Comparison of visual function after bilateral implantation of inferior sector-shaped near-addition and diffractive-refractive multifocal IOLs

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PURPOSE: To compare visual function after bilateral implantation of multifocal Lentis Mplus LS-312 (Group A) or Acrysof Restor SN6AD1 (Group B) intraocular lenses (IOLs).

SETTING: Ophthalmology Unit, Centro Hospitalar e Universitário de Coimbra, and Visual Neuroscience Laboratory, IBILI, Faculty of Medicine, University of Coimbra, Coimbra, Portugal.

DESIGN: Comparative case series.

METHODS: Patients between 49 years and 76 years had bilateral cataract surgery with multifocal IOL implantation. Patients were evaluated preoperatively and 3 months postoperatively for distance, intermediate, and near visual acuities; static photopic and mesopic contrast sensitivity; and visual acuity under a glare source using the Metrovision contrast sensitivity platform. Color vision was evaluated with the Cambridge Colour Test.

RESULTS: Group A comprised 56 eyes and Group B, 44 eyes. Visual and refractive results were comparable between the 2 groups. Photopic contrast sensitivity was significantly better in Group B at intermediate (2.2 cycles per degree [cpd] and 3.4 cpd) and high (7.1 cpd and 23.6 cpd) spatial frequencies. Under low mesopic conditions (0.08 candelas/m²), differences were significant at 1.1 cpd and 2.2 cpd spatial frequencies. There were no differences in visual acuity under a glare source or in color vision.

CONCLUSIONS: Both IOLs provided good distance, intermediate, and near visual acuities. Visual acuity under a glare source and color vision were similar in the 2 groups. However, photopic and low mesopic contrast sensitivities were better in Group B, particularly for intermediate spatial frequencies, which are important for night driving.

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The design of multifocal intraocular lenses (IOLs) has undergone several modifications to improve distance, intermediate, and near vision. However, unwanted side effects, such as glare, halos, and loss of contrast sensitivity, have also often been reported.² Asymmetric IOLs with sector-shaped near-vision zones were developed to reduce these side effects, but recent studies³⁻⁶ found that this asymmetric design may increase optical aberrations and affect ocular optical quality, with a harmful effect on daylight (photopic) contrast sensitivity. However, many patients with multifocal IOLs report halos and glare, especially when driving at night (ie, under low mesopic

conditions). In addition, intraocular higher-order aberrations (HOAs) increase with pupil dilation and in low-light conditions. Therefore, it might be expected that differences in contrast sensitivity detected under photopic conditions would persist or increase under mesopic conditions.^{7–10}

Contrast sensitivity should therefore be tested under low mesopic conditions (ie, 0.08 candelas [cd]/m²) instead of the higher luminance value (3.0 cd/m²) used in most studies. 4,11-14 This low value of luminance (0.08 cd/m^2) is more likely to represent the conditions in which patients have difficulties. 11,13,15 For driving on lit roads, the recommended average road-surface luminance in Europe and in the United States varies between 0.3 cd/m² and 2.0 cd/m².¹⁶ Low mesopic contrast sensitivity is particularly important when evaluating multifocal IOLs because it is known that under low-light conditions, some advantages of specific IOL designs are attenuated by pupil dilation.^{13,17}

The purpose of our study was therefore to compare the visual acuity, glare disability, color vision, and contrast sensitivity under photopic and low mesopic conditions between a sector-shaped near-vision zone multifocal IOL and a diffractive-refractive multifocal IOL.

PATIENTS AND METHODS

Patients

This prospective comparative case series included patients who had bilateral cataract surgery with implantation of multifocal IOLs. The study was performed in accordance with the ethical standards of the Declaration of Helsinki. Institutional review board approval was obtained, and patients provided informed consent after receiving an explanation of the possible consequences of participation had been explained.

