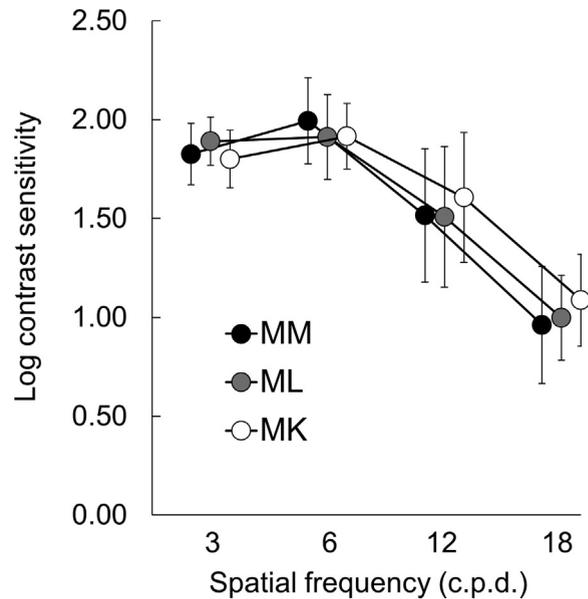


FIGURE 4. Binocular contrast sensitivity values after implantations of in +4.0-D add power IOLs only (group MM), +4.0-D and +3.25-D add power IOLs (group ML), and +4.0-D and +2.75 add power IOLs (group MK). cpd = cycles per degree.

No difference was found between IOLs in the dominant eyes, except for the BDCVA at 1.0 meter in the ML group ($P = .017$, Mann-Whitney test).

The binocular defocus curves were obtained in 21, 17, and 17 patients in the MM, ML, and MK groups, respectively (Figure 3). All groups showed 2 peaks at 0.0 D and -3.0 D, while the peak at -3.0 D became broader with the lower add powers. A significant ($P < .001$, Steel-Dwass multiple comparison) difference was seen between the MM and MK groups with the -2.0 D add power, while no difference was found with the other add powers.

Figure 4 shows binocular contrast sensitivity levels in the 3 groups. No significant ($P > .21$, Kruskal-Wallis test) differences were seen among the groups at any spatial frequency.

The postoperative mean stereopsis resulted in 46 ± 14 , 59 ± 39 , and 58 ± 28 seconds of arc in the MM, ML,

and MK groups, respectively, and the differences did not reach significance ($P = .07$, Kruskal-Wallis test). The rates of normal range (100 seconds of arc or less)¹¹ were 100%, 94%, and 94%, respectively.

Table 4 shows the patient satisfaction rates and the percentages of patients with moderate-to-severe photic symptoms. Although the MK group had the lowest satisfaction rate for intermediate distance and halos, no significant difference was seen in the rates of patient satisfaction ($P > .13$, χ^2 test) and photic symptoms ($P > .42$).

TABLE 4. Patient Satisfaction Rates and Percentages of Patients With Moderate-to-Severe Photic Symptoms

Metric	Group			P Value ^a
	MM	ML	MK	
Satisfaction				
Overall	76%	89%	88%	0.78
Distance vision	86%	83%	94%	0.60
Intermediate vision	71%	89%	59%	0.13
Near vision	67%	67%	71%	0.96
Photic symptom				
Glare	38%	33%	41%	0.89
Halos	38%	44%	24%	0.42
Low contrast sensitivity	38%	44%	53%	0.65

MK = +4.0-diopter (D) and +2.75-D add power intraocular lenses (IOLs); ML = +4.0-D and +3.25-D add power IOLs; MM = +4.0-D add power IOLs.

^a χ^2 test.

TABLE 5. Comparison of Binocular Distance-Corrected Visual Acuity After Contralateral Implantation of Different Add Powers Among Previous Studies and Current Results

