Prospective visual evaluation of apodized diffractive intraocular lenses

José F. Alfonso, MD, PhD, Luis Fernández-Vega, MD, PhD, M. Begoña Baamonde, MD, PhD, Robert Montés-Micó, PhD

PURPOSE: To evaluate distance, intermediate, and near visual performance in patients who had multifocal apodized diffractive intraocular lens (IOL) implantation.

SETTING: Fernández-Vega Ophthalmological Institute, Oviedo, Spain.

METHODS: The best corrected distance visual acuity, best distance-corrected near visual acuity, intermediate visual acuity, distance contrast sensitivity under photopic and mesopic conditions, and patient satisfaction were measured in 325 patients and 335 patients who had bilateral implantation of the model SA60D3 IOL (AcrySof ReSTOR, Alcon) and model SN60D3 IOL (AcrySof Natural ReSTOR), respectively.

RESULTS: At the 6-month postoperative visit, binocular best corrected distance acuity with the ReSTOR IOL and the Natural ReSTOR IOL was 0.034 logMAR $\pm$ 0.004 (SD) and 0.019 $\pm$ 0.020 logMAR, respectively ($\sim$20/20). Binocular best distance-corrected near acuity was 0.011 $\pm$ 0.012 logMAR and 0.035 $\pm$ 0.013 logMAR, respectively ($\sim$20/20). Intermediate visual acuity with both IOL models worsened significantly as a function of the distance of the test (P<.01). Photopic contrast sensitivity was within the standard normal range with both IOLs. Under mesopic conditions, contrast sensitivity with both IOLs was comparable to that with monofocal IOLs and lower, particularly at higher spatial frequencies, than under photopic conditions. No statistically significant differences in visual acuity or photopic and mesopic contrast sensitivity were found between the 2 IOL models (P>.1). A patient satisfaction questionnaire showed that both IOLs performed well and were comparable in satisfaction regarding distance, intermediate, and near activities under different lighting conditions.

CONCLUSIONS: The AcrySof ReSTOR IOL and AcrySof Natural ReSTOR IOL provided good visual performance at distance and near under photopic and mesopic conditions. Intermediate vision with both models was reduced compared with distance and near vision.

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Multifocal intraocular lenses (IOLs) are designed to reduce dependence on eyeglasses after cataract surgery and are gaining acceptance as a potential refractive surgical option in selected patients. Monofocal IOLs provide excellent visual function; however, for many patients, the IOL's limited depth of focus means that they cannot provide clear vision at both distance and near. Patients with traditional monofocal IOLs usually require glasses for near distance tasks such as reading. Monovision techniques may be helpful in some patients but involve sacrifices in binocularity.

Multifocal IOLs, which were introduced in the early 1980 s, may offer patients the potential for a range of uncorrected vision from near to far.[1,2] Multifocality is the brain's natural ability to adapt to near and far vision as it chooses between the 2 (near and far) images produced by the different optical elements of the IOL, depending on what it is looking at. These simultaneous-vision IOLs provide distance, intermediate, and near correction within the area of the ocular pupil. When a distant object is being viewed, a sharp retinal image is provided by the parts of the IOL within the pupillary area that have the distance correction and a somewhat blurred image by the other parts of the IOL, these images being superimposed on the retina. The decrease in contrast of the in-focus image is produced by the split of total light energy between the far focus and near focus, while the contemporary presence (superimposition) on the retina of an in-focus image and out-of-focus image can produce a sort of retinal rivalry or confusion that is overcome by the

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brain's selection of the best retinal image and capability to use multifocality.[3,4]

Many studies to overcome this drawback have been performed. One proposed solution is to direct different amounts of the refracted–diffracted light on the different foci, thus favoring distance or near vision.[5,6] Another approach comes from the pupil and the optical design of the IOL, which create different amounts of light on the different foci depending on pupil diameter.[2,7] However, reduced image contrast and unwanted visual phenomena, including glare and halos, have been associated with multifocal IOL performance.[1,2,6–17]

Newer multifocal IOL models have improved the visual outcomes over those achieved with older designs; however, the visual performance of these IOLs has not been fully evaluated. A popular currently used diffractive multifocal IOL is the AcrySof ReSTOR (Alcon). Recent studies[18–21] report satisfactory visual results with this IOL. However, no studies have been performed to assess the visual performance of this new IOL in a large population over a long follow-up period.

The purpose of this study was to assess distance, near, and intermediate visual acuity; distance contrast sensitivity under photopic and mesopic conditions; and patient satisfaction after bilateral implantation of the 2 ReSTOR IOL models, the original SA60D3 and the blue-light blocking Natural SN60D3, in the capsular bag after cataract extraction.