Exclusion criteria were 1.5 diopters (D) or more of corneal astigmatism, irregular topography, illiteracy, and a history of other ocular comorbidities, such as glaucoma, retinal disease, previous corneal or intraocular surgery, and pupil deformation. The study design was consecutive. Once the patients were selected according to the inclusion and exclusion criteria, patients were implanted sequentially with the Lentis Mplus LS-312 C-loop (Oculentis GmbH) (Group A) or with the Acrysof Restor SN6AD1 IOL (Alcon Laboratories, Inc.) (Group B).

Intraocular Lenses

The Lentis Mplus LS-312 C-loop is a biconvex acrylic refractive 1-piece IOL with a sector-shaped near-vision area with a +3.00 D addition (add) and an aspheric posterior surface. The hydrophilic acrylic copolymer has a hydrophobic surface with ultraviolet light-filtering components. Care was taken to position the salient mark at 6 o'clock.

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The Acrysof Restor SN6AD1 is an apodized hybrid IOL combining diffractive and refractive regions with a ± 3.00 D add. This IOL has a symmetric biconvex design with negative spherical aberration and a blue light-filtering chromophore.

Surgical Technique

Surgeries were performed using topical anesthesia through a 2.75 mm clear corneal incision in the steepest meridian by 1 of 4 experienced surgeons. The Allegro Biograph device (Wavelight AG) and the SRK/T formula were used for IOL calculation. After phacoemulsification and aspiration of the cortex were performed, the IOLs were implanted in the capsular bag.

Preoperative and Postoperative Evaluations

Before surgery, patients had a complete ophthalmic examination including manifest refraction, slitlamp biomicroscopy, topography (Orbscan II, Bausch & Lomb), dilated fundoscopy, and Goldmann applanation tonometry. Distance visual acuity was evaluated with Snellen charts. Intermediate (70 cm) and near (40 cm) visual acuities were evaluated with the near Early Treatment Diabetic Retinopathy Study chart, with an adjustment for intermediate visual acuity, as previously described. ¹⁹ All measurements were taken under photopic conditions (80 cd/m²). Pupil measurements were recorded with a pupillometer (Metrovision) that induced a near infrared illumination (880 nm) under photopic (100 cd/m²) and mesopic (1 cd/m²) conditions.

Contrast sensitivity testing was performed using 2 methods; that is, the Pelli-Robson contrast sensitivity chart (Haag-Streit International) and the Metrovision contrast sensitivity platform (Metrovision MonCv3 system).2 Pelli-Robson testing was performed under only photopic luminance conditions; the log contrast sensitivity of the last triplet for which 2 letters (2 of 3) were named correctly was used as a scoring rule. Contrast sensitivity evaluation based on the Metrovision platform was performed under photopic (mean luminance 80 cd/m²) and low mesopic (mean luminance 0.08 cd/m²) lighting conditions at low (0.6 cycles per degree [cpd] and 1.1 cpd), intermediate (2.2 cpd and 3.4 cpd), and high spatial frequencies (7.1 cpd and 23.6 cpd). Sinusoidal grating parameters (luminance, contrast, and spatial frequency) were computer controlled. The program started with low-contrast gratings. Then, the contrast was progressively increased until the patient could see the shape of the grating. Spatial contrast sensitivity function was calculated using the following equation: Spatial contrast sensitivity function (dB) = $10 \log [(Lmax + Lmin)/$ (Lmax - Lmin)], where Lmin is the minimum luminance of the grating and Lmax is its maximum luminance. Contrast sensitivity testing was performed with the best optical correction for the test distance (2 m). Under low mesopic condition (0.08 cd/m²), patients wore goggles with 3 log unit filters.

A glare test (Metrovision) simulating night-driving conditions was performed by presenting optotypes of calibrated low luminance over a dark background with a lateral highluminance light source (5 cd/m²) at the side of the screen. This test consisted of counting the number of letters the patient correctly identified despite diffusion within the eye. The final score was given as a percentage, with 100% being identification of all letters.

