Comparison of clinical outcomes with 2 small-incision diffractive multifocal intraocular lenses

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PURPOSE: To evaluate and compare the clinical results of 2 diffractive multifocal small-incision intraocular lenses (IOLs) implanted after biaxial microincision cataract surgery (MICS).

SETTING: Atatürk Training and Research Hospital, 2nd Ophthalmology Department, Ankara, Turkey.

DESIGN: Comparative case series.

METHODS: Eyes that had biaxial MICS with implantation of an Acri.Lisa 366D IOL (Group 1) or Acriva Reviol MFM 611 IOL (Group 2) were followed for at least 6 months postoperatively. Uncorrected distance (UDVA), intermediate (UIVA), and near (UNVA) visual acuities; corrected distance visual acuity; distance-corrected intermediate and near visual acuities; and contrast sensitivity measurements with and without glare were determined. Early and late complications and subjective complaints were recorded and evaluated.

RESULTS: The study enrolled 60 eyes of 32 patients. The preoperative and intraoperative data were comparable in the 2 IOL groups. There were no statistically significant postoperative differences in the mean spherical equivalent (Group 1, −0.30 diopter (D) ± 0.30 [SD]; Group 2, −0.26 ± 0.28 D; $P=.584$), mean UDVA (0.80 ± 0.14 and 0.86 ± 0.17, respectively; $P=.158$), and mean Jaeger UNVA (1.46 ± 0.73 and J 1.23 ± 0.50, respectively; $P=.155$). However, there was a significant difference in mean Jaeger UIVA (3.06 ± 0.90 and 2.23 ± 0.72, respectively; $P=.000$). Mesopic contrast sensitivity and the incidence of complications and dysphotopsia symptoms were not significantly different between the 2 IOL groups.

CONCLUSIONS: Both IOLs provided excellent distance and near visual acuity and contrast sensitivity. The Group 2 IOL gave better intermediate distance results.

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Presbyopic small-incision cataract surgery with intraocular lens (IOL) implantation leads to less induced astigmatism and fewer higher-order aberrations, and such techniques are becoming increasingly popular.[1–3] Although few multifocal IOLs that can be implanted through incisions of 2.0 mm or smaller are available, they are reported to resolve some of the problems of conventional small-incision IOLs.[4–8] In addition to multifocality, these IOLs must have the same good uveal and capsular biocompatibility as conventional monofocal IOLs. Most important, they must remain perfectly centered in the capsular bag to restore visual performance and quality of vision and to prevent dysphotopsia symptoms.

In this study, we compared and evaluated the clinical results of 2 multifocal IOL models implanted through 1.7 mm clear corneal incisions using a biaxial microincision cataract surgery (MICS) technique. The 2 IOLs are similar except for slight differences in their diffractive design.

PATIENTS AND METHODS

This prospective study was approved by the hospital's ethics committee and was performed in accordance with the ethical principles in the Declaration of Helsinki. All patients signed an informed consent form before having any procedure.

Patients who had previous eye surgery or eye disease that could affect final visual acuity (eg, amblyopia, retinal or macular abnormalities), corneal pathology, glaucoma, or corneal astigmatism higher than 1.00 diopter (D) were not included

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in the study. Also excluded were patients with intensive computer or car use and a meticulous personality because multifocal IOL implantation may be contraindicated in such cases.

Preoperative Assessment

Preoperatively, all patients had a complete clinical and biomicroscopic ophthalmic examination. All eyes had grade II to IV nuclear or corticonuclear cataract according to the Lens Opacities Classification System (LOCS) III scale.[9] Nuclear hardness was evaluated by biomicroscopy and the LOCS III scale. Refraction and corrected distance visual acuity (CDVA) were determined by Early Treatment Diabetic Retinopathy Study (ETDRS) charts and transformed into logMAR units for statistical analysis. Corneal toricity was assessed by corneal topography (Keratron Scout Corneal Analyzer, Optikon 2000 SpA). Central corneal thickness was measured with an ultrasound pachymeter (B.V. International). Biometry was performed 5 times by the immersion method (Cinescan Ultrasound, Quantel Medical). Intraocular lens power was calculated by targeting emmetropia.

