Apodized diffractive versus refractive multifocal intraocular lenses: Optical and visual evaluation

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PURPOSE: To evaluate the optical and visual performance after implantation of refractive or apodized diffractive multifocal intraocular lenses (IOLs).

SETTING: Military Health Service Institute, Warsaw, Poland.

METHODS: Uncorrected distance visual acuity, best distance-corrected visual acuity, best distance-corrected near visual acuity, distance contrast sensitivity under photopic conditions (CSV-1000), residual refractive error, and wavefront aberrations (LADARWave Hartmann-Shack wavefront analyzer) were measured in 23 patients who had bilateral implantation of the AcrySof ReSTOR SN60D3 IOL and 23 patients who had bilateral implantation of the ReZoom IOL….

RESULTS: At the 6-month postoperative visit, the mean photopic uncorrected distance acuity was 0.03 $\pm$ 0.05 (SD) in the ReSTOR group and 0.02 $\pm$ 0.06 logMAR in the ReZoom group (both approximately 20/20) ($P = .569$). In all patients, the mean photopic best distance-corrected acuity was 0.00 logMAR (approximately 20/20) and the mean photopic best distance-corrected near acuity at 35 cm was 0.10 logMAR. The photopic contrast sensitivity was within the standard normal range in both IOL groups. The difference in photopic contrast sensitivity between groups was statistically significant ($P<.001$). Higher-order aberrations, in particular coma and spherical aberrations, were significantly higher in the ReZoom group (all $P<.001$).

CONCLUSIONS: AcrySof ReSTOR SN60D3 and ReZoom IOLs provided good visual performance at distance and near under photopic conditions. Optical quality measures were significantly worse in patients with ReZoom IOLs.

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Advances in intraocular lens (IOL) design have significantly improved the visual outcomes of cataract surgery. Multifocal IOLs are designed to reduce dependence on eyeglasses after cataract surgery, and IOLs are gaining acceptance as potential refractive surgical options in selected patients.

Monofocal IOLs provide excellent visual function; however, their limited depth-of-focus means that for many patients, they do not provide clear vision at both distance and near. Patients with traditional monofocal IOLs usually require glasses for near tasks such as reading. Monovision techniques may be helpful for some patients but can sacrifice binocularity.

The introduction of the multifocal IOL in the early 1980s provided the potential for a range of uncorrected vision from near to far.[1,2] Providing distance and near vision increases the depth of field and improves visual quality at near,[3,4] visual quality that improves with time.[2] Multifocality is the brain's natural ability to adapt to near and far vision as it chooses, based on the object being viewed, between the 2 images (near and far) produced by the optical elements of the IOL. These simultaneous-vision IOLs provide distance, intermediate, and near correction within the area of the eye's pupil. When a person is viewing a distant object, a sharp retinal image is provided by the parts of the

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IOL within the pupillary area that have the distance correction; a somewhat blurred image is provided by the other parts of the IOL as the images are superimposed on the retina. The decrease in contrast of the in-focus image is produced by the split of the total light energy between the far and near focus, while the simultaneous presence (superimposition) on the retina of the in-focus image and out-of-focus image can produce a sort of retinal rivalry or confusion; however, this is overcome by the brain's capability to use multifocality.[5,6] Multifocality theoretically implies that more straylight reaches the retina. However, psychometric measures show that perceived straylight is not different in eyes with monofocal IOLs,[7] thus the importance of brain adaptation.

Much research to improve the performance of multifocal IOLs has been performed. One proposed solution is to direct different amounts of the refracted–diffracted light to the different foci, thus giving preference to distance or near vision,[8,9] or to direct different amounts of light to the different foci depending on pupil diameter.[1,10] However, reduced image contrast and unwanted visual phenomena, including glare and halos, have been associated with multifocal IOLs.[1–3,9–19]

The most recent multifocal IOLs were developed to improve the visual outcomes over those achieved with older designs; however, the visual performance of these IOLs has not been fully evaluated. One of the most popular new-generation diffractive multifocal IOLs is the AcrySof ReSTOR IOL (Alcon). Recent studies[20–24] report satisfactory visual results with this IOL.