Color vision was evaluated using the Cambridge Colour Test (Cambridge Research Systems), a chromatic contrast sensitivity test used to probe red-green and blue-yellow visual pathways, as previously described. 21,22 The participants viewed a static pattern of circles of various sizes and luminances with superimposed chromatic contrast defining a C; they pressed 1 of 4 buttons to indicate whether the gap was facing up, down, left, or right. The Trivector version was used; in this version, targets differ from the background along 1 of the 3 color confusion lines as follows: protan, deutan, and tritan. This test uses 3 randomly interleaved staircases to dynamically adjust the chromaticity of the target according to the participant's performance. All tests were performed monocularly, with the first tested eye chosen at random. Chromatic thresholds were expressed in Commission Internationale de l'Éclairage 1976 u'v' color space units. High chromatic thresholds relate to lowcontrast sensitivity.

Postoperatively, patients were evaluated at 1 day, 1 week, and 1 and 3 months. The postoperative examination at 1 month and 3 months was identical to the preoperative examination but with the addition of near (40 cm) and intermediate (80 cm) visual acuity measurements. Monocular data are presented to limit the influence of neuroadaptation mechanisms that occur after multifocal IOL implantation.¹¹

Statistical Analysis

Statistical analysis was performed using SPSS for Windows software (version 19.0, SPSS, Inc.). First, the normality of all data samples was evaluated using the Kolmogorov-Smirnov test. When parametric analysis was possible, an independent-samples Student t test was used to compare data between groups. Otherwise the Mann-Whitney U test was used. The Cohen d test and Wilcoxon signed-rank test (r) were used for the statistical measure of effect size. A statistical power analysis was performed with G*Power software (version 3.1.6, Franz Faul, Kiel University, Kiel, Germany) to test whether conclusions conformed the β error testing and sufficient sample size. All results with a P value less than .05 were considered statistically significant.

RESULTS

The study evaluated 100 eyes of 50 patients with a mean age of 66.2 years \pm 0.67 (SD) (range 49 to 76 years). Group A comprised 56 eyes of 16 men and 40 women and Group B, 44 eyes of 12 men and 32 women (P=.83, Mann-Whitney U test). Table 1 shows the preoperative data by IOL group. There were no statistically significant between-group differences in age, corrected distance visual acuity (CDVA), sphere, cylinder, mean keratometry, mean corneal astigmatism, contrast and color sensitivity, or glare results. Thus, the groups were matched across these dimensions. The sample size, evaluated with a post hoc power calculation, had a minimum achieved power of 0.84.

Visual Acuity and Refraction

The visual and refractive results were comparable in the 2 groups with no statistically significant differences (Table 2). The mean 3-month postoperative uncorrected distance visual acuity, uncorrected intermediate visual acuity, uncorrected near visual acuity, CDVA, and distance-corrected near visual acuity improved (Table 2).

Contrast Sensitivity

Static Photopic Contrast Sensitivity Pelli-Robson 3-month photopic postoperative contrast sensitivity log scores did not differ between the IOL groups (Mann-Whitney U = 512.5, P = .08). Concerning photopic contrast sensitivity outcomes of Metrovision testing, both groups had comparable sensitivity at the lowest spatial frequencies (0.6 cpd and 1.1 cpd; Srudent t test, 73 degrees of freedom [t(73)] = -0.53, P = .60, and

Parameter	Group A		Group B		
	Mean ± SE	Range	Mean ± SE	Range	P Value
Age (y)	66.3 ± 6.1	49, 74	66.9 ± 6.9	49, 76	.66*
CDVA (logMAR)	0.26 ± 0.03	0.00, 1.30	0.26 ± 0.02	0.00, 0.70	.36†
Spherical equivalent (D)	0.16 ± 0.36	-7.50, 3.25	-0.43 ± 0.41	-7.50, 2.75	.30†
Sphere (D)	0.42 ± 0.37	-8.00, 4.00	-0.27 ± 0.40	-7.00, 3.00	.18†
Cylinder (D)	-0.58 ± 0.12	-2.50, 1.00	-0.63 ± 0.12	-1.80, 0.50	.57†
Keratometry (D)	44.00 ± 0.28	40.00, 49.40	44.46 ± 0.24	42.15, 48.30	.22†
Corneal astigmatism (D)	0.66 ± 0.04331	0.10, 1.50	0.61 ± 0.05	0.10, 1.50	.46†
PR_CS (log units)	1.50 ± 0.03	0.90, 1.95	1.42 ± 0.04	1.05, 1.95	.09†
Red/green (color units)	73.39 ± 5.07	31.00, 250.50	75.45 ± 9.44	34.50, 292.00	.37†
Blue/yellow (color units)	138.88 ± 7.77	50.00, 322.00	142.00 ± 11.47	49.00, 317.00	.82†
Glare (%)	0.15 ± 0.03	0.00, 0.77	0.09 ± 0.03	0.00, 0.73	.39†