Intraocular Lenses

Patients had implantation of an Acri.Lisa 366D IOL (Carl Zeiss Meditec AG) (Group 1) or an Acriva Reviol MFM 611 IOL (VSY Biotechnologies) (Group 2) (Figure 1). Table 1 shows the characteristics of the IOLs. Both IOLs provide multifocality through a refractive diffractive hybrid optic. They are designed to be implanted through 1.5 to 1.8 mm incisions. There are slight differences in aberration control, light distribution between far and near, and diffractive ring distribution model between the 2 IOLs. According to the manufacturer, the Acriva Reviol MFM 611 IOL has a different diffractive ring distribution model than the Acri.Lisa 366D IOL in terms of the number, interval, width, and elevation. In addition, the Acriva Reviol MFM 611 IOL has smooth ridges at the diffractive ring transitions that were designed to prevent dysphotopsia symptoms and increase retinal image quality.

Surgical Technique

The same surgeon (İ.C.) performed all biaxial MICS procedures using the same phaco machine (Infiniti Vision Systems, Alcon Laboratories, Inc.), the nucleofractis technique (half-moon supracapsular technique[10]), and the same phaco machine and fluidics parameters. After a standard dilation

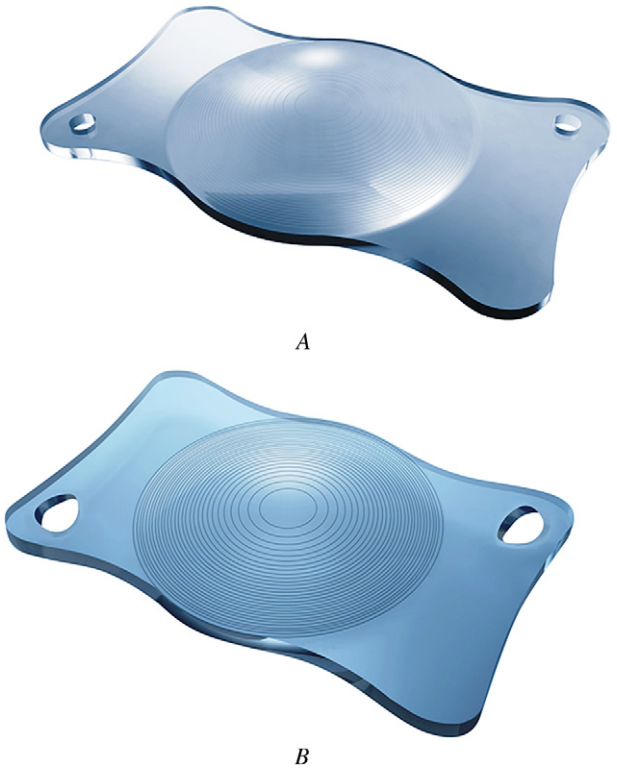

Figure 1. *A*: Acri.Lisa 366D IOL. *B*: Acriva Reviol MFM 611 IOL.

Table 1. General IOL characteristics.

Parameter	Acri.Lisa 366D IOL	Acriva Reviol MFM 611 IOL
Material	Hydrophilic acrylic (25%) with hydrophobic surface	Hydrophilic acrylic (25%) with hydrophobic surface
Optic Design	Aspheric multifocal	Aspheric multifocal
Haptic/angulation	Plate/0°	Plate/0°
Diameter (mm)		
Optic	6.0	6.0
Total	11.0	11.0
Lens design	Single-piece diffractive, +3.75 D add at IOL plane	Single-piece diffractive, +3.75 D add at IOL plane
SA control (µm)	−0.160	−0.165
Light distribution, %far/%near	65/35	60/40
Diopter range	0.0. +32.0	0.0, +45.0
A-constant*	117.8	118.0
Diffractive rings (n)	29	28†
PCO prevention	Square-edged optic and haptic	360° sharp edge

add = addition; IOL = intraocular lens; PCO = posterior capsule opacification; SA = spherical aberration
*Ultrasound
†Active diffractive

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Table 2. Patient characteristics and preoperative data.