The ReZoom (Advanced Medical Optics) is another recent design with the aim of improving visual outcomes. The ReZoom IOL is a multizone refractive multifocal version of the previous Array SA40 IOL. The ReZoom IOL and the Array SA40 IOL are similar but differ in the width of the different refractive areas. Few reports describe visual performance after implantation of ReZoom IOLs[25,26] and, to our knowledge, none discusses the optical performance of the IOL in situ.

The purpose of this retrospective study was to assess the optical and visual performance after bilateral implantation of AcrySof ReSTOR SN60D3 or ReZoom IOLs.

PATIENTS AND METHODS

This retrospective analysis comprised 46 eyes of 23 patients who had bilateral implantation of the AcrySof ReSTOR SN60D3 multifocal IOL (ReSTOR group) and 46 eyes of 23 patients who had bilateral implantation of the ReZoom multifocal IOL (ReZoom group) at the Military Health Service Institute, Warsaw, Poland. The protocols followed the tenets of the Declaration of Helsinki. Institutional review board approval was obtained.

Inclusion criteria were age between 45 years and 75 years, bilateral implantation (chosen based on the visual benefit of bilateral implantation[22,23]), and patient motivation (ie, a desire to no longer wear any form of spectacle or contact lens correction for distance and near). Exclusion criteria included a history of glaucoma or retinal detachment, corneal disease, irregular astigmatism, corneal astigmatism greater than 1.00 diopter (D), previous corneal or intraocular surgery, abnormal iris, pupil deformation, macular degeneration or retinopathy, neuroophthalmic disease, and history of ocular inflammation.

Intraocular Lens Characteristics

The AcrySof ReSTOR SN60D3 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 optical zone of the IOL. This area comprises 12 concentric steps of gradually decreasing (1.3 to 0.2 μm) heights, creating bifocality from near to far (2 foci). The refractive region of the optic surrounds the apodized diffractive region. This area directs light to a distant focal point for a larger pupil diameter 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 IOL power varies from +10.0 to +30.0 D and incorporates a +4.0 D near addition (add).

The ReZoom multizone IOL has 5 concentric refractive zones that refract light toward the main foci. Zones 1, 3, and 5 are distance dominant, and zones 2 and 4 are near dominant. The transitions between the zones are aspherical to provide balanced intermediate vision. The difference in intensity on the focal points makes the ReZoom a distance-dominant IOL. The overall diameter of the IOL is 13.0 mm, and the optic diameter is 6.0 mm. The IOL power varies from +6.0 to +30.0 D and incorporates a +3.5 D near add.

Surgical Technique

All surgeries were performed by the same experienced surgeon (M.R.) using topical anesthesia and a 2.8 mm clear corneal incision. Phacoemulsification was performed with the Infiniti Vision System (Alcon). Phacoemulsification was followed by irrigation and aspiration of the cortex and IOL implantation in the capsular bag.

Postoperative Examinations

All postoperative examinations were performed at 6 months by the same ophthalmic technician. The technician was unaware of the objective of the study and masked to the IOL implanted.

Intraocular Lens Stability Tilt and centration of the IOLs in relation to the visual axis were assessed using Scheimpflug videophotography (EAS-1000, Nidek).

Visual Performance Visual acuity under photopic conditions (85 cd/m^2) was measured using Snellen notation and then converted to logMAR units. Monocular uncorrected distance visual acuity and best distance-corrected visual acuity were measured at 6 m. Monocular best distance-corrected near visual acuity was measured at 35 cm. For near visual acuity measurements, a handheld chart was used following the methodology in previous studies.[22,23] Monocular photopic contrast sensitivity was measured with best distance correction using the CSV-1000 test (VectorVision), which is

Table 1. Patient demographics.

Characteristic	Group: ReSTOR	ReZoom	*P* Value
Eyes (n)	46	46	—
Mean age (y) ± SD	61.4 ± 10.2	60.9 ± 10.8	.82
Sex (M/F)	9/23	11/23	.25

reported to be a reliable method for assessing subtle changes in contrast sensitivity.[27] Absolute values of log contrast sensitivity (logCS) were obtained for each patient, and the spatial frequency and means and standard deviations were calculated. Contrast sensitivity was measured under photopic illumination conditions of 85 cd/m^2, as recommended in the manufacturer's guidelines.

