Visual function after bilateral implantation of apodized diffractive aspheric multifocal intraocular lenses with a +3.0 D addition

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PURPOSE: To evaluate visual function after bilateral implantation of apodized diffractive aspheric multifocal intraocular lenses (IOLs) with a +3.0 diopter addition (add) power.

SETTING: Multicenter study at 5 European sites.

METHODS: Five surgeons prospectively enrolled patients to receive bilateral implantation of AcrySof IQ ReSTOR SN6AD1 IOLs. Assessments included defocus testing, uncorrected and corrected distance visual acuities at various distances, and patient questionnaires.

RESULTS: Ninety-three patients were enrolled. The mean distance-corrected visual acuities at far, intermediate, and near distances were significantly better postoperatively. At 6 months, uncorrected visual acuity (logMAR) was −0.03 ± 0.13 (SD) at 4 m, 0.20 ± 0.14 at 70 cm, 0.13 ± 0.15 at 60 cm, 0.05 ± 0.18 at 50 cm, and 0.04 ± 0.11 at 40 cm. The mean patient-preferred near distance was 41 ± 4 cm, at which distance the mean visual acuity was −0.01 ± 0.11 logMAR. The defocus curve had a plateau of optimum near vision from 40 to 50 cm. Postoperatively, patients reported having minimal to no difficulty with 22 of 27 visual disturbances or visual activities; the other 5 items were ranked minimally to moderately difficult. The mean patient satisfaction with vision was 8.3 ± 1.6 (out of 10); 88% of patients were spectacle independent.

CONCLUSIONS: Bilateral apodized diffractive aspheric multifocal IOLs with a +3.0 D add provided a broad range of optimum near vision, good intermediate visual acuity, and low rates of visual disturbances. Patients were highly satisfied with their vision, and 88% were spectacle independent.

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In 2008, U.S. Food and Drug Administration (FDA) approved the AcrySof IQ ReSTOR SN6AD1 aspheric multifocal intraocular lens (IOL) (Alcon, Inc.). This IOL has a +3.0 diopter (D) addition (add) power at the lens plane, yielding +2.5 D at the spectacle plane. The optic design of the aspheric IOL is similar to that of the aspheric AcrySof IQ ReSTOR SN6AD3 IOL, which has a +4.0 D add power, yielding +3.2 D at the spectacle plane. Both aspheric IOLs are based on the original spherical ReSTOR +4.0 D IOLs (MA60D3, SA60D3, and SN60D3), the use of which decreased patient reliance on spectacles for near, intermediate, and distance vision and provided spectacle independence at all distances to more than 70% of patients in various studies.[1–5]

Both the aspheric IOL models (+3.0 D and +4.0 D) have a 6.0 mm optic that consists of a central 3.6 mm apodized diffractive zone and an outer refractive zone. With apodization, the diffractive steps gradually decrease in height from center to periphery, which reduces the potential for optical phenomena such as glare and halos[6] and provides a smooth transition to distance-dominant vision as the pupil enlarges.[7] The diffractive zone facilitates near and distance vision, while the outer refractive zone facilitates distance vision without loss of light. The +3.0 D IOL has 9 diffractive steps that are more widely spaced than the 12 steps of the +4.0 D IOL (Alcon, Inc. AcrySof IQ ReSTOR, physician labeling, 2009). Both aspheric models have the same IOL platform as the original spherical ReSTOR IOL; however, the aspheric designs incorporate negative spherical aberration to compensate for positive corneal spherical aberration.

In a study of the spherical +4.0 D multifocal IOL,[8] some patients reported intermediate blur, although 75% of patients said the blur was never or only occasionally bothersome. The aspheric +3.0 D IOL was designed as an alternative to the +4.0 D model for patients who desired better intermediate vision or who preferred an extended reading distance. Moving the near point was expected to improve intermediate

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vision because the near and far focal points were closer; therefore, the gradual decline in vision between the points would theoretically be less than with the aspheric +4.0 D IOL.