PATIENTS AND METHODS

This prospective study was of 1320 eyes of 660 consecutive patients who had binocular implantation of the AcrySof ReSTOR multifocal IOL or AcrySof ReSTOR Natural IOL at the Fernández-Vega Ophthalmological Institute, Oviedo, Spain. The ReSTOR SA60D3 IOL was implanted earlier in the study as it was the first model available on the market. The ReSTOR Natural SN60D3 IOL was used after it appeared on the market.

The tenets of the Declaration of Helsinki were followed. Informed consent was obtained from all patients after the nature and possible consequences of the study were explained. Institutional review board approval was obtained.

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From the Fernández-Vega Ophthalmological Institute (Alfonso, Fernández-Vega, Begoña Baamonde), the Surgery Department (Alfonso, Fernández-Vega, Begoña Baamonde), School of Medicine, University of Oviedo, Oviedo, and the Optics Department (Montés-Micó), Faculty of Physics, University of Valencia, Valencia, Spain.

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Corresponding author: José F. Alfonso MD, PhD, Instituto Oftalmológico Fernández-Vega, Avenida Dres. Fernández-Vega 34, 33012 Oviedo, Spain. E-mail: j.alfonso@fernandez-vega.com.

Inclusion criteria were age between 45 years and 75 years, binocular implantation (to determine the visual benefit of binocular implantation[20,21]), and patient motivation (desire to no longer wear spectacles or contact lenses for distance and near vision). Exclusion criteria included history of glaucoma or retinal detachment, corneal disease, previous corneal or intraocular surgery, abnormal iris, pupil deformation, macular degeneration or retinopathy, neuro-ophthalmic disease, and history of ocular inflammation.

Intraocular Lenses

The AcrySof ReSTOR SA60D3 multifocal IOL combines the functions of both the apodized diffractive and refractive regions (Figure 1). The apodized diffractive optic is within the central 3.6 mm optic zone of the IOL. This area comprises 12 concentric steps of gradually decreasing (1.3 to 0.2 μm) step heights, creating multifocality from near to distance (2 foci). The refractive region of the optic surrounds the apodized diffractive region. This area directs light to a distance focal point for larger pupil diameters and is dedicated to distance vision. The overall diameter of the IOL is 13.0 mm and the optic diameter, 6.0 mm. The IOL power varied from +10.0 diopters (D) to +30.0 D incorporating a +4.0 D near addition (add) power.

The material of the AcrySof Natural ReSTOR SN60D3 multifocal IOL includes a blue-light absorbing chromophore designed to more closely approximate the light-transmittance characteristics of the natural lens at wavelengths below approximately 500 nm. It has been shown that the use of a blue-light filter is advisable because it prevents retina ultraviolet light alterations without disturbing contrast sensitivity and chromatic vision.[22,23] The Natural IOL is optically and structurally identical to the ReSTOR SA60D3 IOL except for the blue-light filtering property.

Surgical Technique

All surgeries were performed by 1 of 2 experienced surgeons (J.F.A., L.F.V.) using phacoemulsification with the Infiniti Vision System (Alcon), topical anesthesia, and a 2.8 to

Figure 1. AcrySof ReSTOR multifocal apodized diffractive IOL. *Left*: Model SA60D3. *Right*: Model SN60D3.

3.2 mm clear corneal incision. Phacoemulsification was followed by irrigation and aspiration of the cortex and IOL implantation in the capsular bag.

Clinical Evaluation

Patients were scheduled for clinical evaluation preoperatively and 1 day, 1 week, and 1, 3, and 6 months postoperatively. A standard ophthalmologic examination, including manifest refraction, slitlamp biomicroscopy, Goldmann applanation tonometry, and binocular indirect ophthalmoscopy, was performed at all visits.

Distance, Intermediate, and Near Visual Acuity

Measurement of visual acuity was performed using logarithm of the minimum angle of resolution (logMAR) acuity charts under photopic conditions (85 cd/m^2). Monocular and binocular uncorrected distance visual acuity, best corrected distance visual acuity, uncorrected distance near visual acuity, and best distance-corrected near visual acuity were recorded at 6 m for distance measurements and 33 cm for near measurements in all patients. For near and intermediate visual acuity measurements, a handheld near logMAR chart (#2106, Precision Vision) was used following the methodology in previous studies.[20,21] Near distance was selected considering that the add power of the IOL was +4.0 D, corresponding to approximately 3.2 D in the spectacle plane. Binocular best distance-corrected intermediate visual acuity was measured at 40, 50, 60, and 70 cm in 200 eyes (100 in each IOL group).

