Standard Clinical Outcomes, Light Distortion, Stereopsis, and a Quality-of-Life Assessment of a New Binocular System of Complementary IOLs

Jerónimo Lajara-Blesa, MD, PhD; Miguel Ángel Rodríguez-Izquierdo, MD; Lorenzo Vallés-San-Leandro, MD, PhD; Gurjeet Jutley, MD; María de los Remedios Ortega-García, MD; Juan F. Zapata-Díaz, PhD

ABSTRACT

PURPOSE: To evaluate the visual outcome, light distortion index (LDI), and quality of life (QoL) of patients implanted with two complementary intraocular lenses (IOLs) to treat cataract and presbyopia.

METHODS: Twenty-seven consecutive patients with cataract were treated with the implantation of the Artis Symbiose Mid (Mid) IOL (Cristalens Industrie) in the distance-dominant eye and the Artis Symbiose Plus (Plus) IOL (Cristalens Industrie) in the contralateral eye following phacoemulsification. The primary objective was to ascertain the monocular and binocular defocus curves. Secondary endpoints included uncorrected distance visual acuity, corrected distance visual acuity, uncorrected intermediate visual acuity, and distance-corrected intermediate visual acuity at 90 and 70 cm, uncorrected near visual acuity and distance-corrected visual acuity at 40 cm, contrast sensitivity, LDI with a halometer, stereopsis, and patients' QoL with the validated Visual Function Index (VF-14) questionnaire. These measurements were collected in two visits, at 4.14 ± 3.13 and 10.30 ± 3.14 months postoperatively.

RESULTS: Statistically significant differences in the monocular defocus curves were found at the defocus steps of -1.00, -1.25, -1.50, -1.75, -2.50, -2.75, -3.00, -3.50 diopters and the -4.00 diopters ($P < .050$). The mean binocular defocus curve was 0 logMAR or better from the +0.50 to the -2.50 D defocus steps. Contrast sensitivity was within normal values. The LDI was 12.57 (6.61)% for the Mid eyes, 14.99 ± 5.70% for the Plus eyes, and 10.36 ± 4.42% binocularly. The patients' stereopsis was 40.0 (12.5) arcseconds. The QoL score was 95.99 (7.14) at 10 months.

CONCLUSIONS: The implantation of the Artis Symbiose IOLs was a safe and effective treatment for presbyopia compensation in patients with cataract. Both IOLs are complementary and may produce a binocular depth-of-field of 3.00 diopters over 0 logMAR when used together.

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From the Departamento de Investigaciones Clínicas, Vista Ircovisión Oftalmólogos, Murcia, Spain (JL-B, MAR-I, LV-S-L, MRO-G, JFZ-D); Grupo de Investigación Multidisciplinar en Ciencias de la Visión, Universidad Católica de Murcia (UCAM), Murcia, Spain (JL-B, MAR-I, LV-S-L, GJ, MRO-G); Oxford University Hospitals NHS Foundation Trust, Oxford, United Kingdom (GJ); Hospital Universitario Virgen de la Arrixaca, Murcia, Spain (MR-O-G); Grupo de Ciencias de la Visión de la Universidad de Murcia (CiViUM), Murcia, Spain (JFZ-D); and Cristalens Industrie, Lannion, France (JFZ-D).

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Correspondence: Juan F. Zapata-Díaz, PhD, Vista Ircovisión Oftalmólogos, C/ General Gutiérrez Mellado s/n, 30008 Murcia, Spain. Email: juanf.zapata.diaz@gmail.com

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The surgical management of cataracts enables surgeons to offer the concurrent correction of presbyopia in those patients motivated to decrease their spectacle dependence. Several approaches have been developed to increase the postoperative depth of field, including simultaneous vision intraocular lenses (IOLs) and extended depth of focus (EDOF) IOLs. To provide a full range of vision, various approaches can be used, such as the use of distinct IOLs in the same patient, a so-called mix-and-match approach,[1-5] or the use of new hybrid multifocal/EDOF designs, able to provide a continuity between intermediate and near distances.[6,7]

