Visual performance and biocompatibility of 2 multifocal diffractive IOLs

Six-month comparative study

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PURPOSE: To evaluate the distance and near functional capacity, wavefront error and biocompatibility in patients with 2 diffractive multifocal intraocular lenses (MIOLs).

SETTING: Ophthalmology Department of Chieti-Pescara University (Italy).

METHODS: This prospective study comprised 28 eyes of 28 senile cataract patients having phacoemulsification and implantation of the Tecnis ZM900 MIOL (Group 1) and the AcrySof ReSTOR MIOL (Group 2). The main outcome measures, over a 6-month follow-up period, were spherical equivalent, distance visual acuity at high and low contrast, near visual acuity, and defocus curve. Wavefront error was evaluated in both groups. Capsule opacification was also assessed.

RESULTS: The high and low contrast uncorrected and best corrected visual acuity for distance did not show statistically significant differences between the 2 groups. The distance corrected near visual acuity was 1.86 $\pm$ 1.66 in Group 1 and 1.93 $\pm$ 1.12 in Group 2. The depth of focus was 4.5 diopters in both groups. The root mean square of total aberration and of spherical and coma aberrations were significantly lower in Group 1 than in Group 2. A higher percentage of patients with Tecnis MIOLs showed a more severe grade of anterior fibrosis. Posterior opacification was minimal and not significantly different between the 2 groups.

CONCLUSION: Diffractive MIOLs were effective in improving functional capacity for distance and near and provided a good quality of vision due to a significant reduction in spherical aberration, particularly in the Tecnis MIOLs. The higher capsular biocompatibility of the ReSTOR MIOL compared with the Tecnis MIOL could ensure long-term stability.

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The restoration of near functional capacities is one of the main challenges of modern cataract refractive surgery and refractive lens exchange. Several approaches have been attempted to correct presbyopia after crystalline lens removal based on the implantation of conventional monofocal intraocular lenses (IOLs) such as the monovision strategy and bilateral myopization; however, problems with binocular vision and loss of stereopsis have limited the use of these procedures.[1] Consequently, multifocal IOLs (MIOLs) were designed to provide good uncorrected distance and near vision.[1]

Multifocal IOLs have proved to be effective in ensuring distance and near visual performance because they produce a variable number of foci, either finite or infinite, depending on the lens design.[2–4] However, the light dispersion due to refractive or diffractive optics leads to undesirable symptoms such as glare, halos, and reduction of contrast sensitivity.[5–7] Moreover, the spherical design of the commercially available MIOLs leads to an increase in the overall spherical aberration of the eye due to a disruption of the cornea–lens balance. This is responsible for a degradation in the retinal image quality and thus in the quality of vision.[8]

Recently, 2 diffractive MIOLs with technical innovations have been developed to improve the visual performance of patients (T. Kohnen, MD, "New Multifocal Offers Broad Range of Multifocality," presented at the XXII Congress of the European Society of Cataract and Refractive Surgeons, Paris, France, September 2004; I.H. Fine, MD, "New IOL Designs Offer New Possibilities in the Treatment of Cataract Patients and Presbyopes," EuroTimes, December 2003). The new

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apodized diffractive AcrySof ReSTOR (Alcon Laboratories, Inc.) was designed to achieve distance, intermediate, and near visual acuity without compromising visual performance because of apodization, ie, reduction in the height of the diffractive steps from the center to the periphery and combination of a diffractive–refractive design in the IOL optic. The Tecnis ZM900 (Advanced Medical Optics, Inc.) is an aspheric multifocal diffractive IOL that produces a negative spherical aberration to balance the positive spherical aberration of the cornea. Our study evaluated the long-term efficacy of these 2 diffractive MIOLs by determining their distance and near visual performance and capsule biocompatibility.

PATIENTS AND METHODS

Patients scheduled for cataract surgery from November 2005 to March 2006 were enrolled in this 6-month comparative clinical trial. The inclusion criteria were age between 50 and 75 years, axial length between 23.0 mm and 24.0 mm, and corneal preoperative astigmatism less than 1.0 diopter (D). The exclusion criteria were anterior segment pathological alterations such as chronic uveitis, zonular dialysis, pseudoexfoliation syndrome, glaucoma, and diabetes; other ocular pathologies impairing visual function; previous anterior or posterior segment surgery; and intraoperative or postoperative complications.