Parameter	Group 1	Group 2	All Cases	*P* Value
Patients/eyes (n)	16/30	16/30	32/60	1.000†
Mean age (y) ± SD	51.10 ± 5.63	53.81 ± 8.35	52.04 ± 6.73	.197‡
Sex				.723†
Female	9	8	17	
Male	7	8	15	
Laterality				.796†
Right	15	14	29	
Left	15	16	31	
Mean follow-up (mo) ± SD	6.40 ± 0.85	6.33 ± 0.92	6.36 ± 0.88	.077‡
Mean UDVA ± SD				
Decimal	0.46 ± 0.25	0.36 ± 0.16	0.41 ± 0.21	.080‡
LogMAR	0.39 ± 0.27	0.47 ± 0.22	0.43 ± 0.26	.271‡
Mean CDVA ± SD				
Decimal	0.63 ± 0.29	0.65 ± 0.30	0.64 ± 0.29	.759‡
LogMAR	0.25 ± 0.25	0.26 ± 0.29	0.25 ± 0.27	.963‡
Mean CCT (µm) ± SD	556.70 ± 28.80	543.3 ± 31.90	550.11 ± 30.87	.096‡
Mean corneal toricity* (D) ± SD	0.56 ± 0.23	0.65 ± 0.29	0.61 ± 0.26	.191‡

CCT = central corneal thickness; CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity
*Simulated keratometry
†Chi-square test
‡Student *t* test

regimen, two 1.2 to 1.4 mm trapezoidal incisions were made with a 19-gauge steel knife and a capsulorhexis was created. After removal of the nucleus and cortical materials, 1 incision, which was always on the steep corneal axis, was enlarged to at least 1.7 mm before IOL implantation. The Acri.Lisa 366D IOLs were implanted using an Acri-Shooter A2-2000 injector set (Acri.Tec GmbH). The Acriva Reviol MFM 611 IOLs were implanted using the Viscojet LP604350, 1.8 injector set (Medicel AG). The incision size after IOL implantation (final incision size) was measured with a microcoaxial gauge (Tsuneoka, American Surgical Instruments Corp.).

In all cases, the total surgical time, phaco time, mean phaco power (ie, average power in [%], and effective phaco time were recorded. Intraoperative complications (eg, Descemet membrane detachment, incision burn, posterior capsule rupture, zonular dialysis, iris damage) were also recorded.

Postoperative Protocol

All patients had a follow-up of 6 months or longer. All postoperative evaluations were performed by the same 2 physicians (B.B.C., G.S.). The examinations at 1 day, 1 week, and 1, 3, and 6 months included monocular and binocular uncorrected and corrected distance (6 m), near (33 cm), and intermediate (60 cm) visual acuity measurements (ETDRS chart); detailed slitlamp biomicroscopy; and corneal pachymetry. At 3 months, contrast sensitivity was measured (CSV 1000E, Vector Vision) and corneal topographic measurements were performed (Keratron Scout

Table 3. Surgical parameters.

