

Correlation of pupil size with visual acuity and contrast sensitivity after implantation of an apodized diffractive intraocular lens

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

PURPOSE: To determine whether pupil size is correlated with visual acuity and contrast sensitivity at all distances in eyes with an apodized diffractive intraocular lens (IOL).

SETTING: Private Clinic, Oviedo, Spain.

METHODS: Six months after surgery, the best corrected distance visual acuity, best distance-corrected near visual acuity, intermediate visual acuity, and distance contrast sensitivity under photopic (85 cd/m^2) and mesopic (5 cd/m^2) conditions were measured in 670 eyes of 335 consecutive patients who had implantation of the AcrySof ReSTOR Natural IOL (SN60D3, Alcon). Pupil diameters in distance vision were measured using a pupillometer.

RESULTS: The logMAR best corrected distance acuity was significantly better with larger pupils ($r = 0.297$; $P = 1.36 \times 10^{-8}$), whereas logMAR best distance-corrected near acuity was significantly worse with larger pupils ($r = 0.276$, $P = 1.02 \times 10^{-7}$). For all pupil diameters, intermediate visual acuity worsened significantly as the distance of the test increased ($P < .01$). Statistically significant differences in photopic and mesopic contrast sensitivity at all spatial frequencies were found between the small-pupil and large-pupil groups ($P < .01$). Distance photopic contrast sensitivity and mesopic contrast sensitivity were better in patients with large pupils than in patients with small pupils.

CONCLUSIONS: A larger pupil was correlated significantly with better distance visual acuity and with worse near visual acuity. For all pupil diameters, intermediate visual acuity worsened significantly as the distance of the test increased. Distance contrast sensitivity was better with larger pupils at all spatial frequencies in bright-light and dim-light conditions.

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Multifocal intraocular lenses (IOLs) increase the depth of field and improve intermediate and near vision after cataract or clear lens extraction. The multifocal IOL simultaneously creates images on the retina that are conjugate with 2 or more depth planes. These simultaneous-vision IOLs provide distance, intermediate, and near correction within the area of the pupil of the eye. When the eye views a distant object, a sharp retinal image is provided by the parts of the lens within the pupillary area that have the distance correction and a somewhat blurred image by the other parts of the lens as these images are superimposed on the retina.^{1,2} The unwanted effect of the light in the out-of-focus image is a reduction in contrast of the in-focus image.^{3,4} Some have proposed minimizing this drawback by creating different amounts of the refracted-diffracted light on the different foci.^{5,6} Another approach takes

into consideration the pupil and 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, are associated with multifocal IOLs.^{1,2,6-17}

The optical and visual performance of a multifocal IOL likely depends on pupil size.^{2,6,18} Montés-Micó et al.² point out that visual performance with multifocal IOLs varies as a function of pupil size because it affects the relative areas of the pupil occupied by the near and distance corrections. Hayashi et al.⁷ report that a smaller pupil correlates significantly with worse near visual acuity in eyes with the AMO Array multifocal refractive IOL. They also point out that a pupil diameter smaller than 4.5 mm cannot provide useful near visual acuity. Kawamorita and Uozato¹⁸

investigated the relationship between pupil size and the modulation transfer function (MTF) of the Array multifocal refractive IOL in vitro. They conclude that the near MTF increases at the expense of the far MTF with a large pupil (> 3.4 mm) and, thus, a pupil diameter of 3.4 mm or larger is desirable to enhance near vision.

New multifocal IOLs have improved the visual outcomes over those achieved with older designs. Today, one widely used diffractive multifocal IOL is the AcrySof ReSTOR (Alcon). Recent studies¹⁹⁻²³ report satisfactory visual acuity and contrast sensitivity results. The relative energy between the distance and near focal points of the ReSTOR IOL changes significantly with pupil diameter, as Davison and Simpson²³ detail. However, to our knowledge, there is no report of the influence of pupil diameter on visual acuity and contrast sensitivity in patients with the ReSTOR IOL.

The objective of this study was to determine whether pupil size is correlated with visual acuity and contrast sensitivity at all distances in eyes with the ReSTOR IOL.

PATIENTS AND METHODS

A prospective study comprised 670 eyes of 335 consecutive patients who had implantation of the AcrySof ReSTOR Natural IOL (SN60D3) at the Fernández-Vega Ophthalmological Institute, Oviedo, Spain. 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. Exclusion criteria included ocular disease (eg, glaucoma, macular degeneration, corneal or neuro-ophthalmic diseases) and a history of ocular inflammation.