Patients were included if both eyes matched the inclusion and exclusion criteria because of the possibility of future bilateral implantation. They were randomized into 2 groups and implanted with 2 multifocal diffractive IOLs. Group 1 received the Tecnis ZM900 and Group 2, the AcrySof ReSTOR.

The multifocal Tecnis ZM900 is a 3-piece silicone IOL with a 6.0 mm optic with a modified prolate anterior surface designed to produce negative spherical aberrations and a diffractive posterior surface. The AcrySof ReSTOR IOL has a single-piece 6.0 mm biconvex optic of hydrophobic flexible acrylic material with a central 3.6 mm apodized diffractive design and a peripheral refractive area. Apodization allows gradual tapering of the diffractive steps from the center to the outside edge of the IOL to create a smooth transition of light between the distance, intermediate, and near focal points. This is obtained by means of a precise reduction in step heights from 1.3 to 0.2 μm. The outer ring of the AcrySof ReSTOR IOL, which surrounds the apodized diffractive region, is dedicated to focusing light for distance vision.

In all cases, standardized uneventful small-incision phacoemulsification with IOL implantation was performed by the same surgeon (L.M.). After a 3.2 mm clear corneal tunnel was made, a curvilinear capsulorhexis was created. Phacofracture in the capsular bag was followed by automated irrigation/aspiration of the cortical remnants. The IOL was implanted in the capsular bag, and the incision was not sutured. The postoperative therapy consisted of ofloxacin 0.3% and dexamethasone 0.2% eyedrops 4 times daily for 3 weeks.

Patients were examined over a 6-month follow-up period. The main outcome measures were spherical equivalent (SE) cycloplegic subjective refraction, uncorrected distance visual acuity (UCDVA) at high and low contrast, best corrected distance visual acuity (BCDVA) at high and low contrast, distance corrected near visual acuity (DCNVA), best corrected near visual acuity (BCNVA), near addition (NA), and defocus curve. The root-mean-square (RMS) of total higher-order aberrations (RMS HOA, RMS Z_4^0, RMS Z_3^1, and RMS Z_3^3) and Zernike coefficients of the 4th-order spherical aberration (Z_4^0) were evaluated in both groups. In addition, at each visit, the pupil was dilated and the anterior and posterior capsules were examined to establish the presence of anterior and posterior capsule opacification (ACO and PCO, respectively). The scheduled examinations of the main parameters were at 30, 90, and 180 days.

High and Low Contrast Visual Acuity Evaluation

High contrast logMAR visual acuity with or without best spectacle correction and low contrast logMAR (10% of maximum contrast) visual acuity with or without best refraction in place were measured using the ZyQV kit (Zyoptix Quality of Vision, Technolas Bausch & Lomb). Each patient was asked to read the chart until 4 letters were missed in the smallest line. The final visual acuity was calculated by multiplying the logMAR value of each letter (0.02) by the number of misread letters and adding this value to the smallest line read.

Defocus Curve and Depth of Focus

A defocus curve for each MIOL was obtained by plotting the mean of visual acuity with 14 values of defocus (from +2.0 to −5.0 D). The depth of focus was calculated as half the values with visual acuity better than 0.3 logMAR at different defocus values.

Wavefront Aberration Analysis and Ablation Profile Calculation

The HOA were measured using the WASCA Wavefront Analyzer aberrometer (Carl Zeiss Meditec) based on the principle of the Hartmann-Shack wavefront sensor technique, as described.[9]

The WASCA aberrometer defines and calculates aberrations in terms of Zernike polynomials up to the 4th order. The 3rd (Z_3^1, Z_3^{-1}, Z_3^3, Z_3^{-3}) and 4th (Z_4^0, Z_4^2, Z_4^{-2}, Z_4^4, Z_4^{-4}) order aberrations were expressed as Zernike coefficients and were measured in microns. The total high-order wavefront error (from 3rd to 4th) was expressed in RMS, representing the mean of the square root of the wavefront errors measured in microns.