This multicenter study of patients in Europe was designed to evaluate visual function after bilateral implantation of the new aspheric IOL with a +3.0 D add. Follow-up examinations extended to 6 months postoperatively and included visual acuity measurements at various distances, defocus testing, and patient questionnaires about visual disturbances and spectacle dependency.

PATIENTS AND METHODS

Enrollment and Baseline

This multicenter study at 5 European sites included university-affiliated hospitals and private clinics. Each of the 5 investigators prospectively enrolled 12 to 25 patients at their respective sites, including 1 cohort that has been reported.[9] Eyes required cataract extraction or were candidates for refractive lens exchange. Eligible patients required bilateral lensectomy (for either reason), had less than 1.00 D of corneal astigmatism in both eyes, and were in good ocular health. All patients gave informed consent in accordance with the Declaration of Helsinki.

At intake, patients were tested for corrected distance visual acuity, manifest refraction, and pupillometry (Colvard, Oasis Medical, Inc., or Procyon, Procyon Instruments, Ltd.). Visual acuity (logMAR) was assessed with distance correction using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart at 4 m for distance vision and using the new ETDRS chart at 40 cm for near vision and at 60 cm for intermediate vision.

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At intake and at the postoperative visits, patients completed questionnaires about their vision (Figure 1). Although the questionnaire was not a validated instrument, the visual disturbance questions were based on the survey distributed in the FDA clinical trials (Alcon, Inc. AcrySof IQ ReSTOR, physician labeling, 2009). The questions on lifestyle activities were based on the subscales of near activities, distance activities, and driving in the National Eye Institute Visual Functioning Questionnaire–25 (NEI VFQ–25).[10] The satisfaction scale was similar to that in the NEI VFQ–25.[10] The spectacle independence questions were similar to those in the Cataract TyPE questionnaire.[11]

Surgical Technique

First-eye surgery occurred within 30 days of intake assessment; second-eye surgery was performed 7 to 30 days later. Incisions ranged from 2.2 to 3.2 mm and could be placed on the steep axis to correct corneal astigmatism. Further intraoperative or postoperative correction of corneal astigmatism could be performed at the surgeon's discretion. Longitudinal phacoemulsification was performed using the Accurus Surgical System (Alcon, Inc.), or longitudinal or torsional phacoemulsification was performed using the Infiniti Vision System with the OZil handpiece (Alcon, Inc.). Intraocular lenses were injected using the Monarch II or III system (Alcon, Inc.).

Postoperative Assessments

Postoperative evaluations were performed 1, 3, and 6 months after the second-eye surgery and included assessment of posterior capsule opacification (PCO), IOL centration, and IOL tilt as well as administration of patient questionnaires. Posterior capsule opacification was graded on a 4-point scale as follows: 1 = none; 2 = mild (early development of PCO); 3 = moderate (increased PCO with early visual acuity changes, not requiring secondary capsulotomy); 4 = severe (clinically significant PCO that adversely affects subjective visual acuity and requires secondary capsulotomy). Vision assessments were performed with and without distance correction with the appropriate charts placed at far distance (4 m), at intermediate distances (50 cm, 60 cm, and 70 cm), and at near distances (40 cm and patient-preferred near distance). To test near vision at best distance, the patient held the new ETDRS chart at the optimum distance for reading the smallest line; that distance was measured and recorded. At the 3-month visit, 4 sites also assessed corrected distance visual acuity (CDVA) with a 25.0% contrast ETDRS chart and with a 12.5% contrast ETDRS chart.

In addition, at the 6-month postoperative visit, 4 sites performed defocus testing using manifest refraction as the zero baseline. To generate defocus curves, visual acuity was measured multiple times under photopic conditions with the ETDRS chart at 4 m using a variety of lens powers in a phoropter. Patients were defocused to −5.0 D spherical correction from the manifest refraction. The logMAR acuity at that refraction was recorded. Negative spherical power was decreased in 0.5 D increments (eg, −4.5 D, −4.0 D, −3.5 D); logMAR acuity was recorded at each change in correction until only the manifest refraction remained. Patients then were defocused to +2.0 D spherical correction from the manifest refraction, and the logMAR acuity was recorded. Positive spherical power was decreased in 0.5 D increments (+1.5 D, +1.0 D, +0.5 D); logMAR acuity was recorded at