Optical Quality Measures

Wavefront aberrations were measured using the LADARWave Hartmann-Shack wavefront analyzer (Alcon). This system has been extensively assessed and shown to provide repeatable and reliable measures of ocular aberrations in human and model eyes.[28] Because patients were pseudophakic, there was no risk for instrument-induced myopia[29]; thus, mydriatic agents were not given before the examination. Before the examination began, the technician made sure the pupil was at least 5.0 mm. Data from the central 5.0 mm were analyzed following the protocols of other studies.[29,30]

Statistical Analysis

Data analysis was performed using an Excel spreadsheet (Microsoft Corp.). Normality was checked by the Shapiro-Wilk test, and *t* tests were performed to compare the 3 IOL groups. Differences were considered to be statistically significant when the *P* value was less than 0.01 (ie, at the 1% level). The statistical significance of differences between the 2 groups in contrast sensitivity (absolute logCS values) at each frequency was assessed with a *t* test.

RESULTS

Table 1 shows the demographics of the 46 patients in the study. There were no statistically significant differences between the 2 IOL groups in age or sex. There were no intraoperative complications in any case. After surgery, the pupils in all eyes were round and showed good responsiveness to light. There were no cases of iris trauma.

Intraocular Lens Stability

Intraocular lens centration was good in all eyes. None of IOLs was tilted.

Visual Performance Measures

Table 2 shows the visual performance results. In all patients, the mean photopic best distance-corrected acuity was 0.00 logMAR and the mean best distance-

Table 2. Visual acuity and contrast sensitivity results

	Mean ± SD: ReSTOR Group	ReZoom Group	*P* Value
UCVA (logMAR)	0.03 ± 0.05	0.03 ± 0.06	.569
MSE	−0.04 ± 0.26	−0.13±0.25	.071
BDCVA (logMAR)	0.00 ± 0.00	0.00 ± 0.01	—
BDCNVA (logMAR)	0.10 ± 0.00	0.10 ± 0.00	—
LogCS			
3 cpd	1.50 ± 0.02	1.44 ± 0.03	.081
9 cpd	1.50 ± 0.02	1.43 ± 0.03	.035*
12 cpd	1.26 ± 0.04	1.26 ± 0.03	.861
18 cpd	0.98 ± 0.05	0.98 ± 0.04	.976

BDCNVA = best distance-corrected near visual acuity; BDCVA = best distance-corrected visual acuity; cpd = cycles per degree; CS = contrast sensitivity; MSE = mean spherical equivalent; UCVA = uncorrected distance visual acuity

*Statistically significant at α 0.05

corrected near acuity, 0.10 logMAR. The mean uncorrected distance acuity under photopic conditions was 0.03 ± 0.05 logMAR in the ReSTOR group and 0.02 ± 0.06 logMAR in the ReZoom group (both approximately 20/20); the difference between groups was not statistically significantly different (*P* = .569).

Figure 1 shows the mean logCS values plotted as a series of contrast sensitivity functions. Under photopic conditions (85 cd/m^2), performance was very similar between the 2 groups and was close to, although lower than, the standard contrast sensitivity function. The difference in distance photopic logCS between the 2 IOL groups was not statistically significant at any spatial frequency (*P*>.1).

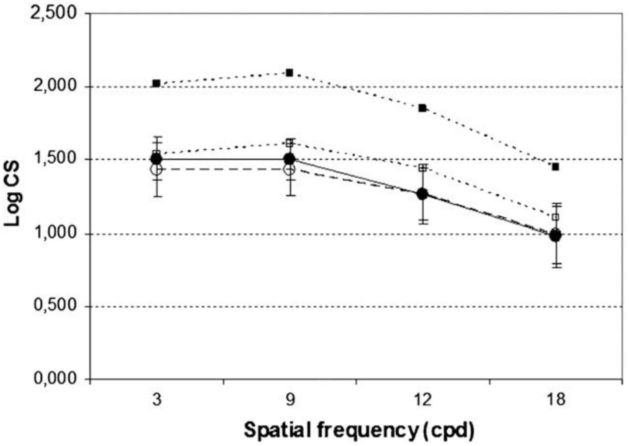

Figure 1. Contrast sensitivity as a function of spatial frequency in the ReSTOR group (*solid circles, solid line*) and ReZoom group (*empty circles, dashed line*). The solid squares represent normal values and the empty squares, the logCS values with the monofocal SI-40NB IOL (PhacoFlex II, Allergan Advanced Medical Optics).[24] Error bars represent 1 standard deviation.