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Aberration measurements were obtained at the baseline preoperative visit and during scheduled follow-up examinations after pupil dilation with phenylephrine chlorhydrate and tropicamide (Visumidriatic fenilefrina). In each patient, 5.0, 6.0, and 7.0 mm pupil diameters were chosen as reference pupil diameters to obtain comparable data. The RMS of total HOAs and of single 3th-order coma (Z_3^1, Z_3^{-1}), 3rd-order trefoil (Z_3^3, Z_3^{-3}), and 4th-order spherical (Z_4^0) aberrations were calculated at each control for each patient examination as the mean value of 3 reliable consecutive measurements. In addition, the Zernike coefficient of 4th-order spherical (Z_4^0) aberration at 5.0, 6.0 and 7.0 mm pupil diameters was calculated in each patient.

Capsule Fibrosis Assessment

Focal and retroillumination photographs were obtained with maximum pupil dilation using a Tomey video slitlamp to evaluate ACO, and digital retroillumination photographs were obtained with the same equipment to evaluate PCO. All digital images were transferred to a personal computer and stored on a hard disk for later evaluation.

All findings were analyzed by the same observer. The ACO was subjectively graded from 0 to 2: 0 = none, 1 = moderate (mild opacification not involving the entire capsulorhexis), 2 = severe (complete whitening of the capsule over the IOL optic). The intensity of central PCO (behind the IOL optic) was subjectively scored from 0 to 4: 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe.

Statistical Analysis

The study was designed to show the lower increment of wavefront error obtainable with the Tecnis ZM900 IOL compared with the AcrySof ReSTOR IOL in RMS HOA reduction 6 months after surgery. Assuming a difference of at least 0.12 μm in RMS HOA, using a 1-sided *t* test for unpaired data at a level of 0.05 with 80% power and the common standard deviation of 0.10 μm, at least 24 patients were required.

All statistical analysis was performed using nonparametric tests. The comparison between age and visual and aberration parameters for each IOL was performed using the Mann-Whitney *U* test. The same test was applied for a statistical comparison of the mean visual acuity for each defocus value for 2 IOLs. A Bonferroni correction for multiplicity (14 pairwise comparisons of visual acuities at different distances with the corresponding defocus points) was applied. The significance level was therefore reduced to 0.008 ($\alpha/14 = 0.05/14 = 0.003$).

Cross-tabulation analyses were conducted to assess the relationship between IOL groups and the presence of inflammatory cells (ACO or PCO). The Fischer exact test was used to assess the statistical significance of differences in the percentage of eyes with either ACO or PCO.

All statistical tests were evaluated at an alpha level of 0.05. Statistical analysis was performed using SPSS Advanced Statistical 11.0 software (SPSS Inc.).

RESULTS

The study comprised 28 eyes of 28 patients. In Group 1 (n = 14), there were 6 men and 8 women; the mean age was 60.86 years ± 6.64 (SD) (range 52 to 71 years). In Group 2 (n = 14), there were 5 men and 9 women; the mean age was 60.79 ± 7.11 years (range 52 to 72 years). The between-group difference in age and sex was not statistically significant.

Visual Outcome

At 6 months, the high and low contrast distance visual acuity between the groups was not statistically significant. The DCNVA was 1.86 ± 1.66 in Group 1 and 1.93 ± 1.12 in Group 2 ($P = .454$). The BCNVA was J1 in 100% of cases in both groups (Table 1).

The defocus curve showed a good functional capacity for distance and near visual performance, with a slight visual decadence in the middle distances (Figure 1). The depth of focus was 5.5 D in Group 1 and 5.0 D in Group 2, and the amplitude of functional vision (0.3 logMAR or better) was 4.5 D in Group 1 (from optical infinity to 25 cm) and 4.0 D in Group 2 (from optical infinity to 25 cm) with a functional vision worse than 0.3 at 50 cm.

Group 1 had significantly better intermediate distance (at 50 cm) and worse near distance (from 0.25 to 0.28 cm) than Group 2.

Refractive Outcome

The mean SE at 6 months is shown in Table 1.

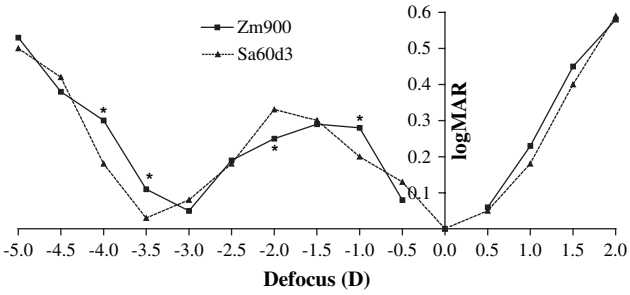
Wavefront Error

The RMS of HOAs and of spherical and coma aberrations and the Zernike coefficient of spherical aaberration were different in the 2 groups. In particular, RMS HOA, RMS Z_4^0, RMS Z_3^1, and Z_4^0 were significantly lower in Group 1 than in Group 2 at 5.0 mm and 6.0 mm of analysis (Table 2).