Parameter	Group 1	Group 2	All Cases	*P* Value
Mean phaco time (min)	0.145 ± 0.198	0.156 ± 0.168	0.150 ± 0.18	.829*
Mean phaco power (%)	4.53 ± 4.49	4.76 ± 4.27	4.65 ± 4.34	.851*
Mean effective phaco time (s)	0.578 ± 0.936	0.658 ± 0.908	0.618 ± 0.91	.739*
Mean total surgical time (min)	17.35 ± 1.89	17.32 ± 1.26	17.34 ± 1.59	.936*
Mean final incision width (mm)	1.975 ± 0.26	1.963 ± 0.17	1.968 ± 0.22	.862*
Complications, n (%)				
PCR	1 (3.3)	1 (3.3)	2 (3.3)	1.000†
Iris prolapse	2 (6.6)	2 (6.6)	4 (6.6)	1.000†

Means ± SD
PCR = posterior capsule rupture
*Student *t* test
†Chi-square test

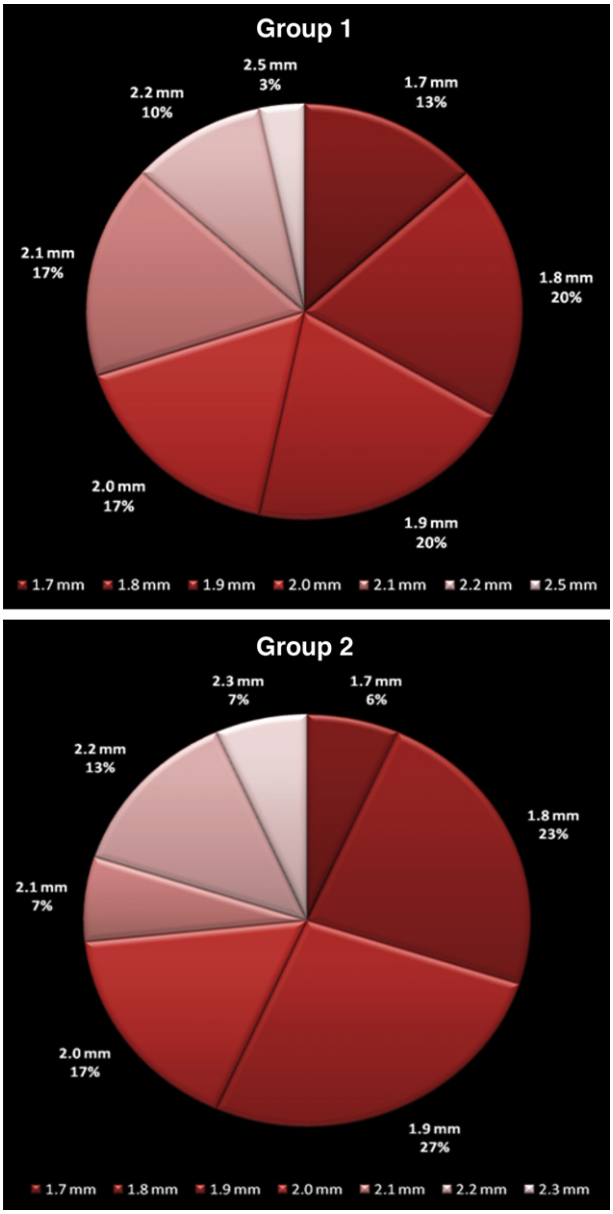

Figure 2. Distribution of incision widths in both groups.

Corneal Analyzer, Optikon). The subjective complaints of the patients were evaluated with the modified version of National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) at the 3-month postoperative visit. The original NEI VFQ-25[11] was modified to add specific questions about halo and glare by asking the patients to grade the symptoms on a scale between 1 and 4, about their overall satisfaction level with the chosen IOL and surgery, and whether they would recommend the same IOL and procedure to their family and friends.

Statistical Analysis

Statistical analysis was performed using SPSS for Windows software (version 17.0, SPSS Inc.). The Pearson chi-square and Student *t* tests were used to compare the parameters. Two-way analysis was used for all tests and a *P* value less than 0.05 was considered statistically significant.

RESULTS

This study comprised 60 eyes of 32 patients. Table 2 shows the patients' characteristics and preoperative data and Table 3, the intraoperative data. There were no statistically significant differences in any preoperative or postoperative parameter between the 2 IOL groups ($P > .05$). Figure 2 shows the incision sizes by group.