Table 3. Higher-order aberrations results with a 5.0 mm pupil.

	Mean (μm) ± SD		
Postoperative Parameter	ReSTOR Group	ReZoom Group	*P* Value
HOA RMS	−0.26 ± 0.01	−0.48 ± 0.07	≤.001*
Coma RMS	0.12 ± 0.01	0.23 ± 0.03	≤.001*
Spherical aberration RMS	0.09 ± 0.00	0.15 ± 0.01	.001*
Total aberration RMS	0.68 ± 0.08	1.80 ± 0.19	≤.001*

HOA = higher-order aberration; RMS = root mean square
*Statistically significant at α = .001

Optical Quality Measures

Table 3 shows the optical quality results. The residual mean spherical equivalent 6 months after the surgery was not statistically significantly different between the 2 IOL groups ($P>.05$). Patients in the ReZoom IOL group had slightly higher levels of residual ametropia.

Differences in higher-order aberrations, mainly coma and spherical aberration, were statistically significantly different between the 2 groups. Patients in the ReZoom IOL had statistically significantly more coma and spherical aberration than those in the ReSTOR group ($P\leq.001$, all cases).

DISCUSSION

Multifocal IOLs alleviate the symptoms of presbyopia by providing some functional near vision by increasing the depth of field of the eye. Depending on the multifocal technology (diffractive or refractive) of current IOLs, different visual outcomes are achieved at far, near, and intermediate distances. From an optical viewpoint, diffractive multifocal IOLs have optical properties that are comparable to the distance vision properties of refractive multifocal IOLs but are better for near vision.[31] However, the optical properties of commercially available IOLs depend on the design and cannot be classified as refractive or diffractive. The AcrySof ReSTOR SN60D3 IOL combines diffractive and refractive optics, whereas the ReZoom is a multizone refractive multifocal IOL.

Visual Performance

In our retrospective study, postoperative best distance-corrected visual acuity was excellent in both the ReSTOR and ReZoom groups; all patients achieved an acuity of approximately 20/20. The uncorrected distance acuity under photopic conditions was also good in all patients. There was a slight difference in photopic contrast sensitivity between the ReSTOR and ReZoom groups, mainly at low spatial frequencies; however, the values were lower than normal in both IOL groups. These differences would change under low-light conditions; future study of this is needed.

The visual performance results in the ReSTOR group agree with those in previous studies of the IOL. Kohnen et al.[22] report similar binocular uncorrected distance acuity and best distance-corrected acuity in 118 patients 120 to 180 days after implantation of the AcrySof ReSTOR IOL. The mean best distance-corrected acuity in their study was −0.05 logMAR (>20/20); all patients had an acuity of 20/40 or better, and 97.5% had an acuity of 20/25 or better. Souza et al.[23] found a mean monocular best distance-corrected acuity of 0.02 ± 0.17 logMAR in 25 patients 120 to 180 days after implantation of the AcrySof ReSTOR SA60D3 IOL. Alfonso et al.[24] report similar results in a large sample of patients.

We could find only 2 studies of the visual performance after implantation of ReZoom IOLs. Both studies found that the AcrySof ReSTOR IOL provided better near vision than the ReZoom IOL,[25,26] and one study[26] found that the ReZoom IOL provided better near vision. In the present study, the 2 IOLs performed equally well under photopic conditions at distance and near.

According to a review by Montés-Micó et al.,[1] several studies have evaluated photopic contrast sensitivity after multifocal IOL implantation. The main literature reports that photopic contrast sensitivity with a multifocal IOL is worse than with a monofocal IOL, although it is still within the normal range. Our results for the AcrySof ReSTOR SN60D3 IOL and ReZoom IOL broadly agree with this (Figure 2). The decreased contrast sensitivity with multifocal IOLs over that 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.[1] The different technology (refractive or diffractive) and optical design of multifocal IOLs result in different contrast sensitivity values. Approximately 50% of the light energy in the full-aperture Array SA-40N IOL, which is similar to the ReZoom IOL but with broader refractive