The ReSTOR multifocal IOL combines the functions of the apodized diffractive region and the refractive region. The apodized diffractive optics are within the central 3.6 mm optic zone of the IOL. This area

comprises 12 concentric steps that gradually decrease from 1.3 to 0.2 μm ; the step heights create multifocality from near to distant (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 is 6.0 mm. The power of the IOL ranges from +10.0 to +30.0 diopters (D), incorporating a +4.0 D near addition (add) power.

All surgeries were performed by 1 of 2 experienced surgeons (J.F.A., L.F.V.) using topical anesthesia and a 2.8 to 3.2 mm clear corneal incision. Phacoemulsification was performed using the Infiniti Vision System (Alcon). Phacoemulsification was followed by irrigation and aspiration of the cortex and IOL implantation in the capsular bag.

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.

Visual acuity was measured using logarithm of the minimum angle of resolution (logMAR) acuity charts under photopic conditions ($85 \text{ cd}/\text{m}^2$). Monocular best corrected distance visual acuity and best distance-corrected near visual acuity at 6 m and 33 cm were recorded in all patients. Near distance was selected considering that the add power of the IOL is +4.0 D, corresponding to approximately 3.2 D in the spectacle plane. Intermediate visual acuity was measured under binocular conditions; thus, patients who had the same pupil diameter in both eyes under photopic conditions were selected from among the initial sample. Binocular best distance-corrected intermediate visual acuity was measured at 40 cm, 50 cm, 60 cm, and 70 cm in 115 patients.

Monocular photopic contrast sensitivity and mesopic contrast sensitivity were randomly measured with best distance correction in 100 eyes. Contrast sensitivity was measured using the Functional Acuity Contrast Test (Stereo Optical), which has shown to be adequate for multifocal IOL contrast sensitivity assessment.^{1,2} Absolute values of log₁₀ contrast sensitivity were obtained for each combination of patient, spatial frequency, and luminance, and the means and standard deviations were calculated. Contrast sensitivity was measured under 2 illumination conditions: $85 \text{ cd}/\text{m}^2$ and $5 \text{ cd}/\text{m}^2$, the first being photopic (ie, the luminance recommended in the manufacturer's guidelines) and the other mesopic. Room illumination was at similar levels. Contrast sensitivity was measured first under photopic conditions and

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From private practice (Alfonso, Fernández-Vega, Baamonde) and the Surgery Department (Alfonso, Fernández-Vega, 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 Doctores Fernández-Vega 114, Oviedo 33012, Spain. E-mail: j.alfonso@fernandez-vega.com.

then under mesopic conditions. Patients adapted to each light level for 5 minutes before testing.

In all patients, pupil diameters in distance vision were measured under the 2 levels of illumination using a Colvard pupillometer (Oasis) before IOL implantation. To determine the role of the pupil size in intermediate visual acuity and contrast sensitivity and considering the optical structure of the IOL, patients were divided into 3 groups based on photopic pupil diameter: 2.0 to 3.5 mm, 4.0 to 5.5 mm, and 6.0 to 6.5 mm. The first group included data only from the central diffractive area (dedicated to distance and near vision), the second group included data from the central diffractive area and the peripheral diffractive area (dedicated to distance vision), and the third group included data from both areas and over the optic diameter of the IOL. Tilt and centration of the multifocal IOL in relation to the visual axis were assessed using the EAS-1000 Scheimpflug videophotography system (Nidek).

All examinations were performed 6 months after IOL implantation by the same ophthalmic technician, who was unaware of the study's objective. Data analysis was performed using SPSS for Windows (version 12.0, SPSS, Inc.). The relationship between the pupil size and distance and near visual acuities was modeled using a regression model (linear model was used in each case), and the differences in intermediate visual acuity between pupil size groups were evaluated by analysis of variance (ANOVA) with contrast analysis. Normality was checked by the Shapiro-Wilk test, and the Mann-Whitney *U* test was used to compare differences in visual acuity and contrast sensitivity between the pupil size groups. Differences were considered statistically significant when the *P* value was less than 0.01 (ie, at the 1% level).

RESULTS

The mean age of the patients was $57.1 \text{ years} \pm 8.9$ (SD). There were 118 men and 217 women. Table 1 shows the patients' demographics.

After surgery, all pupils were round and showed good responsiveness to light; there were no cases of iris trauma. All IOLs were well centered with no tilt. There were no complications. All patients reported being happy with the outcomes of the surgery.

Figure 1, A, shows the relationship between pupil size and visual acuity at distance. The logMAR best corrected distance acuity was significantly better with larger pupils ($r = 0.297$; $P = 1.36 \times 10^{-8}$). The mean values ranged from 0.091 ± 0.051 logMAR with a 2.0 mm pupil to -0.085 logMAR with a 6.5 mm pupil.