 $CDVA = corrected \ distance \ visual \ acuity; PR_CS = Pelli-Robson \ contrast \ sensitivity; SE = standard \ error$

*Mann Whitney test

 † Student t test

Table 2. Between-group comparison of 3-month postoperative visual and refractive outcomes.

	Group A		Group B		
Parameter	Mean ± SE	Range	Mean ± SE	Range	P Value*
UDVA (logMAR)	0.07 ± 0.02	-0.08, 0.40	0.07 ± 0.01	0.00, 0.30	.42
UIVA (logMAR)	0.26 ± 0.02	0.00, 0.40	0.26 ± 0.02	0.00, 0.40	.90
UNVA (logMAR)	0.15 ± 0.02	-0.10, 0.40	0.16 ± 0.03	0.00, 0.40	.84
CDVA (logMAR)	-0.01 ± 0.01	-0.08, 0.16	0.00 ± 0.01	-0.08, 0.10	.43
Sphere (D)	0.11 ± 0.16	-1.25, 1.00	0.29 ± 0.14	-0.50, 0.50	.80
Cylinder (D)	-0.14 ± 0.17	-1.00, 0.50	-0.36 ± 0.09	-0.75, 0.25	.30
DCNVA (logMAR)	0.14 ± 0.02	0.00, 0.50	0.15 ± 0.02	0.00, 0.40	.73
Near addition (D)	1.53 ± 0.19	0.00, 2.80	1.55 ± 0.12	0.00, 1.75	.572
Mean corneal astigmatism (D)	0.63 ± 0.07	0.20, 1.10	0.65 ± 0.07		.89
Pupil diameter (mm)					
Photopic (100 cd/m ²)	3.29 ± 0.00	3.27, 3.32	3.29 ± 0.00	0.1, 1.7	.89
Mesopic (1 cd/m²)	4.06 ± 0.04	3.42, 4.85	4.00 ± 0.05	3.42, 4.73	.38

cd = candelas; CDVA = corrected distance visual acuity; DCNVA = distance-corrected near visual acuity; SE = standard error; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity
*Student t test

t(73) = -1.31, P = .19, respectively). In contrast, there were statistically significant differences in intermediate (2.2 cpd: t(73) = -2.59, P = .011; 3.4 cpd: t(73) = -2.48, P = .015) and 1 high spatial frequency (7.1 cpd: t(73) = -2.59, P = .012; 23.6 cpd: t(73) = -1.91, P = .06), with better visual performance under photopic contrast sensitivity in Group B (Figure 1). Analysis of effect size using Cohen d showed values between 0.60 and 0.63 (higher for intermediate and high spatial frequencies), meaning that Group B IOLs had a moderate to large effect on improving contrast sensitivity at the spatial frequencies studied.

Static Mesopic Contrast Sensitivity Lower contrast sensitivity values were found under mesopic conditions in both groups. Group B had higher mesopic contrast sensitivity values at all spatial frequencies except the highest (23.6 cpd). Differences were statistically significant for 1 low spatial frequency (1.1 cpd: Mann-Whitney U = 741, P = .046) and 1 intermediate spatial frequency (2.2 cpd: Mann-Whitney U = 826.5, P = .022) (Figure 2). Effect size for Mann-Whitney U test showed a small effect at a frequency of 1.1 cpd (r = 0.15) and a medium effect (r = 0.30) at an intermediate spatial frequency of 2.2 cpd.