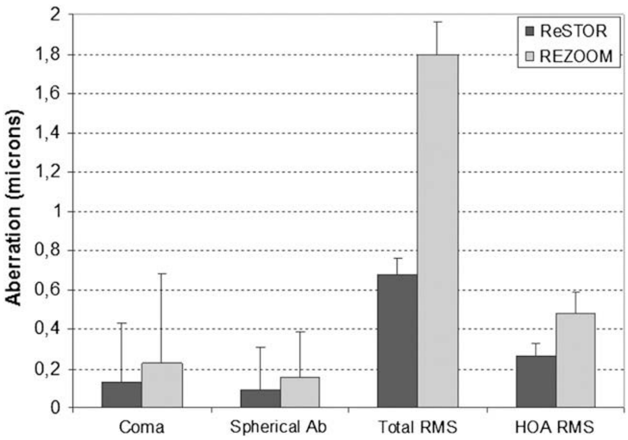

Figure 2. Histogram of the mean and standard deviation wavefront aberrations (μm) with a 5.0 mm pupil in the ReSTOR and ReZoom groups.

zones, is concentrated at the far focus, and approximately 20% is at near focus.[8] Light-energy distribution in the AcrySof ReSTOR IOL depends on pupil diameter and varies from approximately 40% to 90% at far focus and from 9% to 40% at near focus.[32] Given the variation in the light-energy percentage, the role of pupil size is significant in the visual performance of multifocal IOLs. However, clinical studies show that the loss of photopic contrast sensitivity is somewhat smaller, maybe due to the effects of ocular longitudinal chromatic and other types of ocular aberration together with the IOL's blending zones.

Studies[1,24] have found that patients with multifocal IOLs have worse contrast sensitivity under dim conditions, a finding that agrees with classic reports of the effect of luminance level on contrast sensitivity.[33] In the present study, photopic contrast sensitivity was similar with both IOL models, although it was slightly worse at lower spatial frequencies in the ReZoom group. Photopic contrast sensitivity was lower than normal values in both IOL groups (Figure 2).

In our study, near visual acuity under photopic conditions (85 cd/m^2) was also good in both IOL groups; all eyes had best distance-corrected near acuity of 20/25 at 6 months. Our near acuity results agree with those in another study of the AcrySof ReSTOR IOL by Alfonso et al.[24] Kohnen et al.[22] report a lower percentage of patients (83.9%) with 20/25 or better binocular best distance-corrected near acuity after implantation of the AcrySof ReSTOR SA60D3 IOL. Souza et al.[23] also report different results for near vision because they examined visual acuity by locating the near chart at the best distance for the patient instead of a standard distance. A recent report by Chiam et al.[26] showed that patients with bilateral AcrySof ReSTOR IOLs performed better at near distance than patients with ReZoom IOLs, whereas the ReZoom IOL provided better intermediate distance vision. Vision for distance with both IOLs was reported to be excellent. Pepose et al.[25] found that with monocular or bilateral implantation, near vision was better with the AcrySof ReSTOR IOL than with the ReZoom IOL.

It is well know that near visual performance with a multifocal IOL is better than that with a monofocal IOL.[1,16,34] Montés-Micó and Alió[2] found that near contrast sensitivity with the Array multifocal IOL improved over time but was always lower than at distance and than in the monofocal near-corrected group. Alfonso et al.[24] report that binocular best corrected visual acuity for distance and for near with AcrySof ReSTOR IOLs was comparable. The percentage of light energy for near focus under photopic conditions (85 cd/m^2) in the AcrySof ReSTOR IOLs seems to be enough to provide good near visual acuity (approximately 20/20). Lighting conditions and miosis may contribute to a balanced relative energy between the distance focus and near focus, which provides comparable distance and near visual acuity in these patients. Kawamorita and Uozato[34] found low modulation transfer functions at intermediate focus at all effective pupil diameters with the refractive multifocal Array IOL. Pupil size and IOL design play an important role in intermediate visual performance in patients with diffractive IOLs.[24] In our retrospective analysis, we did not include pupil size, which is a drawback of the study and should be included in future assessments of visual performance. This is of special relevance in future studies assessing the ReZoom IOL because at present, there is no report of the IOL's behavior in relation to pupil size. These issues, along with measures of visual performance under mesopic conditions, should be addressed in future studies.