Photopic and Mesopic Contrast Sensitivity

Monocular photopic contrast sensitivity and mesopic contrast sensitivity were measured with best distance correction at the 6-month postoperative visit in 200 eyes (100 in each IOL group). The selection of patients for this examination was random. Contrast sensitivity was measured using the Functional Acuity Contrast Test (FACT) (Stereo Optical), which has been shown to be adequate for multifocal IOL contrast sensitivity assessment.[1,2] Absolute values of $\log_{10}$ contrast sensitivity ($\log_{10}$CS) were obtained for each combination of patient, spatial frequency, and luminance, and the means and standard deviations were calculated.[24] The contrast sensitivity measurements were made under 2 illumination conditions. The chart luminance was 85 cd/m^2 (photopic, the luminance recommended in the manufacturer's guidelines) and 5 cd/m^2 (mesopic) room illumination at similar levels. Contrast sensitivity was measured first under photopic conditions and then under mesopic conditions. Patients were allowed to adapt to each level for 5 minutes before testing.

Considering that visual performance with multifocal IOLs is dependent on pupil size,[2] pupil diameters in distance vision were measured in each patient under the 2 levels of illumination using a Colvard pupillometer (Oasis) before IOL implantation. Tilt and centration of the multifocal IOL in relation to the visual axis was assessed using a Scheimpflug videophotography system (EAS-1000, Nidek).

Patient Satisfaction, Visual Phenomena, and Spectacle Dependency

An assessment of patient satisfaction, visual phenomena, and spectacle dependency was performed at the 6-month postoperative visit in 200 patients (100 in each IOL group). The selection of patients for this examination was random. Patient satisfaction was based on questions about distance, intermediate, near, and night vision. Patients rated the quality of vision on a scale from 0 to 9 (0 = incapacitating; 9 = excellent). Patients rated visual disturbances (eg, glare and halos) on the following scale: 1 = none, 2 = mild, 3 = moderate, and 4 = severe. To assess spectacle dependency, patients were asked about the need to wear glasses for near and intermediate vision.

Data Analysis

All examinations were performed 6 months after IOL implantation by the same ophthalmic technician who was unaware of the objective of the study and masked to the IOL implanted in each patient. Data analysis was performed using SPSS for Windows (version 12.0, SPSS, Inc.). The Shapiro-Wilk test was used to check normality, and the *t* test was used to compare the 2 groups. Differences were considered statistically significant when the *P* value was less than 0.01 (ie, at the 1% level). To explore correlations between the distance of the test and intermediate visual acuity, a 1-way analysis of variance (ANOVA) was performed in which the interactions between the changes in intermediate visual acuity and the distance of the test were assessed. The statistical significance of any intergroup contrast sensitivity difference was assessed with a *t* test that evaluated the data in the 2 groups (absolute log contrast sensitivity values) at each frequency for both illumination conditions.

RESULTS

Six hundred fifty eyes of 325 patients had implantation of the ReSTOR IOL and 670 eyes of 335 patients, of the ReSTOR Natural IOL. Table 1 shows the patients' demographics. There were no statistically significant differences between the 2 IOL groups in age, sex, IOL power, postoperative sphere and cylinder, and pupil diameter under either illumination condition.

After surgery, the pupils in all patients were round, without iris trauma, and showed good responsiveness to light. In all eyes, IOL centration was good and there was no IOL tilt. There were no complications in any case.

Visual Acuity

Table 2 shows the mean distance and near acuities in both IOL groups.

Distance Visual Acuity The mean monocular uncorrected visual acuity (UCVA) was 0.095 logMAR (~20/25) in the ReSTOR IOL group and 0.122 logMAR (~20/25) in the ReSTOR Natural IOL group. When the postoperative residual refractive error (Table 1) was corrected, the mean acuity improved to 0.054 logMAR and 0.039 logMAR (>20/25), respectively. Binocular UCVA was similar in the 2 groups (mean 0.060 logMAR with ReSTOR and 0.073 logMAR with ReSTOR Natural). When binocular best-corrected

Table 1. Patient demographics.

Characteristic	AcrySof ReSTOR IOL (SA60D3)	AcrySof ReSTOR Natural IOL (SN60D3)	*P* Value
Eyes (n)	650	670	—
Age (y)	61.2 ± 9.3	57.1 ± 8.9	.32
Sex (M/F)	109/216	118/217	.39
IOL power (D)	21.4 ± 3.4	20.8 ± 4.8	.57
Mean preop sphere (D) ± SD	0.86 ± 2.34	0.71 ± 2.92	.26
Mean preop cylinder (D) ± SD	−0.78 ± 0.90	−0.94 ± 1.05	.25
Mean postop sphere (D) ± SD	0.08 ± 0.30	0.02 ± 0.37	.21
Mean postop cylinder (D) ± SD	−0.22 ± 0.31	−0.37 ± 0.53	.28
Mean pupil diameter (mm) ± SD			
Photopic (85 cd/m^2)	3.9 ± 0.9	3.8 ± 0.9	.45
Mesopic (5 cd/m^2)	5.4 ± 0.7	5.4 ± 0.8	.56

IOL = intraocular lens

distance acuity was recorded, the means improved to 0.034 logMAR (∼20/20) and 0.019 logMAR (∼20/20), respectively. All patients in both groups achieved binocular best corrected distance acuity of 20/40 or better. A visual acuity of 20/25 or better was achieved in 92% in the ReSTOR IOL group and 95.5% in the ReSTOR Natural IOL group. Table 2 shows a detailed description of the efficacy under monocular and binocular uncorrected conditions.