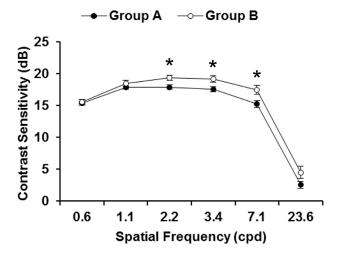


Figure 1. Photopic contrast sensitivity as a function of spatial frequency by group. Error bars represent ± 1 standard error of the mean (* = P < .05; cpd = cycles per degree).

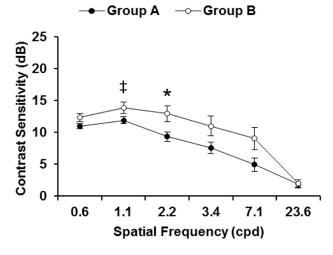


Figure 2. Mesopic contrast sensitivity as a function of spatial frequency by group ($^{\ddagger} = P = .046$; * = P = .022; cpd = cycles per degree).

Chromatic Red-Green and Blue-Yellow Contrast Sensitivity

Red–green values in Group A and Group B were 59.83 ± 4.65 and 58.06 ± 5.45 (u'v' \times 10^{-4} color space units), respectively. Blue–yellow values in Group A and Group B were 81.42 ± 4.67 and 86.28 ± 5.59 (u'v' \times 10^{-4} color space units), respectively. Between-group comparison of 3-month postoperative color sensitivity outcomes showed no significant differences (P>.05, Student t test). Both groups had equivalent color discrimination performance, despite having different light-filtering chromophores.

Glare

There was no significant difference in vision under glare conditions between the 2 groups [t(73) = 0.51, P=.61]. Group A correctly identified 58% \pm 3% (range 0% to 87%) of optotypes, and Group B identified 56% \pm 3% (range 23% to 87%).

Complications

There were 3 cases of significant postoperative rotation (>20 degrees) of the asymmetric IOL. The patients reported blurred vision and difficulty in reading. After surgical repositioning, the symptoms resolved and visual acuity improved. No capsulotomy was required during follow-up.

DISCUSSION

Multifocal IOLs are able to restore distance, intermediate, and near visual acuities. 11,23,24 There is, however, a tradeoff between spectacle independence and visual quality; patients frequently report glare, halos, and a decrease in contrast sensitivity, especially under dimlight conditions.^{2,25,26} Efforts have been made to improve IOL design to avoid these symptoms. An asymmetric IOL (Lentis Mplus LS-312), in which an inferior sector is added for near vision, was developed to reduce visual symptoms; light hitting the transition area of the near sector is reflected away from the optical axis.4 However, because of its asymmetric design with an inferior sector of higher dioptric power, more HOAs, especially primary coma, occur than with several other IOLs. 3-5,12 Because aberrations are known to increase with pupil dilation and under mesopic conditions, it might be expected that differences detected in photopic conditions would persist under mesopic conditions. In addition, in vitro studies⁶ comparing the modulation transfer function (MTF) and point-spread function of the Lentis Mplus LS-312 IOL and Acrysof Restor SN6AD1 IOL found better optical quality at distance focus with the diffractive-refractive IOL (Acrysof Restor SN6AD1). Previous studies^{12,13} found lower contrast sensitivity with the asymmetric IOL (Mplus LS-312) than with a

diffractive–refractive IOL (Acrysof Restor SN6AD1) and with the Mplus LS-312 MF 15 IOL than with an accommodating IOL (Crystalens HD, Bausch & Lomb) under photopic conditions only.