Questionnaire Section	Response Rating Scale
Visual Disturbance Items	
How much difficulty do you have with each of the following?	
Glare/flare (trouble seeing street signs due to bright light or oncoming headlights)	0 = no difficulty 1 = minimal difficulty 2 or 3 = moderate difficulty 4 or 5 = severe difficulty
Night vision	
Color perception (trouble recognizing specific colors)	
Depth perception (trouble lining things up, pouring liquids, or going down stairs)	
Halos (rings around lights)	
Distorted near vision (straight lines look crooked close up)	
Distorted far vision (straight lines look crooked at distances)	
Blurred near vision	
Blurred far vision	
Double vision	
Visual Lifestyle Activities	
How much difficulty do you have with each activity due to your vision? (without glasses or contact lenses)	0 = no difficulty 1 = minimal difficulty 2 or 3 = moderate difficulty 4 or 5 = severe difficulty or Not applicable
Watching TV or movies	
Playing or working outside	
Caring for/playing with children	
Reading the time on an alarm clock	
Seeing clearly when you wake up	
Reading the time on a wall clock	
Performing your job/hobbies	
Participating in sports/recreation	
Participating in social events	
Reading and near work/activities	
Driving at night	
Driving when it is raining	
Using a computer	
Cooking	
Shopping	
Using a cell phone	
Shaving or putting on makeup	
Spectacle Use	
How often do you wear glasses or contacts?	Always, sometimes, never
How often do you wear glasses or contacts...	
...for distance vision?	Never, rarely, occasionally, often, always
...for intermediate vision?	
...for near vision?	
Satisfaction	
On a scale of 1 to 10, how satisfied are you with your vision?	1 = least, 0 = most

Figure 1. Content of patient questionnaire.

each change in correction until only the manifest refraction remained.

Statistical Analysis

Visual acuities at 50 cm, 60 cm, and 70 cm and at the preferred near distance were corrected for use of the 40 cm chart, as previously described.[12] Data were analyzed using Microsoft Excel 2002 (Microsoft Corp.) or Statistica (version 8, StatSoft Inc.) software. The Student t test was used for parametric variables, the chi-square test for categorical variables, and the Wilcoxon matched-pairs test for intrapatient comparisons. Results are presented as the mean ± SD unless otherwise noted. Statistical significance was set at $P<.05$.

RESULTS

Baseline, Surgeries, and Follow-Up

The mean age of the 93 patients (59% women, 41% men) enrolled in the study was 62 ± 8 years. The mean pupil size was 3.6 ± 0.8 mm under photopic conditions and 5.2 ± 0.8 mm under mesopic conditions. The mean preoperative spherical equivalent (SE) was 0.9 ± 1.9 D; 147 eyes (79%) were hyperopic, 37 (20%) were myopic, and 2 (1%) were emmetropic. The maximum hyperopia was +4.5 D SE and the maximum myopia, −7.1 D SE. Preoperative corneal astigmatism was not recorded. The mean incision size was 2.4 ± 0.3 mm; the locations of these incisions (ie, temporal or on-axis) were not recorded. Between the 3-month assessment and the 6-month assessment, 2 patients (3 eyes) had refractive enhancement with laser in situ keratomileusis. No other case report forms contained notes mentioning limbal relaxing incisions or other astigmatism-correcting operations, although these procedures were not prohibited. Six months postoperatively, 84 patients returned for the final study assessment; however, not all patients had all examinations. The size of the population in each analysis is presented in the relevant section.