Recently, newer approaches have appeared in the market with IOLs that increase the depth of field while maintaining a sufficient amount of light energy at each focus to provide sharp vision at all distances. This is achieved by using two complementary IOLs, both of which have slightly different profiles designed to be implanted in the same patient in different eyes.[6,8] In 2018, the Artis Symbiose (Cristalens Industrie) set of complementary IOLs was launched. These IOLs provide a far focus and an additional continuous focus spanning intermediate and near distances. Specifically, the Artis Symbiose Mid IOL (Mid) provides more light energy at intermediate distances, whereas conversely the Artis Symbiose Plus IOL (Plus) provides more light energy at near distances.[6] A recent clinical study with patients bilaterally implanted with Plus IOLs showed that this approach was able to provide a continuous range of vision from far to near without discontinuity.[9] However, to the best of our knowledge, no clinical outcomes have been published with the combination of Mid and Plus IOLs.

In this study, we describe the visual performance outcomes of patients implanted with the Artis Symbiose complementary IOLs. Furthermore, secondary measurements include the assessment of photic phenomena, stereopsis, and quality-of-life (QoL) surveys.

PATIENTS AND METHODS

This prospective case series pilot study followed the tenets of the Declaration of Helsinki and received ethics approval by the Ethics Committee of the Universidad Católica de Murcia (UCAM, Murcia, Spain). Informed consent from patients was acquired prior the inclusion in the study. Inclusion criteria were: age 50 years or older, bilateral age-related cataracts, multifocal IOL indication, photopic pupils between 2 and 4 mm, and IOL power between 18.00 and 27.00 diopters (D). Exclusion criteria included ocular comorbidities limiting corrected distance visual acuity (CDVA), previous ocular surgery, amblyopia, dry eye greater than grade 2 of the Dry Eye Workshop II scale, and eyes with an expected residual astigmatism of greater than 0.75 D.

PATIENTS

Thirty-two patients were recruited and underwent uncomplicated bilateral implantation with the study IOLs. Two patients who had an adverse event (macular edema and age-related macular degeneration) and 2 eyes from different patients with photorefractive keratectomy correction of a refractive surprise were excluded from the analysis. Three patients were lost to follow-up. Twenty-seven patients (63 ± 9 years) attended at the first visit. Of these, only 23 (62 ± 7 years) attended at the second scheduled visit, because 2 of them were excluded after developing posterior vitreous detachment, another had troubling dry eye syndrome, and another was lost to follow-up. The distribution of patients and eyes on each follow-up visit is shown in **Figure A** (available in the online version of this article).

SURGERY

All surgeries were performed at the Vista Ircovisión Ophthalmology Clinic (Murcia, Spain) between March 2019 and July 2020 by the same experienced surgeon (JL-B) under topical anesthesia using phacoemulsification and a 2.2-mm incision. The Mid IOL was always implanted in the distance-dominant eye and the Plus IOL in the contralateral eye.

IOLS

Artis Symbiose is a set of two complementary apodized hybrid (multifocal/EDOF) aspheric diffractive IOLs, Mid and Plus, designed to be implanted in different eyes of the same patient. Both IOLs induce -0.23 μm (for a 6-mm aperture) of spherical aberration to partially correct that of the cornea and use the 0th order of diffraction to produce a far focus, whereas the 1st order of diffraction produces a secondary focus spanning intermediate and near distances, with a continuous addition from +1.50 to +3.75 D, with peaks at +1.75 (Mid) and +3.25 (Plus) D. The amount of light energy at the far focus is similar in both IOLs, but the Mid IOL provides more energy at intermediate distances, whereas the Plus IOL provides more energy at near distances. The complementary nature of their through-focus modulation transfer functions has been demonstrated on an optical bench.[6] Both lenses use a 6-mm optical zone in which the central 4.2-mm zones contain the diffractive rings (10 for the Mid IOL, 12 for the Plus IOL), whereas the outer ring zone (from 4.2 to 6.0 mm) is purely refractive. The material of both IOLs is hydrophobic acrylic with a refractive index of 1.54, and the platform uses a 4-closed-loop system for stabilization, with a total diameter of 10.79 mm (**Figure B**, available in the online version of this article). Both IOLs are preloaded in Accuject 2.1-1P injectors (Medicel).