Table 1. Demographics of patients.

Characteristic	Value
Eyes (n)	670
Age (y)	57.1 ± 8.9
Sex (M/F)	118/217
Mean IOL power (D)	20.8 ± 4.8
Mean postop sphere (D)	0.02 ± 0.37
Mean postop cylinder (D)	-0.37 ± 0.53
Mean BDCVA (logMAR)	0.046 ± 0.071
Mean BDCNVA (logMAR)	0.052 ± 0.072
Mean pupil diameter (mm)	
Photopic (85 cd/m^2)	3.8 ± 0.9
Mesopic (5 cd/m^2)	5.4 ± 0.8

Means \pm SD
 BDCNVA = best distance-corrected near visual acuity; BDCVA = best distance-corrected visual acuity; IOL = intraocular lens

Figure 1, B, shows the relationship between pupil size and visual acuity at near. The logMAR best distance-corrected near acuity was significantly worse with larger pupils ($r = 0.276$, $P = 1.02 \times 10^{-7}$). The mean values ranged from 0.006 ± 0.024 logMAR (approximately J1) with a 2.0 mm pupil to 0.325 ± 0.035 logMAR (approximately J5) with a 6.5 mm pupil.

Figure 2 shows the change in binocular best distance-corrected intermediate visual acuity as a function of pupil diameter. The mean values changed from 0.013, 0.028, and 0.038 logMAR (approximately 20/20) at 33 cm to 0.426, 0.387, and 0.340 logMAR (approximately 20/50) at 70 cm in the 2.0 to 3.5 mm pupil group, 4.0 to 5.5 mm pupil group, and 6.0 to 6.5 mm pupil group, respectively. The binocular visual acuity values shown were fitted with a 3rd-order polynomial equation using the least-squares fitting method (version 8.0, SigmaPlot). Binocular visual acuity became worse as the distance of the test increased in all pupil groups; the legend for Figure 2 shows the trend equation. The ANOVA showed a statistically significant correlation between the distance of the test and the change in intermediate visual acuity in all pupil groups ($P < .01$). No statistically significant differences were found except between the 2.0 to 3.5 mm group and 6.0 to 6.5 mm group at 60 cm ($P = .007$); the *P* value at 60 cm in the 4.0 to 5.5 mm group versus the 2.0 to 3.5 group and versus the 6.0 to 6.5 mm group was 0.108 and 0.093, respectively.

Figure 3 shows a plot of the contrast sensitivity log₁₀ values at 85 cd/m^2 and 5 cd/m^2 luminance in the 3 pupil groups. Under photopic conditions (85 cd/m^2), performance was similar in the 4.0 to 5.5 mm group and 6.0 to 6.5 mm group; there was no statistically significant difference between the 2 groups at any spatial frequency ($P > .1$) (Figure 3, A). However,