Binocular Visual Acuity

The mean binocular distance-corrected visual acuity at near, intermediate, and far distances was statistically

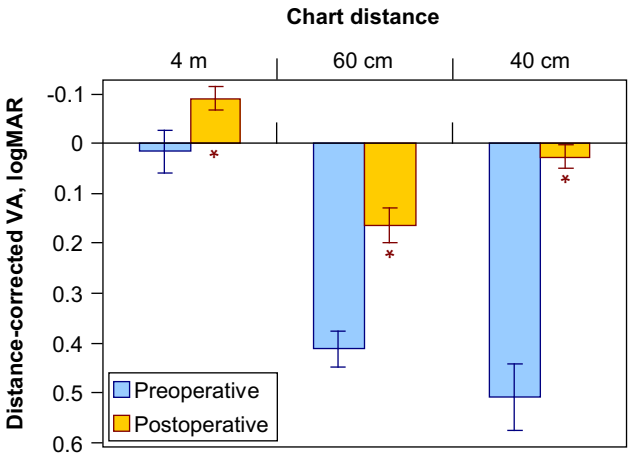

Figure 2. Mean binocular distance-corrected visual acuity at far, intermediate, and near for the 81 patients who had assessments at all 3 distances preoperatively and 6 months postoperatively. The error bars represent 95% confidence intervals. The asterisks represent a significant difference between preoperative and postoperative values ($P < .001$) (VA = visual acuity).

significantly better in the 81 patients assessed preoperatively and 6 months postoperatively ($P < .001$) (Figure 2). Table 1 shows the binocular uncorrected visual acuities 6 months postoperatively. The mean patient-preferred near distance was 41 ± 4 cm. The Snellen equivalent was at least 20/40 for near and distance acuity in more than 98% of patients and for all 3 intermediate distances in 76% of patients. The mean low-contrast photopic binocular CDVA in 62 patients 3 months postoperatively was 0.20 ± 0.13 logMAR at 12.5% contrast and 0.11 ± 0.15 logMAR at 25.0% contrast. The mean mesopic low-contrast binocular CDVA was 0.34 ± 0.15 logMAR and 0.25 ± 0.13 logMAR, respectively.

The defocus curve in Figure 3 shows a plateau of optimum near vision that is 0.04 logMAR from the vergence of −2.0 to −2.5 D, the equivalent of 40 to 50 cm from the eye. The minimum intermediate vision occurred at a vergence of −1.5 D, or 67 cm from the eye. The mean intermediate visual acuity at this point on the defocus curve remained good (0.23 ± 0.18 logMAR; Snellen equivalent approximately 20/34).

Visual Disturbances

The mean score for 7 of 10 items on the visual disturbance questionnaire indicated minimum to no difficulty at all postoperative time points. The 7 items were color perception, depth perception, distorted near vision, distorted far vision, blurred near vision, blurred far vision, and double vision. A mean score indicating minimum difficulty was reported for halos, glare, and night vision (Table 2). Similarly, 15 of the 17 items on the lifestyle activities questionnaire had a mean score of less than 1 (minimum or no difficulty) at all postoperative time points. The 15 items were watching television or movies, reading the time on an alarm clock, participating in sports, reading and near work, using a computer, and using a cell phone. The 2 items on the lifestyle activities questionnaire that were rated minimally difficult (mean score ≥1 out of 5) at any postoperative time point were driving at night and driving in the rain (Table 2).

From preoperatively to 1 month postoperatively, there was a statistically significant improvement in the mean score for difficulty with glare, night vision, driving at night, and driving in the rain (all $P < .05$) (Table 2). In contrast, the mean score for difficulty with halos increased slightly, from 1.5 ± 1.7 preoperatively to 2.1 ± 1.6 at 1 month. During the adaptation period (from 1 to 6 months postoperatively), the improvement in intrapatient difficulty with halos was statistically significant ($P = .01$). There was no statistically significant difference in the mean score for halos at 6 months and the mean score preoperatively.

At 6 months, no patient reported severe difficulty with 12 lifestyle activities. For the other 5 lifestyle activities, 1 patient (1%) reported severe difficulty for sports or hobbies, 1 (1%) for reading or near work, 2 (3%) for using a computer, 4 (6%) for driving in the rain, and 5 (7%) for driving at night. No patient reported severe difficulty for 4 visual disturbance items.

Table 1. Binocular uncorrected visual acuity at various distances 6 months postoperatively.