Refraction, Visual Acuity, and Contrast Sensitivity

The mean 6-month postoperative refractive astigmatism was 0.43 ± 0.20 D in Group 1 and 0.34 ± 0.25 D in Group 2 ($P = .114$). In all eyes, the topographic simulated keratometry was 0.61 ± 0.27 D preoperatively and 0.59 ± 0.24 D postoperatively (Tables 2 and 4). Both IOL groups had a statistically significant increase in uncorrected distance visual acuity (UDVA) and CDVA postoperatively ($P = .000$).

Table 4 shows the postoperative visual acuity, refraction, central corneal thickness, surgically induced astigmatism, and dysphotopsia symptoms. There was a statistically significant difference in monocular and binocular uncorrected (UIVA) and monocular distance-corrected intermediate distance (DCIVA) visual acuities between groups, with all 3 being significantly better in Group 2 than in Group 1 ($P = .000$, $P = .028$, and $P = .004$, respectively). Figure 3 shows the mesopic contrast sensitivity with and without glare by group.

Subjective Problems and Complications

No inflammatory anterior chamber reaction was observed on biomicroscopy during follow-up in either group.

All patients who reported halo/glare on the modified NEI VFQ-25 questionnaire rated the symptoms as less than 3 on the 4-point scale. In no case were the symptoms severe, and no patient had mentioned the symptoms to the surgeon before completing the questionnaire. All patients reporting problems with intermediate vision were in Group 1; these patients rated problems (eg, computer use, climbing up and down the stairs, cooking, and finding an object on a crowded shelf) as less than 2 points. Spectacle use was recommended to 1 patient (3.3%) for computer use. When patients were asked whether they would suggest the IOL and surgery to others, all said they would.

One eye (3.3%) in each group developed posterior capsule opacification (PCO) 4 months and 5 months after surgery. Both eyes had a neodymium:YAG

Table 4. Postoperative visual acuity, refraction, and spectacle independence at 3 months.

Parameter	Group 1	Group 2	*P* Value
Mean monocular UDVA ± SD			
Decimal	0.80 ± 0.14	0.86 ± 0.17	.158†
LogMAR	0.10 ± 0.07	0.07 ± 0.08	.113†
Mean binocular UDVA ± SD			
Decimal	0.98 ± 0.06	0.96 ± 0.09	.647†
LogMAR	0.01 ± 0.02	0.007 ± 0.01	.647†
Mean monocular CDVA ± SD			
Decimal	0.98 ± 0.05	0.96 ± 0.09	.219†
LogMAR	0.01 ± 0.02	0.02 ± 0.05	.219†
Mean monocular UNVA ± SD			
Jaeger	1.46 ± 0.73	1.23 ± 0.50	.155†
LogMAR	0.08 ± 0.20	0.02 ± 0.05	.104†
Mean binocular UNVA ± SD			
Jaeger	1.06 ± 0.25	1.00 ± 0.00	.155†
LogMAR	0.007 ± 0.03	0.00 ± 0.00	.155†
Mean monocular DCNVA ± SD			
Jaeger	1.20 ± 0.55	1.13 ± 0.34	.577†
LogMAR	0.06 ± 0.20	0.01 ± 0.03	.219†
Mean monocular UIVA ± SD			
Jaeger	3.06 ± 0.90	2.23 ± 0.72	0.000†,§
LogMAR	0.16 ± 0.055	0.11 ± 0.064	0.002†,§
Mean binocular UIVA ± SD			
Jaeger	2.36 ± 1.32	1.73 ± 0.78	.028†,§
LogMAR	0.11 ± 0.10	0.07 ± 0.07	.041†,§
Mean monocular DCIVA ± SD			
Jaeger	2.76 ± 0.81	2.16 ± 0.74	.004†,§
LogMAR	0.14 ± 0.051	0.11 ± 0.066	.013†,§
Mean SE refraction (D)	−0.30 ± 0.30	−0.26 ± 0.28	.584†
Mean corneal toricity* (D)	0.53 ± 0.26	0.66 ± 0.22	.057†
Subjective complaints, n (%)			
Halo	7 (23.3)	8 (26.6)	.766‡
Glare	6 (20.0)	6 (20.0)	1.000‡
Spectacle			
Independence (%)			
Far	100.0	100.0	—
Near	100.0	100.0	—
Intermediate	96.6	100.0	.313‡