Near Visual Acuity The mean monocular uncorrected distance visual acuity at the standard distance of 33 cm was 0.015 logMAR (∼20/20) with the ReSTOR IOL and 0.057 logMAR (∼20/25) with the ReSTOR

Table 2. Visual acuity (logMAR) results for distance, intermediate, and near vision.

	AcrySof ReSTOR IOL (SA60D3)			AcrySof ReSTOR Natural IOL (SN60D3)		
		Number (%)			Number (%)	
Near and Distance Acuity	Mean ± SD	20/40 or Better	20/25 or Better	Mean	20/40 or Better	20/25 or Better
Distance (6 m)						
Monocular uncorrected	0.095 ± 0.016	609/650 (93.7)	448/650 (68.9)	0.122 ± 0.038	584/670 (87.2)	404/670 (60.3)
Monocular best distance corrected	0.054 ± 0.005	630/650 (96.9)	546/650 (84.0)	0.039 ± 0.006	658/670 (98.2)	610/670 (91.0)
Binocular uncorrected	0.060 ± 0.006	321/325 (98.7)	277/325 (85.2)	0.073 ± 0.015	317/335 (94.6)	258/335 (77.1)
Binocular best distance corrected	0.034 ± 0.004	325/325 (100)	299/325 (92.0)	0.019 ± 0.002	335/335 (100)	320/335 (95.5)
Intermediate (70–40 cm)						
Binocular best distance corrected (70 cm)	0.352 ± 0.040	33/100 (33)	0/100	0.401 ± 0.042	34/100 (34)	0/100
Binocular best distance corrected (60 cm)	0.321 ± 0.031	50/100 (50)	1/100 (1)	0.356 ± 0.030	52/100 (52)	1/100 (1)
Binocular best distance corrected (50 cm)	0.223 ± 0.038	75/100 (75)	10/100 (10)	0.273 ± 0.041	77/100 (77)	11/100 (11)
Binocular best distance corrected (40 cm)	0.101 ± 0.033	97/100 (97)	72/100 (72)	0.109 ± 0.031	98/100 (98)	74/100 (74)
Near (33 cm)						
Monocular uncorrected	0.015 ± 0.011	650/650 (100)	626/650 (96.1)	0.057 ± 0.010	670/670 (100)	594/670 (88.7)
Monocular best distance corrected	0.014 ± 0.013	650/650 (100)	630/650 (96.9)	0.049 ± 0.011	670/670 (100)	630/670 (94.0)
Binocular uncorrected	0.013 ± 0.010	325/325 (100)	319/325 (98.1)	0.041 ± 0.012	335/335 (100)	320/335 (95.5)
Binocular best distance corrected	0.011 ± 0.012	325/325 (100)	320/325 (98.5)	0.035 ± 0.013	335/335 (100)	332/335 (99.1)

IOL = intraocular lens

Natural IOL. When near visual acuity was recorded with the best distance correction, it improved slightly (0.014 logMAR and 0.049 logMAR, respectively). Mean binocular uncorrected and best corrected distance acuity were, respectively, 0.013 logMAR and 0.011 logMAR in the ReSTOR IOL group and 0.041 logMAR and 0.035 logMAR in the ReSTOR Natural group (∼20/20 in all cases). In all situations (monocular and binocular; uncorrected and best corrected distance acuity), all eyes in both groups achieved a visual acuity of 20/40 or better. The binocular best corrected distance acuity was 20/25 or better in 98.5% patients in the ReSTOR IOL group and 99.1% in the ReSTOR Natural IOL group.

Intermediate Visual Acuity Figure 2 shows the change in binocular best distance-corrected intermediate visual acuity and Table 2, data on logMAR values and efficacy. The mean acuity was 0.025 ± 0.031 logMAR (∼20/20) at 33 cm and 0.350 ± 0.037 logMAR (∼20/50) at 70 cm in the ReSTOR IOL group and 0.036 ± 0.038 logMAR at 33 cm and 0.401 ± 0.042 logMAR at 70 cm in the ReSTOR Natural IOL group. The binocular visual acuity values were fitted with a 3rd-order polynomial equation using the least-squares fitting method (SigmaPlot, version 8.0). There was a worsening in binocular visual acuity as a function of the distance of the test in both IOL groups (Figure 2 legend shows trend equation). The 1-way ANOVA showed a statistically significant correlation between the distance of the test and the change in intermediate visual acuity in both groups ($P < .01$). No statistically significant differences were found between the 2 IOL groups at any distance evaluated ($P > .01$).