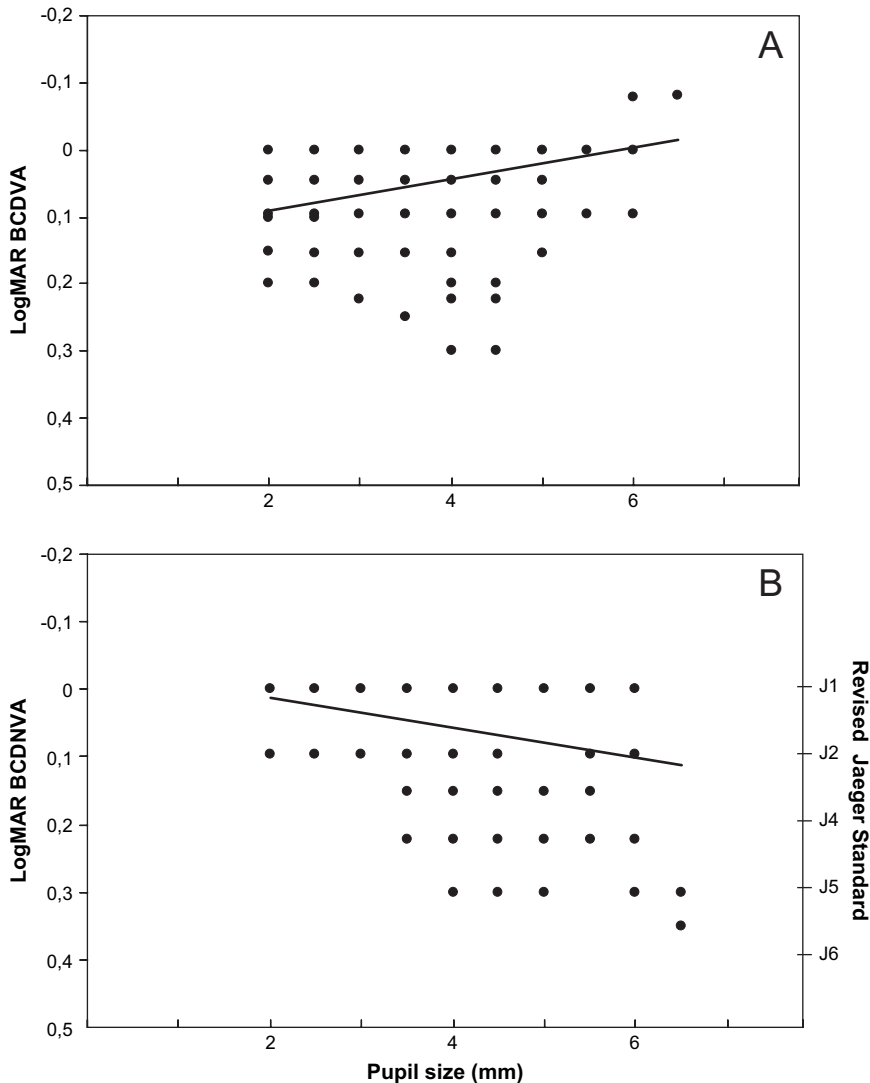


Figure 1. Scatterplot of the association between the pupil size and best corrected distance logMAR acuity (A) and best corrected distance logMAR near acuity (B). Continuous lines represent the best linear trend equation at distance ($r = 0.297$; $P = 1.36 \times 10^{-8}$) and near ($r = 0.276$; $P = 1.02 \times 10^{-7}$).

log₁₀ contrast sensitivity was statistically significantly lower in the 2.0 to 3.5 mm pupil group than in the other 2 groups ($P < .01$) (Figure 3, A). At a mesopic level of 5 cd/m², all patients had a pupil diameter of 4.0 mm or larger; thus, only the 4.0 to 5.5 mm and 6.0 to 6.5 mm pupil groups were considered. In both groups, there was a reduction in log₁₀ contrast sensitivity that was greater at high spatial frequencies (Figure 3, B). The decrease in contrast sensitivity was greater in the 4.0 to 5.5 mm group. Differences between the 2 groups were statistically significant across all frequencies ($P < .01$); Figure 3, B, shows all P values for this comparison.

DISCUSSION

The ReSTOR IOL has a diffractive–refractive design concept to provide improved control of energy distribution. The lens has 2 primary focal points, 1 at distance and the other at near. The base lens provides

the distance power using its refractive shape; 12 diffractive steps are incorporated in the anterior surface to provide the diffractive add power. The diffractive steps cover the central 3.6 mm diameter of the IOL, while the optic peripheral to the 3.6 mm diameter out to the 6.0 mm edge is a refractive surface dedicated to distance vision. For distance and near visual tasks, we generally use bright light, which makes the pupils smaller. Considering the light-distribution energy of the IOL, enough light energy for distance and near vision is distributed. When we perform distance activity under mesopic conditions, a large pupil helps distance vision because of the peripheral refractive region of the IOL. The limited diffractive region limits the size and energy of defocused light under large pupil conditions. In contrast, if a near visual task is performed under mesopic conditions, near visual acuity may be compromised. However, near activity is usually performed under photopic conditions.