Means ± SD
CCT = central corneal thickness; CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; SE = spherical equivalent; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity
*Simulated keratometry
†Student *t* test
‡Chi-square test
§Statistically significant

(Nd:YAG) laser capsulotomy. No other complications were reported. All IOLs were well centered, and none was tilted (Figure 4).

DISCUSSION

In this prospective study, 2 diffractive multifocal IOLs with similar properties were compared. Patients in the 2 groups had similar demographic features and nuclear hardness, and all surgeries were performed using the same technique and similar ultrasound power. There was no difference in the final incision width or postoperative corneal pachymetry between the 2 IOL groups. Thus, the groups were considered compatible in terms of suitability for evaluation and comparison of IOL functionality and postoperative safety.

Both groups had a statistically significant increase in UDVA and CDVA postoperatively ($P=.000$), with

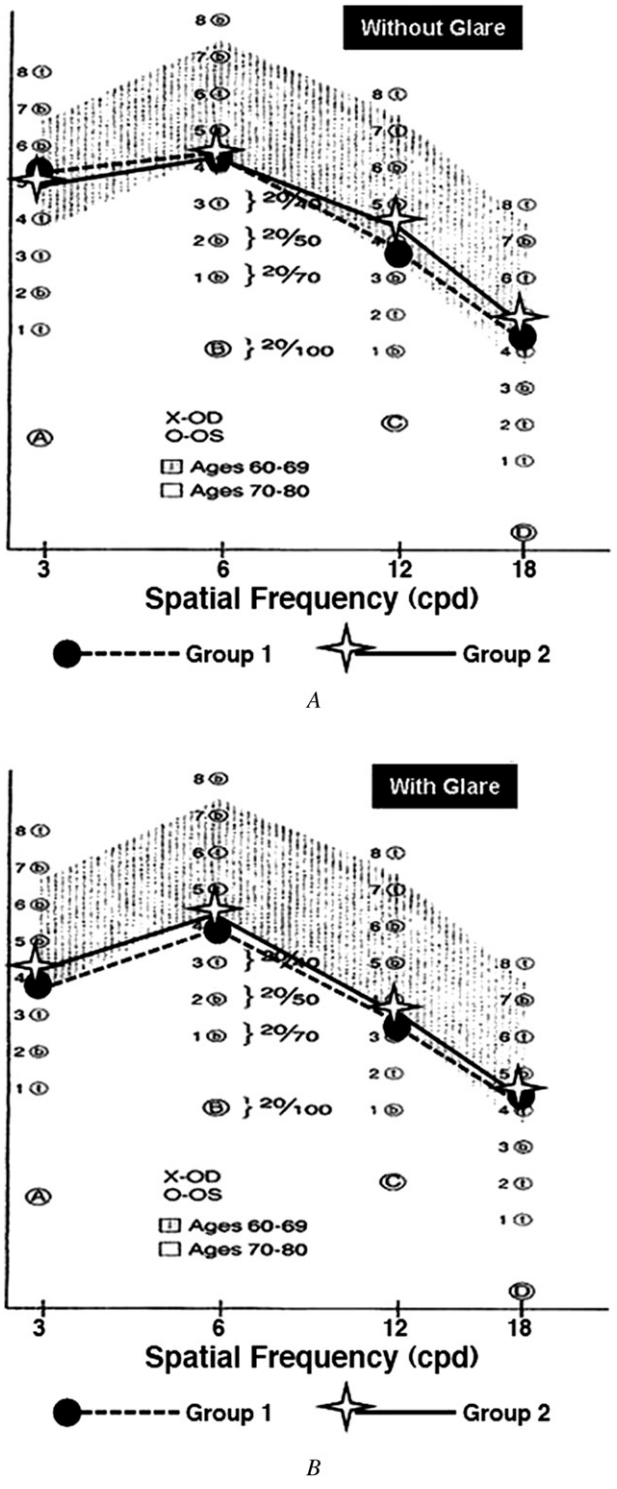

Figure 3. Mesopic contrast sensitivity with glare and without glare.