Table 1. Visual parameters for the 2 MIOLs at 6 months.

Variable	Group 1 (n = 14)	Group 2 (n = 14)	*P* Value*
SE	0.26 ± 0.38	−0.16 ± 0.27	.001
HUCDVA	0.16 ± 0.22	0.13 ± 0.12	NS
HBCDVA	−0.01 ± 0.08	0.00 ± 0.00	NS
LUCDVA	0.51 ± 0.21	0.50 ± 0.11	NS
LBCDVA	0.40 ± 0.18	0.33 ± 0.09	NS
DCNVA	1.86 ± 1.66	1.93 ± 1.12	NS
BCNVA	1.00 ± 0.00	1.00 ± 0.00	NS
Add	0.39 ± 0.63	0.68 ± 0.86	NS

Means ± SD
BCNVA = best corrected near visual acuity; DCNVA = distance corrected near visual acuity; HUCDVA = high contrast uncorrected distance visual acuity; HBCDVA = high contrast best corrected distance visual acuity; LUCDVA = low contrast uncorrected distance visual acuity; LBCDVA = low contrast best corrected distance visual acuity; SE = spherical equivalent
*Mann-Whitney *U* test ReSTOR versus Tecnis



* p<0.05; ** p<0.01 Mann-Whitney U test Sa60d3 vs Zm900

Figure 1. Visual acuity at various defocus levels in Groups 1 and 2. The values are a mean of logMAR visual acuity.

Capsule Biocompatibility

At 6 months, the percentage of patients with grade 1 ACO was 7.1% in Group 1 and 78.6% in Group 2 (Figure 2, *left*); the percentage with grade 2 ACO was 92.8% and 21.4%, respectively. The difference between the 2 IOLs was statistically significant for anterior fibrosis ($P<.001$, chi-square test). The percentage of patients with PCO was 28.6% in Group 1 and 21.4% in Group 2 (difference not significant) (Figure 2, *right*).

DISCUSSION

The ability to focus at varying distances is lost after cataract surgery with monofocal IOL implantation. Multifocal IOLs were designed to provide both distance and near vision without additional spectacle correction as they form separate images of near and distance objects. The goal of MIOLs is to enable patients to be less dependent on spectacles following surgery.

Table 2. Aberrometric parameters for the 2 MIOLs at 6 months.

Variable	ZM900 (n =14)	Sa60d3 (n =14)	*P* Value*
RMS HOA, 5.0 mm	0.26 ± 0.08	0.34 ± 0.11	.032
RMS Z_3^1, 5.0 mm	0.11 ± 0.06	0.17 ± 0.03	.014
RMS Z_3^3, 5.0 mm	0.20 ± 0.09	0.20 ± 0.09	NS
RMS Z_4^0, 5.0 mm	0.05 ± 0.04	0.13 ± 0.04	.000
RMS HOA, 6.0 mm	0.38 ± 0.15	0.54 ± 0.17	.005
RMS Z_3^1, 6.0 mm	0.18 ± 0.10	0.27 ± 0.09	.017
RMS Z_3^3, 6.0 mm	0.28 ± 0.15	0.28 ± 0.15	NS
RMS Z_4^0, 6.0 mm	0.04 ± 0.04	0.23 ± 0.07	.000
Z_4^0, 5.0 mm	0.00 ± 0.05	0.10 ± 0.09	.008
Z_4^0, 6.0 mm	0.02 ± 0.04	0.23 ± 0.07	.000

Means ± SD
*Mann-Whitney *U* text ReSTOR versus Tecnis

Multifocal IOLs, either diffractive or refractive, have been shown to restore near vision effectively, with a near visual performance higher than J3 in between 92% and 99% of patients.[1,2,10–12] Nevertheless, a degradation of image clarity resulting from the multifocal vision is one of the main consequences of MIOL implantation.[1–7] The distribution of incoming light through several foci, generating out-of-focus images that overlap the image of a distant focus, reduces image sharpness, particularly at low contrast levels. Several authors demonstrate significant differences between MIOLs and monofocal IOLs in low contrast visual acuity and in visual symptoms such as halos, glare, and blurred far vision in favor of the monofocal IOLs.