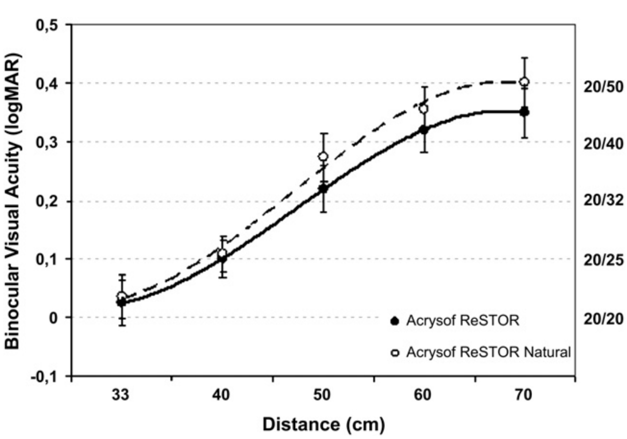

Figure 2. Binocular best distance corrected intermediate visual acuity (logMAR) as a function of distance (cm) wth the ReSTOR SA60D3 IOL and the ReSTOR Natural SN60D3 IOL. Continuous lines represent the best polynomial trend equation (cubic) for the AcrySof ReSTOR IOL [*solid line*: visual acuity = $0.01x^3 - 0.08x^2 + 0.09x - 0.05$, × (distance)] and the AcrySof Natural ReSTOR IOL [*dashed line*; visual acuity = $0.01x^3 - 0.09x^2 + 0.09x - 0.05$ × (distance)]. The *y*-axis on the right shows the Snellen feet equivalent of visual acuity.

Contrast Sensitivity Under Bright and Dim Conditions

The mean $\log_{10}$CS values are plotted as a series of contrast sensitivity functions in Figure 3. Figure 3, *A* and *B*, shows distance contrast sensitivity functions at the 2 luminance levels. Under photopic conditions (85 cd/m^2), performance was similar in the 2 IOL groups and was close to the standard contrast sensitivity function (Figure 3, *A*, *dashed line*). At a mesopic

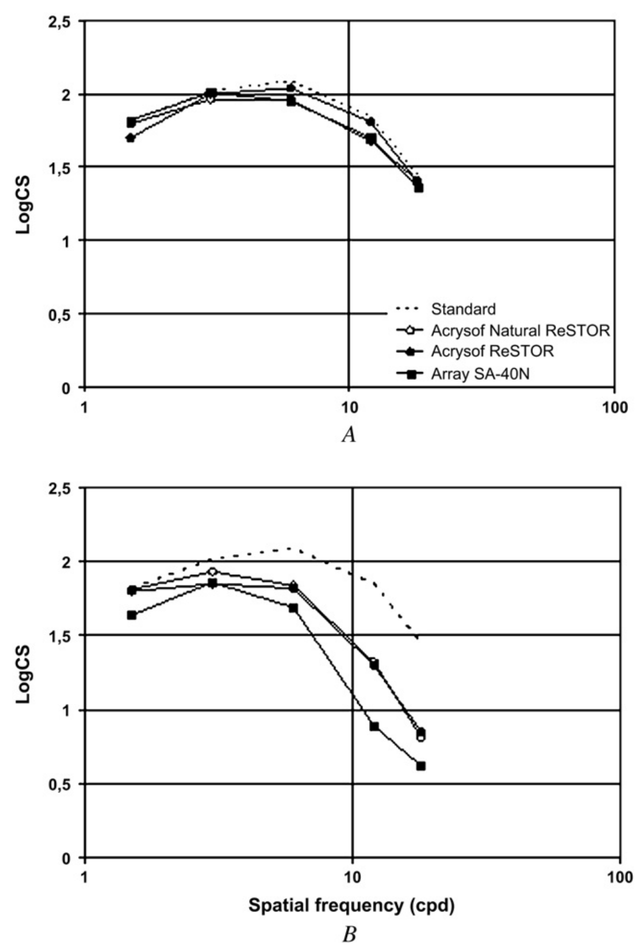

Figure 3. Contrast sensitivity functions for the AcrySof ReSTOR IOLs as a function of FACT chart luminance: photopic (85 cd/m^2) (*A*) and mesopic (5 cd/m^2) (*B*). For comparison, the "standard" data (*dashed lines*) are photopic (85 cd/m^2) results in normal, healthy emmetropic eyes as found by Boxer Wachler and Krueger[24] and the contrast sensitivity functions after multifocal Array SA-40 N IOL (AMO) implantation as found by Montés-Micó et al.[2] at 85 cd/m^2 and 5 cd/m^2. Standard deviation (SD) error bars were omitted for clarity. The typical SD varied from 0.03 to 0.05.

level of 5 cd/m^2, however, contrast sensitivity in both IOL groups was generally lower, particularly at higher spatial frequencies (Figure 3, *B*). No statistically significant differences in photopic and mesopic $\log_{10}$CS values were found between the ReSTOR IOL and the ReSTOR Natural IOL at any spatial frequency ($P > .1$).