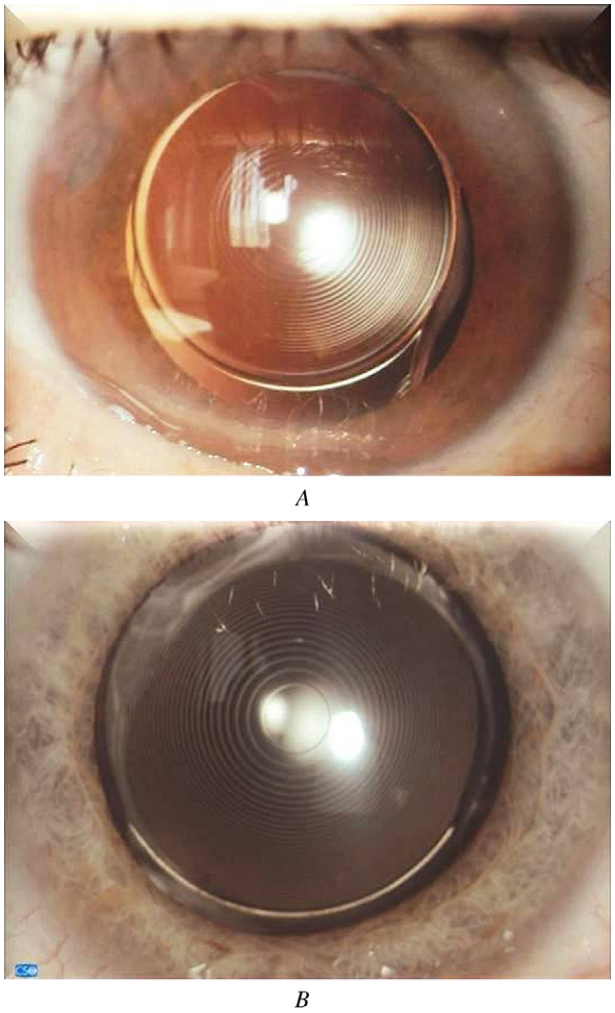

Figure 4. Perfect centration of IOLs 8 months postoperatively. *A*: Eye in Group 1. *B*: Eye in Group 2.

no significant between-group difference in the amount of increase. All patients were within ±0.50 D of emmetropia postoperatively, and the difference in final refraction between the 2 IOL groups was not statistically significant ($P=.584$). Thereby, the A constants that were anticipated for both IOLs were verified.

Several studies[12–14,A] have assessed the Acri.Lisa 366D microincision multifocal IOL, and reported satisfactory distance and near visual acuity results. The mean binocular CDVA was 0.89 ± 0.77 in a study by Alfonso et al. (162 eyes),[12] 1.17 ± 0.81 in a study by Kaymak and Mester (49 eyes),[13] and 0.96 ± 0.17 in anther study by Alió et al.[14] The mean binocular uncorrected near visual acuity in these 3 studies was reported as 0.96 ± 0.88, 0.91 ± 0.74, and 0.90 ± 0.15, respectively, and the mean distance-corrected near visual acuity was 0.97 ± 0.82, 0.91 ± 0.74, and 0.97 ± 0.07, respectively. The Acri.Lisa 366D IOL allocates 65% of the light for far focus and 35% for near focus; with a +3.75 D near addition, it has a total +3.00 D effect at the spectacle plane, which explains the satisfactory near visual acuity results. In our study, the mean monocular UDVA was 0.80 ± 0.14, the mean

binocular UDVA was 0.98 ± 0.06, and the mean binocular CDVA was 0.98 ± 0.05. The increase in all distance visual acuities was statistically significant ($P = .000$).