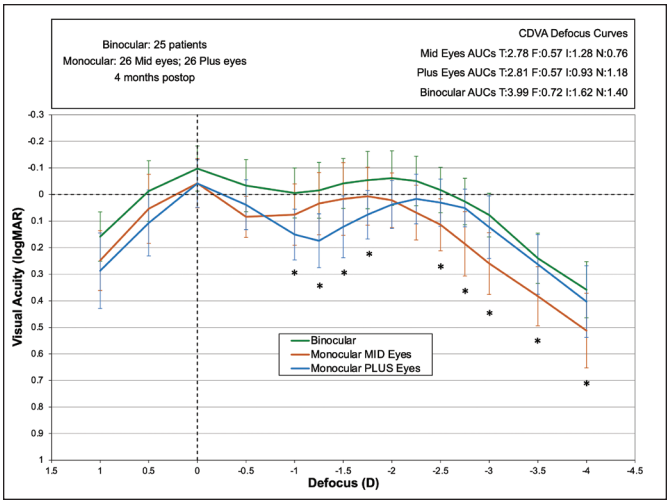

Figure 1. Monocular and binocular defocus curves with best distance correction. The red line represents the mean visual acuity (VA) of the eyes implanted with the Artis Symbiose Mid intraocular lens (IOL) (Cristalens Industrie), whereas the blue line represents the mean VA of the eyes implanted with the Artis Symbiose Plus IOL. The green line represents the mean binocular VA defocus curve. Error bars represent ± standard deviation. Asterisks represent statistically significant difference (*t* test, $P < .050$) between the monocular defocus curves. AUCs = areas under the curve

The power of the IOLs was calculated using the Haigis formula with constants A0 = 0.088, A1 = 0.233, A2 = 0.2, except for eyes with axial lengths of greater than 24.5 mm in which the SRK/T formula was used with an A-constant = 119.74.

Clinical Examinations

A preoperative evaluation within 1 month prior to surgery and two postoperative clinical assessments were arranged at day 1 and day 7. Two visits were designed at 6 weeks and 6 months following surgery. Unfortunately, due to the coronavirus disease 2019 pandemic during 2020, the majority of the visits were delayed, with patients evaluated as soon as restrictions permitted. Hence the visit periods were 4.14 ± 3.13 months for the 6-week visit and 10.30 ± 3.14 months for the 6-month visit after surgery. The details of the examinations undertaken are described in **Table A** (available in the online version of this article).

Manifest Refraction and Visual Acuity

The patients' manifest refraction was measured using the "maximum plus/minimum minus to maximum visual acuity" approach at 4 m and adjusted to infinity by adding -0.25 D to the obtained refraction. The vergence of the optotype was compensated for the measurement of the distance-corrected visual acuities.[10,11] All visual acuities were assessed using the Early Treatment of Diabetic Retinopathy Study (ETDRS) charts with Sloan letters (Good-Lite) in photopic conditions (87.8 ± 0.3 cd/m^2, mean ± standard deviation [SD] of three measurements). If the patient could not read an entire line, -0.02 for each letter correctly read was added to the logMAR score of the last line entirely read.[12] However, individual logMAR scores were rounded to the nearest line (0.1 logMAR steps) for the standard graphs for reporting clinical outcomes (**Figure 1**). The illuminance of the room was 503.3 ± 37.9 lux at the head of the patients for all tests, except for the Scheimpflug corneal tomography (106.6 ± 23.1 lux) and the photic phenomena evaluation (dark room, < 1 lux). Intermediate visual acuities at 90 and 70 cm were assessed using two ETDRS charts (Good-Lite) calibrated at 40 cm and recalculating visual acuity for the aforementioned distances. Defocus curves were assessed from -4.00 to +1.00 D in 0.50-D steps, except for the range between -3.00 and -1.00 D, where they were evaluated in 0.25-D steps to test the continuity of visual acuity at intermediate-to-near distances. To avoid letter memorizing, two different ETDRS charts were used along with a non-sequential placement of the defocus lenses, starting from -4.00 to +1.00 D in 1.00-D steps with the first chart, and following from -3.50 to -0.50 D in 1.00-D steps with the second chart. The 0.50-D steps from -2.75 to -1.25 D were then evaluated with the first chart again.