In addition, the spherical design of the commercially available MIOLs may induce disturbing visual symptoms associated with the increase of spherical aberration that can lead to decreased quality of the optical system. Young healthy crystalline lenses have negative spherical aberration that compensate for the positive spherical aberration of the normal cornea.

After surgery, there is a disruption in the cornea–lens balance, leading to an increase in the overall positive spherical aberration of the eye responsible for a degradation in the retinal image quality and thus in the quality of vision.[8]

Recently, technical innovations have been introduced and new MIOLs manufactured to improve the visual performance of post-cataract-surgery patients. The apodization of the optics of the ReSTOR MIOL, consisting of a smooth decrease in step heights from the central zone to the diffractive periphery, is intended to improve light transmission through the optic and reduce light dispersion. Several studies demonstrate an improvement in the near visual performance after implantation of the ReSTOR IOL, with low or no significant decrease in the quality of vision compared with monofocal IOLs.[13–17]

Souza et al.[13] observed a statistically better near uncorrected and distance corrected visual acuity in the ReSTOR group than the monofocal group, with no significant difference in contrast sensitivity when evaluated binocularly. Chiam et al.[14] found an uncorrected near visual acuity of 20/30 or higher in 75% of patients with the ReSTOR IOL compared with 3.8% in the monofocal group. In the same study, a higher percentage of glare and halos were observed in the multifocal group than in the monofocal group; nevertheless, a high level of satisfaction in the overall vision was found in the multifocal group. The quality of vision in terms of contrast sensitivity after ReSTOR IOL implantation was reported to be within normal limits by de Oliveira et al.[15] In addition, patients with ReSTOR IOLs were associated with a smaller amount of

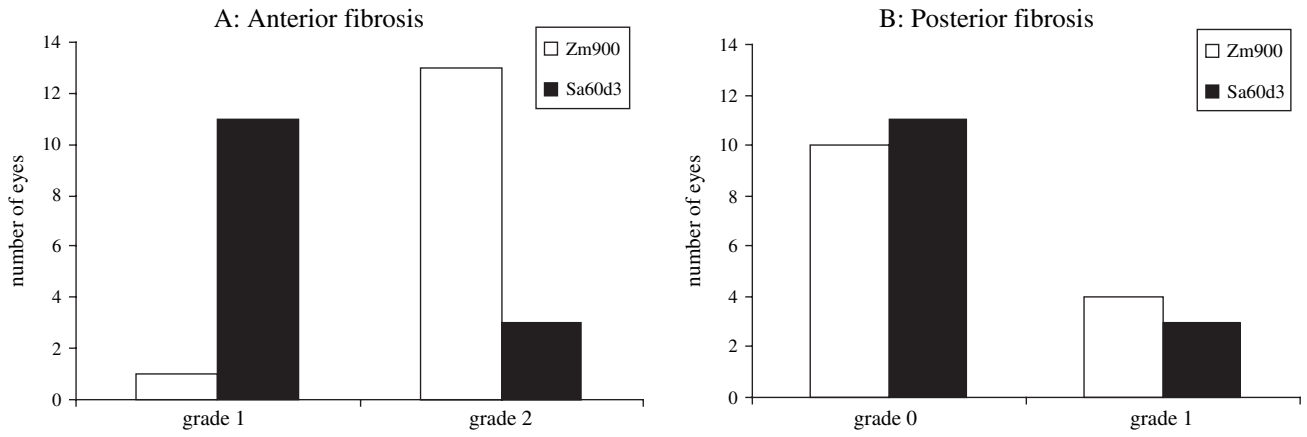


Figure 2. The percentage of patients with ACO (*left*) and PCO (*right*).

spherical aberrations than patients with monofocal IOLs and with no significant difference compared with young pseudophakic eyes.[16,17]

The aspheric optics associated with the diffractive multifocal design of the silicone Tecnis ZM900 IOL is another innovation to reproduce the optical quality of the young crystalline lens. The asphericity of the optics has been realized in monofocal IOLs to improve the vision quality of post-cataract-surgery patients.