	Chart Distance					
Parameter	Near	40 cm	50 cm	60 cm	70 cm	4 m
Mean VA (logMAR) ± SD	−0.01 ± 0.11	0.04 ± 0.11	0.05 ± 0.18	0.13 ± 0.15	0.20 ± 0.14	−0.03 ± 0.13
VA 20/25 or better (%)	89	78	59	43	26	93
VA 20/40 or better (%)	99	98	94	85	76	99
Patients assessed (n)	81	82	82	82	82	84

VA = visual acuity

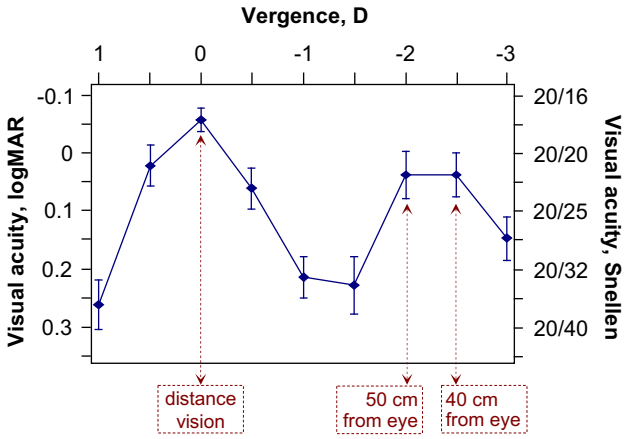

Figure 3. Mean defocus curve (51 patients) 6 months postoperatively. The error bars represent 95% confidence intervals.

For the other 6 visual disturbance items, 7 patients (8%) reported severe difficulty for halo, 4 (5%) for glare, and 3 (4%) for night vision. In addition, 1 patient (1%) each reported severe difficulty for blurred near vision, blurred far vision, and color vision.

Intraocular Lenses and Posterior Capsules

At 6 months, 126 of 134 eyes (94%) had no PCO and 10 eyes (7%) had mild PCO. None of the eyes had PCO rated moderate or severe, and none required capsulotomy. All IOLs were centered in the capsular bag. One IOL (0.7%) was tilted; however, the patient's binocular visual acuity remained good. Uncorrected distance visual acuity (UDVA) at 4 m and uncorrected near visual acuity (UNVA) at 40 cm and at the preferred near distance) were 20/16 or better. Uncorrected intermediate visual acuity (UIVA) at 50 cm, 60 cm, and 70 cm was 20/30 or better.

Adverse Events

Two patients were excluded from data analysis because of serious adverse events. One patient had cloudy vitreous in both eyes at the 3-month assessment and had a retinal detachment in 1 eye at the 6-month assessment. The other patient had significant cystoid macular edema in both eyes at the 1-month postoperative assessment. Four patients had minor adverse events. Of these, 2 patients (1 at 1 month and 1 at 3 months) had dry eye associated with sicca syndrome. Another patient reported metamorphopsia in 1 eye at 3 months; the metamorphopsia was not directly related to the IOL and was not present at the 1-month visit. The other patient reported bilateral dysphotopsia at 1 month and 6 months.

Patient Satisfaction and Spectacle Independence

Of the 83 patients who completed questionnaires at the 6-month postoperative visit, 88% were completely independent of spectacles for near, intermediate, and distance vision. Overall, 11% of patients chose the response "sometimes" for spectacle use for near vision, intermediate vision, or both (Figure 4). One patient (the one with metamorphopsia) always used glasses, although sphere and cylinder in each eye were 0.50 D or less. Overall, 99% of patients were spectacle independent for distance vision, 94% for intermediate vision, and 89% for near vision.

The mean patient satisfaction score was 8.3 ± 1.6 (out of 10); 96% of patients rated satisfaction as 6 or higher. Three patients (4%) reported a satisfaction rating of less than 6 at the 6-month assessment. Two of these 3 patients had an adverse event postoperatively, and 1 had residual refractive error and was scheduled for bilateral photorefractive keratectomy.

Table 2. Mean visual disturbances and visual lifestyle activities scores 6 months postoperatively excluding the 22 items with a score indicating minimum or no difficulty.