Semi-objective Assessment of Photic Phenomena

The Light Distortion Analyzer[13] device was used for the semi-objective assessment of photic phenomena. Patients were seated in a darkened room (< 1 lux) with their best correction placed in a trial frame. The device was placed at 2 m from the patient. To avoid error, one monocular trial was performed and discarded before the two separate monocular and the binocular measurements were taken. The vergence of the device was not compensated for these measurements because it has been reported that no significant difference was found.[13] The metric reported by the device was the light distortion index (LDI). A full description of the device, the protocol, and the reported metric can be found elsewhere.[13,14]

Data Processing and Statistical Analysis

Areas under the defocus curve (AUCs) were calculated using Matlab software (Mathworks, Inc) and its trapz function for the intervals -4.00 to +1.00 D (total), -0.50 to +0.50 D (far), -2.00 to -0.50 D (intermediate), and -4.00 to -2.00 D (near) of the defocus curves.[15] Matlab software was also used to calculate the effective total depth of field (TDOF) for a threshold of 0.1 logMAR or less and for the range between -4.00 and 0.00 D of the defocus curves, adapting the method used in a previous laboratory study[6] to clinical defocus curves. The Statistical Package for the Social Sciences (SPSS, v25; IBM Corporation) was used for the statistical analysis. Mid

TABLE 1
Patient Demographics

Characteristic	1st Follow-up		2nd Follow-up	
	Mid Eyes	Plus Eyes	Mid Eyes	Plus Eyes
No. of patients	27		23	
Sex, F/M, (%)	63/37		63/37	
Age (years), mean ± SD (range)	63 ± 9 (50, 84)	63 ± 9 (50, 84)	62 ± 7 (50, 73)	62 ± 7 (50, 73)
Photopic pupil diameter (mm) , mean ± SD (range)	2.88 ± 0.45 (2.21, 3.96)	2.80 ± 0.53 (2.07, 3.92)	2.87 ± 0.44 (2.21, 3.96)	2.81 ± 0.54 (2.07, 3.92)
Chord μ (mm), mean ± SD (range)	0.23 ± 0.12 (0.06, 0.48)	0.22 ± 0.12 (0.05, 0.43)	0.23 ± 0.12 (0.07, 0.39)	0.22 ± 0.12 (0.05, 0.43)
Corneal SA (6-mm pupil, μm), mean ± SD (range)	0.297 ± 0.111 (0.129, 0.590)	0.316 ± 0.109 (0.123, 0.573)	0.282 ± 0.098 (0.129, 0.534)	0.296 ± 0.101 (0.123, 0.522)
AL (mm), mean ± SD (range)	23.28 ± 0.68 (22.26, 25.57)	23.27 ± 0.69 (22.22, 25.37)	23.30 ± 0.72 (22.26, 25.57)	23.30 ± 0.75 (22.22, 25.37)
Km (D), mean ± SD (range)	43.32 ± 1.31 (39.95, 45.31)	43.25 ± 1.34 (40.09, 45.77)	43.52 ± 1.49 (39.95, 45.31)	43.37 ± 1.43 (40.09, 45.49)
Preoperative SE (D), mean ± SD (range)	1.15 ± 1.90 (-4.50, 4.00)	0.99 ± 2.15 (-5.13, 3.63)	0.96 ± 2.11 (-4.50, 3.63)	0.93 ± 2.20 (-5.13, 3.63)
IOL power (D), mean ± SD (range)	23.60 ± 1.80 (20.00, 26.50)	23.80 ± 1.80 (19.50, 26.00)	23.23 ± 1.97 (18.00, 26.00)	23.59 ± 2.04 (18.00, 26.00)

AL = axial length; D = diopters; IOL = intraocular lens; Km = mean keratometry; SA = spherical aberration; SD = standard deviation; SE = spherical equivalent
The Artis Symbiose Mid and Plus intraocular lenses are manufactured by Cristalens Industrie.

eyes and Plus eyes were treated as independent samples, because different IOLs were implanted in each group. The Shapiro-Wilk test was used to determine data distribution. The parameters that followed a normal distribution are reported as mean ± SD, and the *t* test was used for comparisons, whereas parameters that showed a non-normal distribution are reported as median (interquartile range [IQR]), and the Mann-Whitney *U* test was used for comparisons.