Patient Satisfaction, Visual Phenomena, and Spectacle Dependency

The patient satisfaction questionnaire shows that the 2 IOLs were comparable in satisfaction regarding distance, intermediate, and near activities under different lighting conditions ($P > .1$) (Table 3). The questionnaire allowed patients to quantify the level of global satisfaction with their vision, and both groups reported good performance in terms of patient satisfaction; intermediate visual tasks had the lowest score rate (∼7.3). No patient reported severe visual phenomena. The presence of halos was reported more than glare disturbance; patients rated halos as mild to moderate. Only 2% of patients reported needing spectacle for near distance. This percentage increased to 4% when patients were asked about the use of spectacles for intermediate vision.

DISCUSSION

Multifocal IOLs alleviate the symptoms of presbyopia by providing some functional near vision through increased depth of field of the eye. Depending on the multifocal technology (diffractive or refractive), different depths of field are achieved and different distance, near, and intermediate visual performance obtained with current IOLs. From an optical viewpoint (measuring the modulation transfer function [MTF]), diffractive IOLs and refractive multifocal IOLs have comparable optical properties for distance vision but diffractive IOLs provide better near vision.[25] However, the optical properties of a specific commercial IOL depend on its design and cannot be classified as refractive or diffractive. The AcrySof ReSTOR IOL combines both diffractive and refractive optics, and to date, no study showing its optical performance in vitro or in vivo has been published.

In the current study, we assessed the performance of this new IOL using visual indexes such as visual acuity and contrast sensitivity measured at different distances and light conditions. Rates of postoperative patient satisfaction, visual phenomena, and spectacle dependency were recorded to illustrate the patients' quality of vision.

Table 3. Results of patient questionnaire administered 6 months after IOL implantation.

Parameter	ReSTOR IOL (SA60D3)	ReSTOR Natural IOL (SN60D3)	*P* Value
How is your (mean ± SD)			
Far vision?	8.5 ± 0.7	8.5 ± 0.6	.81
Intermediate vision?	7.3 ± 1.6	7.3 ± 1.5	.79
Near vision?	7.5 ± 1.7	7.5 ± 1.5	.83
Night vision?	7.8 ± 1.4	7.4 ± 1.3	.56
Global satisfaction	8.6 ± 1.3	8.7 ± 1.4	.74
Glare	1.3 ± 0.7	1.4 ± 0.8	.48
Halos	2.8 ± 0.7	2.5 ± 0.6	.44
Percentage of patients who wear glasses for seeing objects at			
Near distance	2	2	—
Intermediate distance	4	4	—

IOL = intraocular lens

Distance Visual Performance

Our study found excellent binocular best corrected distance acuity in both groups, with 92.0% (ReSTOR) and 95.5% (ReSTOR Natural) of patients with a binocular best corrected distance acuity of 20/25 or better at 6 months. Efficacy under monocular conditions was also good, although slightly reduced in relation to binocular conditions. These result agrees with those in the literature that considers the visual benefit of binocular implantation.[20,21] Kohnen et al.[20] report similar values and percentages of binocular uncorrected and best corrected distance acuity in 118 patients 120 to 180 days after the AcrySof ReSTOR IOL implantation (mean best distance-corrected acuity, −0.05 logMAR [> 20/20]); all patients had an acuity of 20/40 or better and 97.5%, of 20/25 or better. Souza et al.[21] assessed 25 patients with the ReSTOR SA60D3 model 120 to 180 days after surgery and found a mean monocular best corrected distance acuity of 0.0 ± 0.17 logMAR (∼20/20). Our results, obtained from a large sample of patients, agree with preliminary results[20,21] on the best corrected distance acuity of the AcrySof ReSTOR IOL. Comparison with previous studies on the visual performance of the AcrySof ReSTOR Natural is not possible because to our knowledge, this is the first study to evaluate it.