	Mean Score* ± SD (Patients)			
		Postoperative		
Parameter	Preoperative	1 Month	3 Months	6 Months
Visual disturbance				
Halos	1.5 ± 1.7 (89)	2.1 ± 1.6† (88)	2.0 ± 1.6 (83)	1.7 ± 1.5 (83)
Glare	2.3 ± 1.6 (89)	1.6 ± 1.5† (88)	1.7 ± 1.5 (82)	1.3 ± 1.3 (83)
Night vision	2.5 ± 1.7 (89)	1.4 ± 1.5† (88)	1.5 ± 1.5 (82)	1.1 ± 1.4 (83)
Visual activity				
Driving at night	3.6 ± 1.8 (81)	1.6 ± 1.7† (66)	1.6 ± 1.6 (68)	1.2 ± 1.5 (67)
Driving in the rain	3.5 ± 1.7 (81)	1.3 ± 1.6† (67)	1.5 ± 1.5 (71)	1.0 ± 1.4 (68)

*0 = no difficulty; 1 = minimal difficulty; 2 or 3 = moderate difficulty; 4 or 5 = severe difficulty
†$P < .05$ versus preoperative

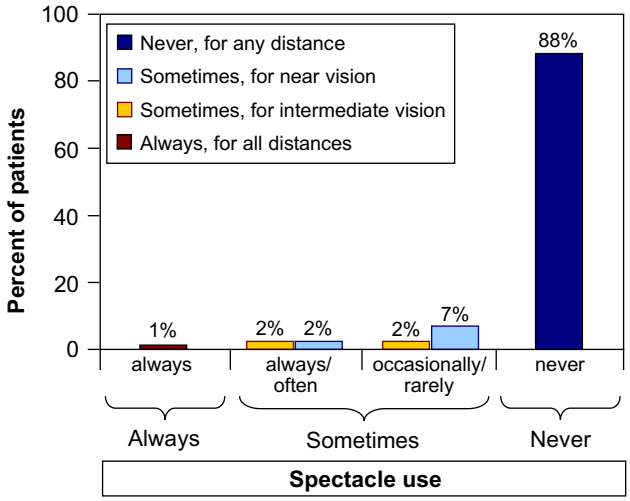

Figure 4. Spectacle use by 83 patients who completed a questionnaire 6 months postoperatively. No patient reporting the use of spectacles sometimes said he or she required them for distance vision.

DISCUSSION

The UNVA and UDVA in the 84 patients assessed 6 months after bilateral implantation of aspheric IQ ReSTOR +3.0 D IOLs (model SN6AD1) in our study were similar to the 6-month results in 335 patients in the largest published study of bilateral implantation of spherical ReSTOR SN60D3 IOLs.[2] The UNVA and UDVA were similar to 3-month postoperative results in a study of 18 patients with bilateral implantation of the +4.0 D aspheric model (SN6AD3).[13] The UIVA at all distances in our patients was better than distance-corrected intermediate visual acuity in patients with the spherical model[2] and in patients with the +4.0 D aspheric model[13] (Table 3). These indirect comparisons are consistent with results in the comparative FDA clinical trials, which report that the mean CDVA at 50 cm was significantly better in patients with the +3.0 D aspheric model than in patients with the +4.0 D aspheric model; the difference between the 2 IOL groups was at least 1 Snellen line (Alcon, Inc. AcrySof IQ ReSTOR, physician labeling, 2009).

In this study, the mean patient-preferred near distance was 41 ± 4 cm. This distance correlates well with the defocus curve, on which the plateau of optimum near vision was at the equivalent of 40 to 50 cm from the eye. This result contrasts with results in a study of patients with bilateral +4.0 D aspheric IOLs, in which the defocus curve had a sharp point (not a plateau) of optimum near vision at the equivalent of approximately 33 cm from the eye.[14] The difference in defocus curves helps explain the better intermediate vision with the +3.0 D aspheric model. Moving the near point from +4.0 D to +3.0 D improves intermediate vision because the near and far focal points are closer, which lessens the gradual decline in vision between the near and distance points.