The Acriva Reviol MFM 611 IOL, which resembles the Acri.Lisa 366D IOL in many ways, allocates 60% of light for far focus and 40% for near focus. The mean UDVA in the eyes with this IOL was 0.86 ± 0.17 monocularly and 0.99 ± 0.05 binocularly, and the mean monocular CDVA was 0.96 ± 0.09. The increase in visual acuity was statistically significant ($P = .000$). Thus, the distance and near visual acuities with these 2 IOLs were nearly identical.

A review of Acri.Lisa IOL results in the literature showed slightly low intermediate visual acuities. Alfonso et al.[12] report a binocular DCIVA of 20/20 (0.012 ± 0.084 logMAR) at 33 cm, 20/25 at 50 cm, 20/32 at 60 cm, and 20/40 (0.26 ± 0.099 logMAR) at 70 cm. In a study by Mai et al.,[A] the DCIVA at 60 cm was 0.79. In our study, we evaluated the intermediate visual acuities at 60 cm. The monocular Jaeger UIVA in the Acri.Lisa group was 3.06 ± 0.90, the binocular Jaeger UIVA was 2.36 ± 1.32, and the Jaeger DCIVA was 2.76 ± 0.81; the values were 2.23 ± 0.72, 1.73 ± 0.78, and 2.16 ± 0.74, respectively, in the Acriva Reviol IOL group. The differences in these values between the 2 IOL groups were statistically significant ($P = .000$, $P = .028$, and $P = .004$, respectively). Diffractive multifocal IOLs separate light into near and distance by creating a phase difference. Thus, the better intermediate visual acuity with the Acriva Reviol MFM 611 IOL may be a result of the different number, height, interval, and width of its rings.

Although differences in mesopic contrast sensitivity with glare and without glare between the 2 IOL groups were not statistically significant, the results were better with the Acriva Reviol MFM 611 IOL. Both IOLs provide similar spherical aberration control and have smooth transition between the diffractive steps. The loss from the division of light for near and far focus is diminished with both IOLs, as shown by the normal mesopic contrast sensitivity results.

In our study, 20% to 25% of patients reported mild halo and glare problems; the difference between the 2 IOL groups was not statistically different. Alió et al.[14] report night photic visual phenomenon in less than 10% of patients, whereas Kaymak and Mester[13] report that 80% had mild halo (level 2, on a scale of 1 to 6) and Mai et al.[A] report 75% had mild halo and 35% had glare. The mild photic visual symptoms in both our groups can be explained with the success of the design of the diffractive steps.

No eye in our study had an inflammatory reaction in the anterior chamber postoperatively, showing both IOLs have good uveal biocompatibility. By the 6-month follow-up, only 3.3% (1 eye) in each group had PCO that necessitated Nd:YAG laser treatment. Even though both IOLs have a hydrophobic surface and a square-edged design, the plate haptic and 0-degree haptic angle seem to lead to PCO. In addition, IOL stabilization and centration in the capsular bag are important for maintaining capsular biocompatibility. Even small amounts of IOL decentration and tilt can induce coma aberration and diminish the quality of vision with aspheric IOLs.[15,16] We believe the plate-haptic design is the reason for the excellent centration of both IOLs used in our study.

All patients in both IOL groups reported spectacle independence for near and distance. All with an Acriva Reviol MFM 611 IOL also reported spectacle independence for intermediate distance.

In addition, all patients in both IOL groups said they would recommend the surgery and the IOL to friends and family. This indicates strong overall patient satisfaction.

In conclusion, both microincision IOLs provided good outcomes in presbyopic cataract surgery and had high patient satisfaction. The Acriva Reviol MFM 611 IOL seemed to provide better intermediate visual acuity.

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