Montés-Micó et al.[2] provide a review of several studies of photopic contrast sensitivity after multifocal IOL implantation. The main literature on this topic points out that photopic contrast sensitivity with a multifocal IOL is reduced compared with that with a monofocal IOL, although it is within the normal range. Our results with the ReSTOR IOL and ReSTOR Natural IOL broadly agree with this. Decreased contrast sensitivity in patients with multifocal IOLs as compared with that in patients with monofocal IOLs is explained by the multifocal IOL's division of the available light energy in the image between 2 or more focal points.[2] Different technology (refractive or diffractive) and optical design for multifocal IOLs make contrast sensitivity results different. Approximately 50% of the light energy in the full-aperture Array SA-40 N IOL is concentrated at the far focus, and about 20% at the near focus.[26] Light energy distribution for the AcrySof ReSTOR IOL depends on pupillary diameter and varies approximately from 40% to 90% at the far focus and from 9% to 40% at the near focus.[27] Considering the variation of light energy percentage, the role of the pupil size becomes crucial for the multifocal IOL visual performance (discussed at the end of this section). However, clinical studies, including our own, show that the loss in photopic contrast sensitivity is somewhat smaller. It may be that the effects of ocular longitudinal chromatic and other types of ocular aberration, together with the blending zones of the IOL, tend to mask the differences in contrast sensitivity.

Montés-Micó, et al.[2] report that patients with multifocal IOLs had worse contrast sensitivity under dim conditions. We also found a reduction in contrast sensitivity when luminance level was reduced, particularly at the higher spatial frequencies. This trend agrees with classic data on the effect of luminance level on contrast sensitivity.[28] Pupil diameters are substantially larger under mesopic conditions; therefore, it seems reasonable to attribute the observed reduction in mesopic contrast sensitivity at higher spatial frequencies to the additional blur introduced by the larger diameter, out-of-focus zones of the multifocal IOL. Both 0 ReSTOR IOLs provided better contrast sensitivity than the Array SA-40 N IOL (AMO) at high spatial frequencies. This difference may be attributed to the effect of the peripheral refractive region of the AcrySof ReSTOR IOL (dedicated for distance vision; from 3.6 to 6.0 mm), which helps the distance focus and becomes important with large pupil diameters (dim-light conditions).

It has been reported that the use of yellow filters by healthy phakic patients improves image contrast and thus contrast sensitivity function.[29] Recently, Rodríguez-Galietero et al.[22,23] found no differences in contrast sensitivity between the AcrySof Natural IOL and an IOL without a yellow filter. They argued that depending on the spectral transmittance of each filter, the effect on contrast sensitivity might vary. We agree with this because we found no differences in contrast sensitivity function between the ReSTOR IOL and the ReSTOR Natural IOL (same light-transmission spectrum than the monofocal AcrySof Natural IOL) under both light conditions.

Near Visual Performance

Both the AcrySof ReSTOR IOL and the AcrySof ReSTOR Natural IOL resulted in good near visual performance, with 98.5% and 99.1% of eyes, respectively, with binocular best distance-corrected near acuity of 20/25 or better at 6 month. Kohnen et al.[20] report a low percentage of patients with 20/25 or better binocular best distance-corrected near acuity at the same near distance (83.9% of patients at 33 cm with the SA60D3 model). Souza et al.[21] also report different results for near vision because they examined visual acuity with the near chart at the best distance for the patient instead of at a standard distance.

It is well know that near visual performance with a multifocal IOL is better than with a monofocal IOL.[2,13,30] Montés-Micó and Alió[1] found that near contrast sensitivity in the Array multifocal IOL improved over time but was always lower than at distance and in the monofocal near-corrected patients. Our study found that binocular best corrected distance acuity for distance and near vision with both ReSTOR IOLs were comparable. The percentage of light energy for near focus under photopic conditions (85 cd/m^2) with the both ReSTOR IOLs seems to be enough to provide good near visual acuity (∼20/20). Lighting conditions and miosis may contribute to a balanced relative energy between distance and near focus, which provides comparable distance and near visual acuity in these patients. Similar relative energy percentages between distance and near focus (∼40% for each) with the AcrySof ReSTOR IOL are achieved in the pupil diameter range from 1.0 to 2.0 mm.[27]

Intermediate Visual Performance

There was statistically significant worsening of binocular visual acuity as a function of the distance of the test. However, better intermediate visual performance than with monocular IOLs is expected. Souza et al.[21] found that binocular distance-corrected intermediate visual acuity was better in patients with the AcrySof ReSTOR IOL than patients with the monofocal AcrySof SA60AT IOL at 50, 60, and 70 cm.