The improved intermediate vision with the +3.0 D aspheric model is similar to the UIVA reported in eyes with refractive IOLs that have a similar near add (+3.5 D, yielding 2.6 D at the spectacle plane).[5] The mean UIVA at the preferred intermediate distance (range 60 to 80 cm) in patients with +3.5 D refractive IOLs was 20/34 Snellen, or the equivalent of 0.23 logMAR.[5] The mean UIVA in our patients was 0.13 logMAR at 60 cm and 0.20 logMAR at 70 cm, and the defocus curve suggests that visual acuity out to 1 m was as good as or better than visual acuity at 67 cm.

At the 6-month postoperative visit, patients reported having no to minimum difficulty with 22 of

Table 3. Binocular intermediate visual acuity in studies of bilateral +3.0 D or +4.0 D multifocal IOLs.

Study/IOL	Patients (n)	FU (Mo)	Mean Intermediate VA* (logMAR) ± SD		
			50 cm	60 cm	70 cm
Present					
SN6AD1 (+3.0 D)	82	6	0.05 ± 0.18	0.13 ± 0.15	0.20 ± 0.14
US clinical trials[9]					
SN6AD1 (+3.0 D)	138	3	0.06	0.12	0.18
SN6AD3 (+4.0 D)	131	3	0.24	0.32	0.34
Alfonso et al.[2]					
SN60D3 (+4.0 D)	335	6	0.27 ± 0.04	0.36 ± 0.03	0.40 ± 0.04
Alfonso et al.[13]					
SN6AD3 (+4.0 D)	18	3	—	0.20 ± 0.08	—

FU = follow-up; IOL = intraocular lens; VA = visual acuity
*With distance correction except in present study, for which the values are uncorrected

27 items on the subjective questionnaire. Patients rated 4 of the 5 remaining items (driving at night, driving in rain, glare, night vision) as minimally to moderately difficult; these ratings were significantly lower than the corresponding preoperative ratings, which indicates improvement in visual performance for these items. The mean difficulty rating for halos was in the minimum to moderate range and was not significantly different from the mean preoperative value. The good outcomes for visual disturbances may be ascribed partly to the apodization of the diffractive optic, which should reduce photic phenomena over the incidence with a traditional diffractive optic.[3,6] Our visual disturbance findings cannot be easily compared with those in the literature because of the use of different rating scales. However, the visual disturbance results in our study are comparable with 6-month outcomes in a large study of patients with bilateral implantation of spherical ReSTOR SN60D3 IOLs.[2] In that study, glare was generally rated as mild and halos as moderate on a 4-point scale. It is not clear whether the different number of diffractive rings in the IOL (12 in the spherical IOL and 9 in the +3.0 D aspherical IOL) affected the patients' perception of visual disturbances, such as halos and glare.

Visual disturbances and visual acuity are not only products of IOL optic design but are also caused by ocular straylight resulting from PCO.[15] In our cohort, no eye developed significant PCO that required capsulotomy. Our results with the 136 single-piece multifocal IOLs compare well with the 6-month capsulotomy rate (2.1% in 187 eyes) with single-piece monofocal IOLs.[16]

After bilateral implantation of the +3.0 D aspheric multifocal IOL, 88% of our patients had complete spectacle independence for vision at all distances. This rate compares well with outcomes with the other ReSTOR IOL models in the FDA clinical trials (76%, SN6AD1; 76%, SN6AD3; 81%, MA60D3; 76%, SA60D3) (Alcon, Inc. AcrySof IQ ReSTOR, physician labeling, 2009). High rates of spectacle independence for distance vision,[17] low levels of visual disturbances,[18] and freedom from PCO[19] have been correlated with patient satisfaction. These correlations are reflected in our high patient satisfaction rate (mean 8.3 ± 1.6 out of 10).

In summary, bilateral implantation of diffractive aspheric multifocal IOLs with a +3.0 D add provided good visual acuity at far and intermediate distances and over a range of near and intermediate distances. Overall difficulty with visual disturbances was low 6 months postoperatively. Most patients were satisfied and were spectacle independent for near, intermediate, and distance vision.

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