One possible explanation for the apparent contradiction between studies in aberrometry (higher values of HOAs with asymmetric IOLs for a 5.0 mm zone) and contrast sensitivity (no differences under mesopic conditions between IOLs) may be the relatively high levels of luminance (3 cd/m²) used for creating a mesopic environment. 4,5,11-13,24 Mesopic light levels range from 0.001 to 3.0 cd/m².²⁷ For driving on lit roads, the recommended average road-surface luminances are between 0.3 cd/m² and 2.0 cd/m² in Europe and between 0.3 cd/m² and 1.2 cd/m² in the U.S. 16 Luminance levels for evaluating visual performance under night-driving conditions vary between 0.01 cd/m² and 1.00 cd/m², and night-driving performance deteriorates with decreasing luminance levels from 1.00 to 0.01 cd/m². Therefore, luminance values of 3.0 cd/m² will not likely reproduce real-world mesopic conditions. We measured mesopic contrast sensitivity under 0.08 cd/m², and lower contrast sensitivity was detected with the asymmetric IOL. It is likely that in previous studies, the light conditions (3 cd/m^2) were too bright to detect the deleterious effect of HOAs on contrast sensitivity. In addition, in 1 study, 13 the differences may not have been detected because contrast sensitivity was measured binocularly.

Concerning photopic conditions (80 cd/m²), we measured lower contrast sensitivity values in the asymmetric IOL group at intermediate spatial frequencies and 1 high spatial frequency, in accordance with previous studies. This is expected because the asymmetric IOL induces higher intraocular aberrations and it is known that aberrations have little effect on the transfer factors of very low and very high spatial frequencies. Aberrations mainly reduce transfer factors of intermediate frequencies. 11,12,29

The performance of the 2 IOLs was similar in the presence of a glare source. Previous studies comparing these IOLs did not evaluate visual acuity under a glare source, despite stating the importance of glare disability with multifocal IOLs. The absence of differences between IOLs despite the improved design (ie, containing only 1 transition zone to reduce sources of scattering and aberrations that cause disturbing reflections, halos, and glare⁴) may be explained by the optical quality provided by the IOLs. In fact, the Group B IOL had higher MTF values than the Group A IOL at all spatial frequencies.⁶ Because the MTF shows how an optical system transmits spatial frequencies, lower MTF values mean a loss of information about the details of an object, which decreases image quality and hence visual acuity. The glare test we used consists of recognizing letters on a screen in the presence of a light source at the side of the screen. Therefore, it is likely to have been influenced by the tradeoff between the optical quality of the IOL and the design, rendering glare results the same across the IOLs.

In terms of color vision, we found no differences in chromatic sensitivity in any of the color pathways studied, despite the presence of a yellow filter in the Group B IOL. The absence of color discrimination differences between clear and yellow IOLs has been reported.³⁰

There were 3 cases of IOL rotation in Group A; all required surgical repositioning. This is in accordance with findings in a previous study,¹⁴ in which haptic design was found to be insufficient to provide IOL stabilization.

Near, intermediate, and distance visual acuities were similar in the 2 groups, confirming the usefulness of these IOLs for uncorrected visual acuity. One limitation of this study is the absence of defocus curves. However, this has been extensively reported. 3-5,11-14

In conclusion, both IOLs provided good distance, intermediate, and near visual acuities. Contrast sensitivity at intermediate spatial frequencies under photopic and mesopic conditions was better in Group B. Lower luminance values for mesopic conditions (0.08 cd/m² instead of 3.0 cd/m²) and glare evaluation are useful in recreating real-world scenarios, such as night driving, thus showing important differences between the IOLs.

WHAT WAS KNOWN

- Photopic contrast sensitivity has been reported to be higher with the Acrysof Restor SN6AD1 IOL than with the Lentis Mplus LS-312 IOL; however, similar outcomes have been found under mesopic light levels of 3 cd/m².
- Glare is an important symptom with multifocal IOLs; however, visual acuity under a glare source has not been compared between these 2 IOLS.

WHAT THIS PAPER ADDS

- Contrast sensitivity under low mesopic lighting conditions (0.08 cd/m²), which is important for night vision, was higher with the Acrysof Restor + 3.0 D add IOL.
- Visual acuity under a glare source was similar for the 2 IOLs.

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