RESULTS

The demographic data of the patients can be found in **Table 1**.

DEFOCUS CURVES AND CONTRAST SENSITIVITY

Monocular and binocular defocus curves with best distance correction are shown in **Figure 1**. A statistically significant difference between the monocular defocus curves was found at the -1.00 D (P = .013, Cohen's d = -0.713), -1.25 D (P < .001, Cohen's d = -1.278), -1.50 D (P = .005, Cohen's d = -0.824), -1.75 D (P = .018, Cohen's d = -0.692), -2.50 D (P = .002, Cohen's d = 0.888), -2.75 D (P < .001, Cohen's d = 1.355), -3.00 D (P < .001, Cohen's d = 1.169), -3.50 D (P < .001, Cohen's d = 1.073), and -4.00 D (P = .006, Cohen's d = 0.793) defocus steps. The mean AUCs of the Mid eyes monocular defocus curves were 2.78 ± 0.97, 0.57 ± 0.17, 1.28 ± 0.52, and 0.76 ± 0.36 area units for the total, far, intermediate, and near intervals, respectively.

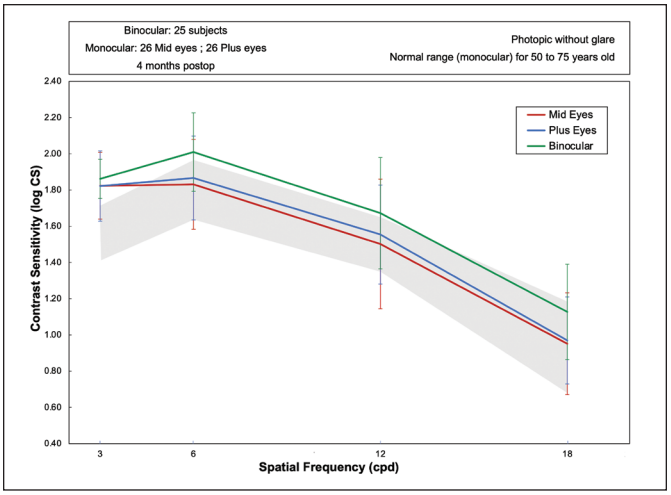

Figure 2. Mean binocular (green line) and monocular photopic contrast sensitivity without glare for Artis Symbiose Mid IOL (Cristalens Industrie) implanted eyes (red line) and for Artis Symbiose Plus IOL (Cristalens Industrie) implanted eyes (blue line). The gray area represents the normal monocular contrast sensitivity values for patient age between 50 and 75 years. Error bars represent ± standard deviation. cpd = cycles per degree

For the monocular defocus curves of the Plus eyes, the mean AUCs were 2.81 ± 0.88, 0.57 ± 0.17, 0.93 ± 0.40, and 1.18 ± 0.38 area units for the total, far, intermediate, and near intervals, respectively. For the binocular defocus curves, the average AUCs were 3.99 ± 1.02, 0.72 ± 0.17, 1.62 ± 0.49, and 1.40 ± 0.38 area units for the total, far, intermediate, and near intervals, respec-

tively. The median (or mean ± SD) effective TDOF at 0.1 logMAR was 2.26 (1.01) D, 2.03 ± 0.89 D, and 3.13 (0.48) D, for the Mid eyes, the Plus eyes, and binocularly, respectively. No difference was found between the distribution of the monocular TDOFs ($P = .934$).

The average monocular and binocular photopic contrast sensitivities without glare are shown in **Figure 2**.

Binocular Visual Acuity and Monocular Refractive Outcomes

At 6 weeks, binocular uncorrected distance visual acuity (UDVA) was -0.02 ± 0.12 logMAR and binocular uncorrected near visual acuity (UNVA) was 0.08 ± 0.10 logMAR. The binocular visual acuities at 6 months were median (IQR) -0.10 (0.10) and mean ± SD -0.11 ± 0.10, -0.03 ± 0.20, 0.05 ± 0.12, 0.03 ± 0.11, 0.00 ± 0.09, 0.06 ± 0.10, 0.04 ± 0.09 logMAR for UDVA, CDVA, uncorrected intermediate visual acuity at 90 cm, distance corrected intermediate visual acuity at 90 cm, uncorrected intermediate visual acuity at 70 cm, distance corrected intermediate visual acuity at 70 cm, UNVA, and distance-corrected near visual acuity, respectively.