Analysis of the binocular intermediate visual acuity change versus distance suggests that the observed behavior cannot be accounted for by the location of the distance and near foci in relation to the retina's plane. This is presumably because the relative energy distribution for distance and near foci that depends on the pupil diameter causes visual acuity to vary gradually from near to distance. The resultant progressive change in relative energy for the distance and near foci as function of the pupil size,[27] from 40% to 90% at the far focus and from 9% to 40% at the near focus in the 1.0 to 6.0 mm pupil range, is reflected in a change in visual acuity from approximately 20/20 (0.025/0.036 logMAR) at 33 cm to approximately 20/50 (0.350/0.401 logMAR) at 70 cm. It seems more reasonable to attribute the change in visual acuity to the changes in pupil size and analogous changes in relative energy for both foci. For example, Kawamorita and Uozato[30] found low MTFs at intermediate focus at all effective pupil diameters for the refractive multifocal Array IOL. This supports that intermediate visual acuity is reduced in relation to distance and near visual acuity. A low percentage of light is allocated to intermediate focus (∼13%) in relation to distance or near focus in refractive multifocal IOLs. For diffractive IOLs, pupil size change through intermediate vision should be considered as an explanation of the visual performance differences between patients. Pupil size and IOL design play an important role in intermediate visual performance in patients with diffractive IOLs.

Pupil Size

Hayashi et al.[31] report that pupil size is correlated significantly with near visual acuity in the presence of a multifocal refractive IOL (Array IOL), although it does not influence distance or intermediate visual acuity. They found that a smaller pupil was related to worse visual acuity; patients with pupil diameter smaller than 4.5 mm did not reach 20/63. Kawamorita and Uozato,[30] considering MTF measurements in vitro, report that for the Array IOL, the desirable pupil diameter to acquire good near visual performance is a minimum of 3.4 mm and is optimally 3.8 mm or larger.

Diffractive IOLs generate 2 focal points by diffraction of light. Although some quantity of the incident light is lost because of higher orders of diffraction, the relative power distribution of the remaining light in our patients was between 70% and 85% to the distance focus and between 15% and 10% to the near focus at pupil diameters of 3.8 mm and 5.4 mm, respectively.[27] This unequal light distribution between the distance and the near focus is caused by the refractive region of the optic (from 3.6 mm) that surrounds the diffractive region, which directs light only to the distance focus. Because of this, for large pupil diameters, the relative light energy decreases for near focus and increases for distance focus. We found good visual acuity for distance, intermediate, and near vision. showing that the balance of relative energy between both foci is adequate in terms of visual performance. The patients we evaluated had a preoperative photopic pupil of approximately 3.8 mm, greater than the diffractive optics of the AcrySof ReSTOR IOL. Thus, it becomes important to measure pupil size before surgery to achieve the best visual performance at any distance when this IOL is implanted. However, Koch et al.[32] showed that preoperative pupil size does not necessarily predict postoperative size after IOL implantation, so it may be difficult for a surgeon to decide on appropriate patients based on preoperative pupil size. Hayashi et al.[31] also report that the degree of IOL decentration in relation to the pupil correlates with both distance and intermediate visual acuity, but not with near visual acuity. However, tilt does not influence visual acuity when the IOL is implanted in the capsular bag. Neither tilt nor decentration was found in our patients; thus, no correlation between pupil size and IOL decentration and visual performance was possible.

Quality of Life

Previous quality-of-life studies[20,21] report a high level of satisfaction in patients with the AcrySof ReSTOR IOL. Patients with this IOL in our study achieved good visual acuity at various distances. The patient satisfaction questionnaire completed at the 6-month visit showed that the AcrySof ReSTOR IOL offers good distance and near visual acuity. Intermediate vision had the lowest score rate, which correlates with the worse intermediate visual acuity data in Figure 2. Visual disturbances such as glare or halos were classified between none and moderate. No patient classified these visual disturbances as severe. One may argue that the apodized (step-heights blending) diffractive optic of the AcrySof ReSTOR IOL plays a role. Apodization reduces the loss of light because of the higher orders of diffraction and allows for smooth transition of the distribution of light energy between distance and near focal points. Then, image quality at both foci is expected to be improved, minimizing visual disturbances such as glare and halos. The percentage of patients who wore glasses for near or intermediate vision was low (2% to 4%). A higher percentage of patients who used glasses for intermediate vision may be correlated with the reduction in intermediate visual acuity. However, a larger percentage of patients who need spectacles for intermediate tasks would be expected in relation to the intermediate visual acuity results. It seems plausible that other factors, such as the specific visual task, may play a role in determining the use of glasses at this distance.

CONCLUSION

In conclusion, the AcrySof ReSTOR IOL and AcrySof ReSTOR Natural IOL provided a satisfactory full range of vision in terms of visual acuity and contrast sensitivity under bright and dim conditions with low incidences of visual disturbances. However, several studies must still be performed. The first is to include a monofocal control group to compare visual acuity between groups at different distances. The second would be to include lifestyle and activity of the patients evaluated in the patient satisfaction questionnaire, which would add useful information to correlate with visual acuity and contrast sensitivity outcomes. Another would be to evaluate optical aberrations and pupil size at different distances. Future investigations of the visual and optical performance of the AcrySof ReSTOR IOL should include these considerations.

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