Optical Performance

Theoretical predictions suggest that multifocal IOLs will induce more scatter than monofocal IOLs.[35] Dick et al.[36] did not find statistically significant differences in contrast sensitivity between monofocal IOLs and multifocal IOLs; however, they found halos were larger in patients older than 70 years in the multifocal group. Dick et al. concluded that in addition to IOL design, age and corneal surface quality have an important effect on scatter values. A recent report by Cerviño et al.[7] concluded that despite the theoretical differences in intraocular scatter induced by the different IOLs, perceived retinal straylight was not different between patients with monofocal IOLs and patients with multifocal IOLs. Furthermore, retinal straylight values were not different between the AcrySof ReSTOR IOL and ReZoom IOL. This finding implies that the brain plays the most important role in overcoming optical quality defects resulting from IOL design. Chiam et al.[26] found, however, that patients with ReZoom IOLs reported more glare and halos than those with AcrySof ReSTOR IOLs, although differences were not significant.

These differences in design could account for the differences in wavefront aberrations observed. In our study, the total root mean square (RMS) and higher-order RMS, mainly for coma and spherical aberration, were considerably higher with the refractive multifocal IOL. Hayashi et al.[10] report that the degree of IOL decentration in relation to pupil correlates with both distance and intermediate visual acuities but not with near visual acuity. Intraocular lens decentration could account for some of the differences in coma aberration between the 2 IOLs in our study. Rocha et al.[20] also report lower spherical aberration values with the AcrySof ReSTOR than with 3 monofocal IOLs (MA30AC and SA60AT, Alcon, and Acqua, Mediphacos), behaving like an aspherical IOL. The results in our study agree with those of Rocha et al.[20]; that is, that spherical aberration values were lower with the apodized diffractive IOL than with the refractive multifocal IOL.

The results obtained by the Hartmann-Shack aberrometer must be interpreted with care when examining multifocal IOLs, in particular diffractive IOLs. 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 is between 70% and 85% to the distance focus and between 15% and 10% to the near focus with a pupil diameter of 3.8 mm and 5.4 mm, respectively.[32] This unequal light distribution between the distance focus 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 to only the distance focus. Recently, Charman et al.[37,38] suggested that there are possible problems when reporting wavefront aberration data for eyes with diffractive IOLs. The simultaneous distribution of light on the far and near foci means that 2 wavefronts of different curvature emerge from the IOL. This could make it difficult for the aberrometer to locate the sample centroids, from which derive the aberration values. According to Charman et al.'s results for longer wavelengths, diffractive efficiency falls and, therefore, Hartmann-Shack aberrometers that use longer wavelengths of infrared light are more likely to produce satisfactory results for eyes with diffractive IOLs. This was proven for the LADARWave system used in the present study; studies[37,38] have concluded that the system provides satisfactorily accurate and reliable measurement of aberrations in eyes with diffractive IOLs. This may not be the case for other aberrometers, and this should be taken into account in future studies that reference previous work on aberrometry and diffractive IOLs.

Quality-of-life studies[22–24] report a high level of satisfaction in patients with the AcrySof ReSTOR IOL. The importance of the role of the AcrySof ReSTOR's apodized (step-height blending) diffractive optic is not clear. Apodization reduces the lost of light because of the higher orders of diffraction and allows a smooth transition of the distribution of light energy between the distance and the near focal points. Thus, image quality at both foci should be improved, minimizing visual disturbances such as glare or halos.

CONCLUSION

Both the AcrySof ReSTOR SN60D3 and ReZoom multifocal IOLs provided a satisfactory photopic range of vision in terms of visual acuity and contrast sensitivity under bright illumination conditions. Differences in optical performance of both IOLs would be manifest in visual performance under mesopic conditions. Patients should be selected for a particular IOL design based on their visual demands and activities, and pupil diameter should be taken into account. In addition to careful patient selection, surgeons should perform preoperative measurements, use proper intraoperative technique, and provide appropriate postoperative management to achieve the best visual performance after multifocal IOL implantation. Future studies assessing the visual performance under dim lighting conditions are needed for a more strict comparison between the 2 IOLs and to assess the impact of optical quality measures on visual performance of multifocal IOLs of different design.

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