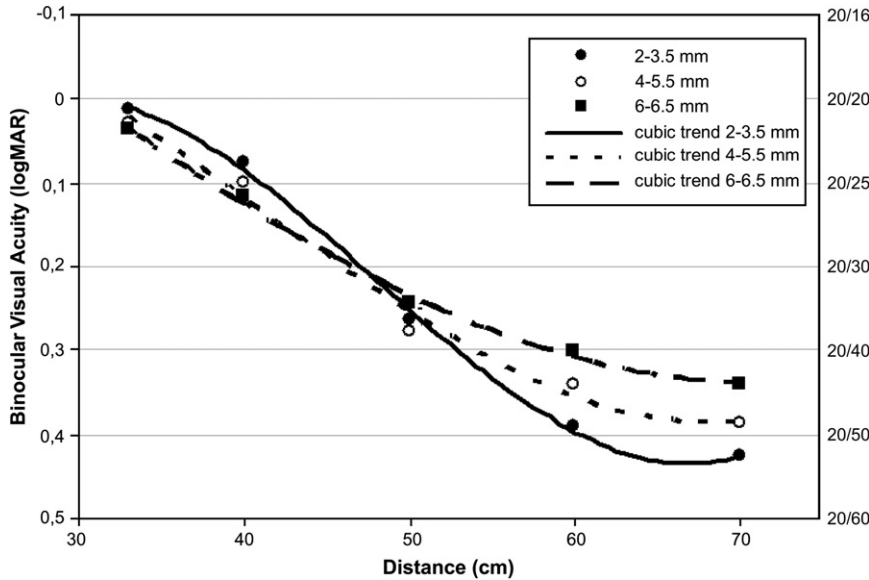


Figure 2. Binocular best distance-corrected intermediate visual acuity (logMAR) as a function of distance of the test (cm) and pupil size (mm). Lines represent the best polynomial trend equation (cubic) for the 2.0 to 3.5 mm pupil group ($y = 2^{-5}x^3 - 2.4^{-3}x^2 + 9.5^{-2}x - 1.1$), 4.0 to 5.5 mm pupil group ($y = 8^{-6}x^3 - 1^{-3}x^2 + 2.8^{-2}x - 0.1$), and 6.0 to 6.5 mm pupil group ($y = -5^{-7}x^3 + 2^{-4}x^2 - 2.7^{-2}x - 0.6$). Standard deviation error bars were omitted for clarity. Typical standard deviation values ranged from 0.03 to 0.05. The y -axis on the right shows Snellen feet equivalent of visual acuity.

In the current study, we assessed the visual performance of the ReSTOR IOL taking into account pupil diameter. We found the corrected distance acuity was best with large pupil diameters. This result is in keeping with the relative light-energy distribution of the ReSTOR IOL.²³ Light energy for distance and near power is equally distributed up to 2.0 mm of pupil diameter. However, for large pupil diameters, more energy is provided for the distance focus (peripheral refractive region of the IOL, which directs light only to the distance focus), improving distance acuity. In contrast, best distance-corrected near acuity was worse with large pupil diameters (Figure 1, B). The relative energy for near power is reduced as pupil diameter increases.²³ Theoretically, a wide pupil should affect depth of focus, leaving the best distance-corrected near acuity unchanged. However, the energy light distribution between the distance focus and near focus seems to have more weight clinically than the depth of focus. The worst best distance-corrected near acuity (approximately J5) was obtained with the largest pupil (6.5 mm), which corresponds to less than 10% of relative energy at near power. For near vision, patients with large pupil diameters may benefit from increased lighting (light miosis).

It is helpful to correlate distance vision results and near vision results to find the photopic pupil size that provides the optimum distance and near visual acuities, as seen in Figure 4, which shows the trends in distance and near acuities and how both correlate with pupil size. Two similar trends, 1 positive and 1 negative, correlate visual acuities with pupil diameter.

The cross point between the 2 trends, about 3.75 mm, indicates the pupil diameter that balances distance and near visual acuities. Patients with values smaller than 3.75 mm have better near than distance visual acuity and vice versa. The relative energy between the distance and near powers makes the equal distribution between the 2 foci at approximately 2.00 mm. However, the visual results in our study move the balance (in terms of visual acuity) to approximately 3.75 mm. Perhaps the effects of higher-order optical aberrations of the whole eye (cornea plus IOL) or corneal astigmatism make this pupil size more able to limit the defocused light for both foci under photopic and mesopic conditions. In addition, but not considered here, are factors such as the neural system^{1,2} (ie, brain adaptation or eye dominance^{24,25}) that affect visual function with refractive multifocal IOLs.

There was statistically significant worsening of binocular visual acuity as a function of the distance of the test. However, better intermediate visual performance is expected with multifocal IOLs than with monocular IOLs. Souza et al.²⁰ found that binocular distance-corrected intermediate visual acuity was better in patients with the ReSTOR IOL than in patients with the monofocal AcrySof SA60AT IOL (Alcon) at 50 cm, 60 cm, and 70 cm. Note how the cubic trend changes as a function of the pupil group. At near vision (33 to 40 cm), the small pupil group (2.0 to 3.5 mm) had the best values and the large pupil group (6.0 to 6.5 mm), the worst values. This changed when the distance increased from 50 to 70 cm, at which the large-pupil group had better visual acuity than the small-pupil group. There is a cross point between the 3 cubic trends at