Study	Implanted MIOL	Add Power (D)	LogMAR BDCVA				
			5.0 m	1.0 m	0.5 m	0.4 m	0.3 m
Kohnen et al ¹² (2009)	SN6AD1	+3.0	-0.03 ± 0.13 ^a	NA	0.05 ± 0.18 ^a	0.04 ± 0.11 ^a	-0.01 ± 0.11 ^a
Nuijts et al ⁶ (2016)	SV25T0	+2.5	-0.04 ± 0.10 ^a	NA	0.13 ± 0.02 (0.6 m)	0.26 ± 0.02	NA
	SV25T0	+2.5	-0.02 ± 0.13 ^a	NA	0.10 ± 0.02 (0.6 m)	0.11 ± 0.02	NA
	SN6AD1	+3.0					
Nakamura et al ⁵ (2015)	SN6AD1	+3.0	-0.16 ± 0.07	0.13 ± 0.09	0.07 ± 0.09	0.00 ± 0.09	0.05 ± 0.11
	SN6AD3	+4.0					
Hayashi et al ⁸ (2015)	SN60D1	+3.0	-0.07	0.04	0.05	NA	-0.04
	SN60D3	+4.0					
Yang et al ⁹ (2018)	ZKB00	+2.75	-0.12 ± 0.08	0.12 ± 0.14 ^a (0.8 m)	0.07 ± 0.11 ^a	0.14 ± 0.09 ^a	0.25 ± 0.11 ^a
	ZLB00	+3.25					
Current results	ZMB00	+4.0	-0.15 ± 0.06	0.06 ± 0.13	0.05 ± 0.07	0.02 ± 0.07	0.08 ± 0.10
	ZMB00	+3.25	-0.17 ± 0.09	0.00 ± 0.13	-0.02 ± 0.08	0.00 ± 0.11	0.07 ± 0.14
	ZLB00	+4.0					
	ZMB00	+2.75	-0.18 ± 0.06	-0.03 ± 0.10	-0.06 ± 0.09	-0.03 ± 0.06	0.06 ± 0.09
	ZKB00	+4.0					

BDCVA = binocular distance-corrected visual acuity; D = diopter; logMAR = logarithm of the minimum angle of resolution; MIOL = multifocal intraocular lens; NA = not available.

Data are expressed as the mean ± standard deviation.

^aUncorrected visual acuity.

DISCUSSION

THE INTERMEDIATE VA AT 0.5 METER WAS BETTER IN THE ML and MK groups than in the MM group. The improvement in the VA at 0.5 meter also was confirmed in the binocular defocus curves. Table 5 shows the BDCVAs after contralateral implantation of the different add powers, as well as

binocular implantation of the same add powers. The binocular VAs after contralateral implantation of apodized diffractive MIOLs with +3.0-D and +4.0-D add powers^{5,8} agreed well with the results of the ML group (add powers of +3.25 and +4.0 D). An MIOL with a +4.0-D add power is suitable for reading, but the intermediate VA remains degraded. The current and the previous results showed

that contralateral implantation of +4.0-D and lower add powers provides near and intermediate VAs, with most improvement found in the MK group.

In the first eyes, the ZMB00 IOLs were implanted in either the dominant or nondominant eyes. In previous studies, MIOLs with lower add powers were implanted in the dominant eyes,^{8,9} according to the classical monovision protocol.¹³ Whereas, the cross monovision that intended to correct near vision in the dominant eye is considered as effective and comparative for phakic eyes.¹⁴ When the ZMB00 MIOL was implanted in the dominant or nondominant eyes, significant difference was not found except for BDCVA at 1 m in the ML group. Further assessment with more subjects is necessary to confirm the difference attributable to the dominant eye implantation.

There was no difference in contrast sensitivity, stereopsis, and spectacle use. Hayashi and associates reported no difference in stereopsis between bilateral and contralateral implantations,⁸ and the results were comparable to the current results. Thus, the current staged implantations using 3 levels of add powers provided variations in the depth of focus without degradation of the visual function.

Currently, EDOF IOLs such as the ZXR00V IOL (Johnson & Johnson Surgical Vision) are available. The defocus characteristics of the EDOF IOL is similar to that of the

ZKB00 IOL, except for a smaller add power (+1.75 D).¹⁵ Hence, the combination of the ZMB00 IOL and EDOF MIOLs is expected to be effective for providing a wider DOF.

The current study had limitations. The sample sizes varied among the 3 groups. Previously, contralateral implantations had been evaluated in retrospective⁵ or prospective^{8,9} study designs and compared between 2 groups. Owing to the prospective comparison of the 3 groups in the staged implantations, the current study could compare results among the 3 groups. However, because of the staged implantation, it was difficult to adjust the sample sizes to accommodate the patient preferences. Although the sample sizes were not the same, we believe that the outcomes demonstrated the differences in binocular visual function in the 3 different IOL combinations. Another limitation was limited sample sizes, which made the evaluations of the differences in the BDCVA and the effect of the dominant eye difficult. Further assessments with adequate patients are necessary.

In conclusion, staged implantations of MIOLs with different near add powers obtained better intermediate vision. There are more possible combinations of the 3 different add powers as well as the use of EDOF IOLs. Staged implantations of the various add powers would provide different levels of postoperative binocular VAs.

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