Several authors demonstrate a better visual performance, particularly a higher contrast sensibility, in patients with aspheric monofocal IOLs than in those with conventional IOLs. Moreover, a significant reduction in spherical aberration has been observed after the implantation of aspheric IOLs compared with spherical IOLs.[18–20]

In our study, we compared the AcrySof ReSTOR IOL and the silicone Tecnis ZM900 IOL, evaluating the functional capacities, wavefront error, and capsule biocompatibility in the implanted patients. After surgery, both groups of patients showed excellent distance and near vision, with a mean DCNVA of 1.86 $\pm$ 1.66 J in Group 1 and of 1.93 $\pm$ 1.12 in Group 2, with no statistically significant difference. In all patients, as observed by other authors, there was a decrease in the intermediate visual performance; nevertheless, the Tecnis IOL performed better than the ReSTOR IOL for intermediate distances of 50 and 100 cm as shown by the defocus curve. For near distances such as 25 cm, better visual acuity was observed in patients with the ReSTOR IOL than in those with the Tecnis IOL. Both IOLs showed good visual performance at low contrast without significant differences. Moreover, a low spherical aberration error was observed in both MIOLs compared with a conventional spherical IOL, as demonstrated in other studies,[21,22] with a lower value of spherical RMS with the Tecnis IOL than with the ReSTOR IOL.

It is possible to hypothesize that the apodization of the ReSTOR IOL (ie, the gradual tapering of the diffractive steps from the center to the periphery) reduces spherical aberration in a way similar to that of an aspheric IOL. In our group, we found a lower value of spherical aberration at 5.0 mm of analysis than at 6.0 mm, thus demonstrating the greater sphericity of the peripheral part of the IOL compared with the central apodized diffractive part.

A smaller amount of coma aberration was also detected in the Tecnis patients than in the ReSTOR patients. Muñoz et al.[18] suggest that an improvement of 1 aberration, spherical, could improve another aberration, coma. Since we performed total ocular aberration measurements, it is possible there was a difference between the 2 groups in coma aberrations of the corneal surface.

Dietze et al.[23] studied the theoretical limitations of correcting spherical aberration with aspheric IOLs and concluded that these IOLs could produce more coma aberration when decentered. The small amount of coma aberration in the Tecnis group suggests that there was not significant IOL decentration. This finding indirectly suggests that the high incidence of anterior capsule fibrosis observed in the Tecnis group is not critical for IOL stability and position. All patients showed ACO; however, a higher grade of fibrosis was found in the Tecnis patients. Posterior capsule opacification was minimal, and there was no between-group difference.

Intraocular lens decentration associated with the asymmetric contraction of a fibrotic capsule has been demonstrated by several authors.[24–26] Since we did not evaluate the entity of capsule contraction or lens decentration, we cannot establish a correlation

between capsule fibrosis, decentration, and coma aberration. Studies are needed to better understand the possible effect of capsule fibrosis on IOL centration, particularly for aspheric and apodized IOLs. However, the lower incidence of capsule fibrosis of the ReSTOR IOLs compared with the Tecnis IOLs confirms the better biocompatibility of the AcrySof material than the silicone material, as demonstrated in several studies.[27–29]

In conclusion, the ReSTOR IOL and the Tecnis IOL provided a satisfactory full range of vision, with less dependence on spectacles and with fewer induced spherical aberrations. We found better biocompatibility of the ReSTOR IOL than the Tecnis IOL, particularly in capsule behavior.

This study had some limitations, and the results cannot be generalized to all populations and to all viewing conditions. First, only subjects with an axial length between 23 mm and 24 mm were selected; thus, functional and aberrometric results do not include eyes with axial myopia and hyperopia. Moreover, corneal astigmatism less than 1.0 D was another inclusion criterion; thus, the influence of high astigmatism on visual performance with an MIOL was not ruled out. In addition, a monolateral IOL was implanted in all cases and this means that our study provides no information about binocular viewing conditions with MIOLs. Finally, all patients had a total ocular aberrometric evaluation, which does not allow us to distinguish between the internal aberration associated mainly with the IOL and the external aberration related mainly to the cornea. Larger groups of patients and different inclusion criteria and methods of analysis are needed to draw definite conclusions.

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