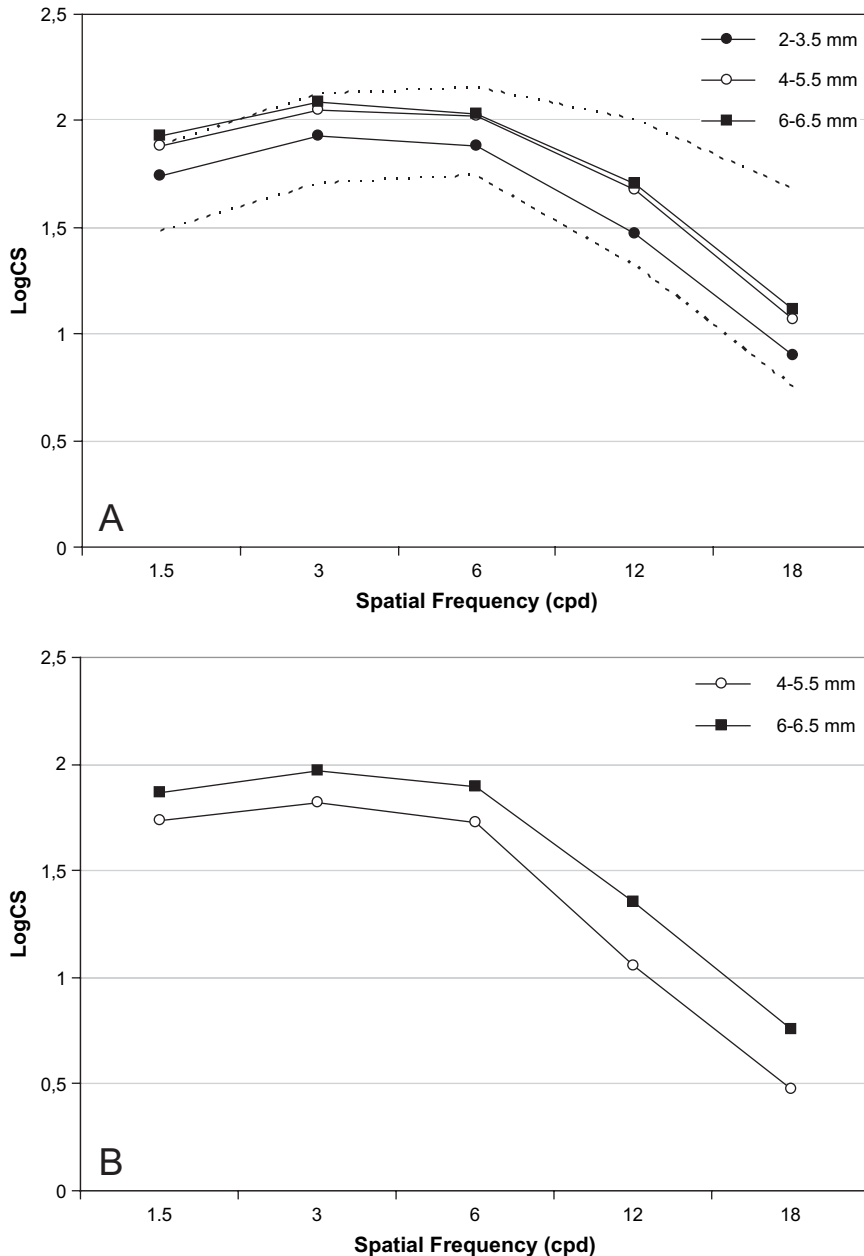


Figure 3. Distance contrast sensitivity functions as a function of pupil size under photopic (85 cd/m^2) conditions (A) and mesopic (5 cd/m^2) conditions (B). All patients showed a pupil diameter equal or larger than 4-mm under mesopic conditions. *P* values are shown for photopic conditions: above 6.0 to 6.5 mm versus 4.0 to 4.5 mm groups and below 4.0 to 5.5 mm versus 2.0 to 3.5 mm (A); and mesopic conditions: 6.0 to 6.5 mm versus 4.0 to 4.5 mm groups (B). Standard deviation error bars were omitted for clarity. Typical standard deviation values ranged from 0.04 to 0.07. The dotted lines in A indicate the upper and lower normal photopic contrast sensitivity range.

approximately 45 cm. Despite the pattern shown in Figure 3, the only statistically significant differences were between the extreme pupil groups (2.0 to 3.5 mm and 6.0 to 6.5 mm) at 60 cm. We believe the reason there were no differences between the 3 groups at near distances was pupil miosis at near; there was a reduction in distance of approximately 0.5 to 1.0 mm depending on the patient and the visual task. This reduction may overlap original pupil size groups and thus modify the relative energy distribution between distance and near foci. The differences at 60 cm might be explained by the different relative energy

distributions between the extreme pupil groups. This does not seem plausible at a distance of 70 cm, where no significant differences were found between groups. This suggests that the behavior can be explained by the location of the distance and near foci in relation to the retina's plane (balance between in-focus image and out-focus image) rather than the relative energy distribution for both foci. Visual acuities at greater distances (ie, 80 cm, 90 cm) should be evaluated to corroborate this hypothesis.

In general, the progressive change in relative energy for the distance and near foci as a function of pupil

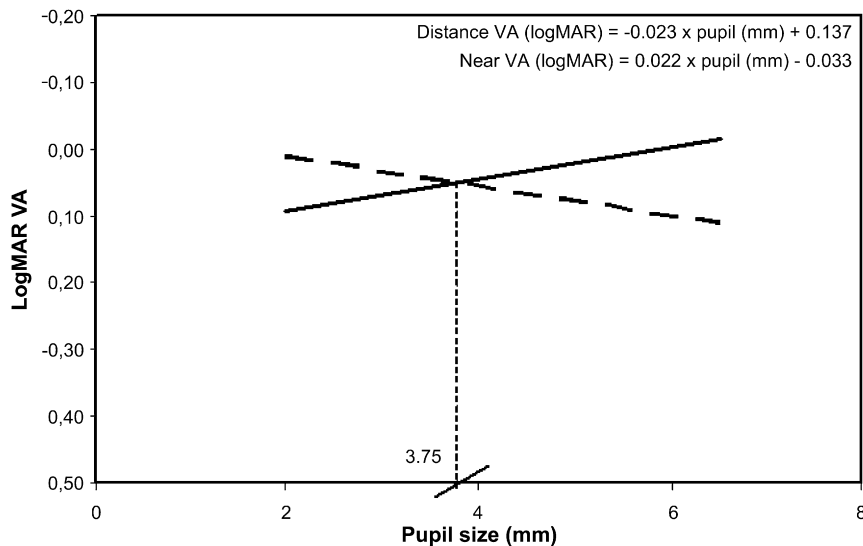


Figure 4. Best corrected distance acuity (logMAR) and best distance-corrected near acuity (logMAR). Continuous and dashed lines represent the best linear trend for distance acuity and near acuity, respectively (equations depicted in graph). Data points were omitted for clarity. (See Figure 2 for a full description.)

size,²³ 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 at 33 cm to approximately 20/50 at 70 cm. Considering the general tendencies and the differences between groups, it seems reasonable to attribute the change in visual acuity to the changes in pupil size, the analogous changes in relative energy for both foci, and the location of the distance and near foci in relation to the retina's plane.

Clinical feedback on visual quality at intermediate vision can be assessed by the use of spectacles in patients with the ReSTOR IOL. We administered a patient satisfaction questionnaire to 755 patients with the ReSTOR IOL; 4% reported wearing spectacles for viewing objects at intermediate distance (unpublished data). Taking into account the important role of the pupil in intermediate vision, Figure 5 shows the relationship between photopic and mesopic pupil diameters. Patients who needed glasses for intermediate vision fall within the oval area in the figure. The relative light energy distribution for a 4.0 to 4.5 mm pupil diameter is approximately 80% for the distance focus and 20% for the near focus, leaving near and intermediate vision compromised. Patients with a photopic pupil between 4.0 mm and 4.5 mm and a mesopic pupil between 6.0 mm and 6.5 mm may have compromised intermediate vision. Surgeons should consider this before implanting multifocal IOLs.

In a review of the literature on contrast sensitivity after multifocal IOL implantation, Montés-Micó et al.² found that most studies report photopic contrast sensitivity and mesopic contrast sensitivity are lower with a multifocal IOL than with a monofocal IOL, although the values are within the normal range. The

results in our study of the ReSTOR Natural IOL broadly agree with this. Decreased contrast sensitivity in patients with multifocal IOLs is explained by the multifocal IOL's division of the available light energy in the image between 2 or more focal points.² Light-energy distribution for the ReSTOR Natural IOL depends on pupil diameter and varies from approximately 40% to 90% at far focus and from 9% to 40% at near focus.²³ However, clinical studies, including ours, show that the loss of photopic contrast sensitivity and mesopic contrast sensitivity is somewhat smaller. The effects of ocular longitudinal chromatic and other types of ocular aberration, together with the blending zones of the IOL, may tend to mask the differences in contrast sensitivity.

We also found a reduction in contrast sensitivity when the luminance level was reduced, particularly at higher spatial frequencies. This trend agrees with classic data on the effect of luminance level on contrast sensitivity.²⁶ The 4.0 to 5.5 mm and 6.0 to 6.5 mm pupil groups had better photopic contrast sensitivity than the 2.0 to 3.5 mm pupil group at all spatial frequencies. These differences may be attributed to the effect of the peripheral refractive region of the IOL dedicated to distance vision (from 3.6 to 6.0 mm), which helps distance focus and becomes important with large pupil diameters. Differences between the 4.0 to 5.5 mm pupil group and 6.0 to 6.5 mm pupil group were not significant, probably because the relative light-energy increment between both groups was small (approximately 10%). It seems reasonable to attribute the observed better mesopic contrast sensitivity in the 6.0 to 6.5 mm pupil group to the increase in relative energy distribution at distance focus introduced by the larger pupil diameter; the increase was approximately 10% larger

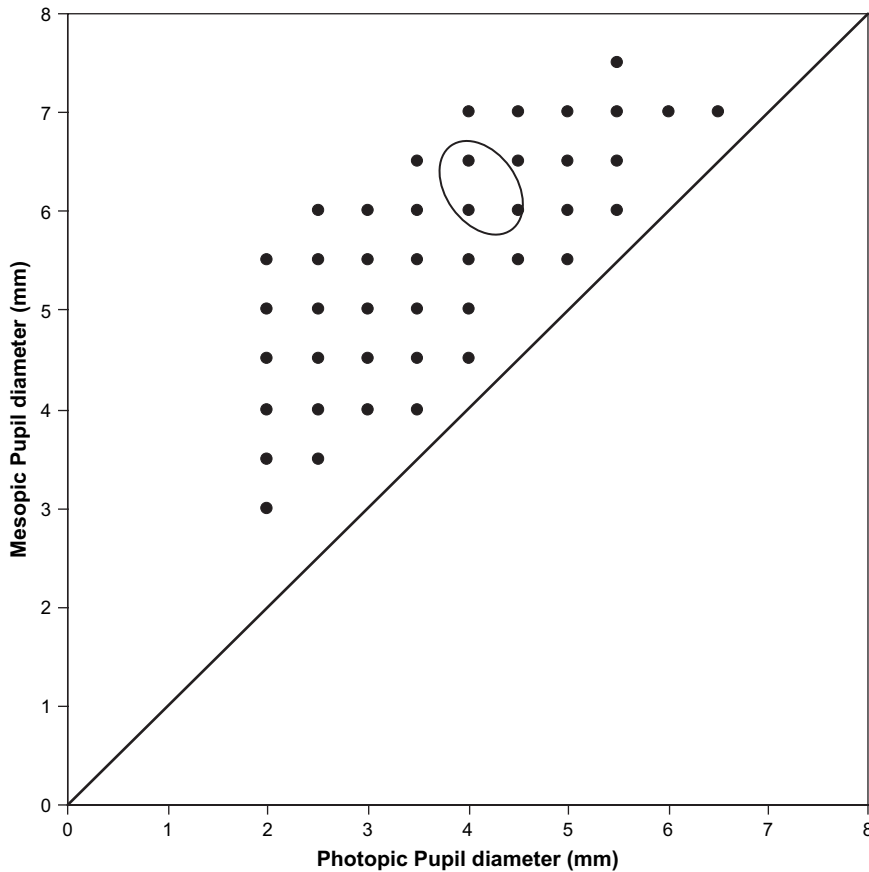


Figure 5. Photopic (85 cd/m^2) versus mesopic (5 cd/m^2) pupil diameters (mm). Oval area represents the pupil diameters in patients who needed spectacles for seeing objects at intermediate vision.

than in the 4.0 to 5.5 mm pupil group. However, the same percentage increase in relative energy is proposed as the origin of the similar results in the 4.0 to 5.5 mm group and 6.0 to 6.5 mm group under photopic conditions. Despite the same percentage increase under both lighting conditions, the visual performance with the ReSTOR IOL may differ as a function of the luminance level. A percentage weighted on a low luminance level becomes more important than the same percentage weighted on a high luminance level. However, this must be confirmed by seeking means to assess a correlation between relative energy and contrast sensitivity.

In conclusion, a larger pupil correlated significantly with better distance visual acuity and worse near visual acuity. Intermediate visual acuity worsened significantly as a function of the distance of the test with all pupil sizes. Pupil size influenced distance contrast sensitivity under photopic and mesopic conditions. Larger pupils had the best distance contrast sensitivity at all spatial frequencies under bright and dim lighting conditions. Further studies are needed to correlate visual performance with optical performance of the ReSTOR Natural IOL and to consider

pupil size to help identify patients for whom multifocal IOLs are indicated.

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