The standard binocular clinical outcomes are shown in **Figure 3**.

Photic Phenomena, Stereopsis, and Quality-of-Life

The LDI was 12.57 (6.61)%, 14.99 ± 5.70%, and 10.36 ± 4.42%, for the Mid eyes, Plus eyes, and binocularly, respectively. A Mann-Whitney *U* test was used to determine whether there were differences in the LDI distribution between Mid eyes and Plus eyes. No statistically significant differences were found in the LDI between Mid eyes and Plus eyes (Mann-Whitney $U = 409.0$, $P = .19$).

The stereopsis of the sample was 40.0 (12.5) arcsec. The score of the V-14 questionnaire at 6 months was 95.99 (7.14).

Safety

Mean preoperative monocular corrected distance visual acuity (CDVA) was 0.09 ± 0.17 logMAR, whereas mean postoperative monocular CDVA was -0.05 ± 0.09 logMAR. One hundred percent of eyes achieved a CDVA of 0.3 logMAR or better, and 0% of eyes had a decreased postoperative CDVA of two or more lines of the optotype in comparison to the preoperative CDVA. **Table 2** shows the adverse events found during the study period. No posterior capsular opacification was found during the study period.

DISCUSSION

To our knowledge, this is the first study to analyze the monocular and binocular defocus curves with a new binocular complementary system of IOLs. We have presented the standard clinical outcomes, patient satisfaction, and evaluation of photic phenomena.

The comparison of the monocular defocus curves of the eyes implanted with the Mid and Plus IOLs demonstrated they function in a synergistic manner to afford the patient excellent binocular vision. No difference in visual acuity was found at their far foci. Conversely, the Mid IOL provided better intermediate vision and the Plus IOL showed better outcomes at near distances in the monocular defocus curves. Our results correlate with a recent laboratory study in which simulated visual acuity defocus curves were obtained from optical bench measurements.[17] This difference in the mean visual acuity between both monocular curves is only clinically relevant (> 0.1 logMAR, > 1 line of the optotype) at the -4.00, -3.50, -3.00, -2.75, and -1.25 D defocus steps, and always less than two lines at any step. This small difference in the monocular visual acuity and the fact that the mean binocular defocus curve was always better than the best eye suggests that the difference in light energy produced by both IOLs is small enough to guarantee the binocular summation (ie, patients were using both eyes at all distances). This is also supported by the stereoacuity outcomes at 40 cm, showing a median of 40 arcseconds, which is the lowest value of our Titmus test.

A recent study of patients bilaterally implanted with Plus IOLs showed a monocular defocus curve shape similar to our study for the Plus eyes but with worse visual acuity at closer distances (below -2.50 D of defocus).[9] This difference might be due to the IOL apodization and the different illuminance conditions between studies (10 vs 503 lux in our study). The mean binocular defocus curve showed a plateau shape with visual acuity within one line (0 to -0.10 logMAR) from -2.50 to +0.50 D. From the shape of the binocular defocus curve, one can infer that the combined use of both Artis Symbiose IOLs potentiates intermediate vision, avoiding the typical decrease in visual acuity between -1.00 and -2.00 D of defocus shown by other multifocal IOLs such as the FineVision (PhysIOL)[18] or the Tecnis Synergy (Johnson & Johnson Vision) IOLs,[7] maintaining a continuous visual acuity within the near-to-intermediate range and showing a more stable curve within the whole range compared to either the AcrySof IQ PanOptix (Alcon Laboratories, Inc) IOL[19] or the bilateral implantation of Plus IOLs in mesopic conditions.[9] The binocular effective TDOF was 3.13 (0.48) D, which is in keeping with the TDOF described by a previous laboratory study (2.90 D),[6] and adequate enough (> 3.00 D) to provide complete spectacle independence to presbyopic patients.

Postoperatively, the contrast sensitivity seen in photopic conditions without glare was in the range comparable with virgin eyes in age-appropriate controls,[16] which

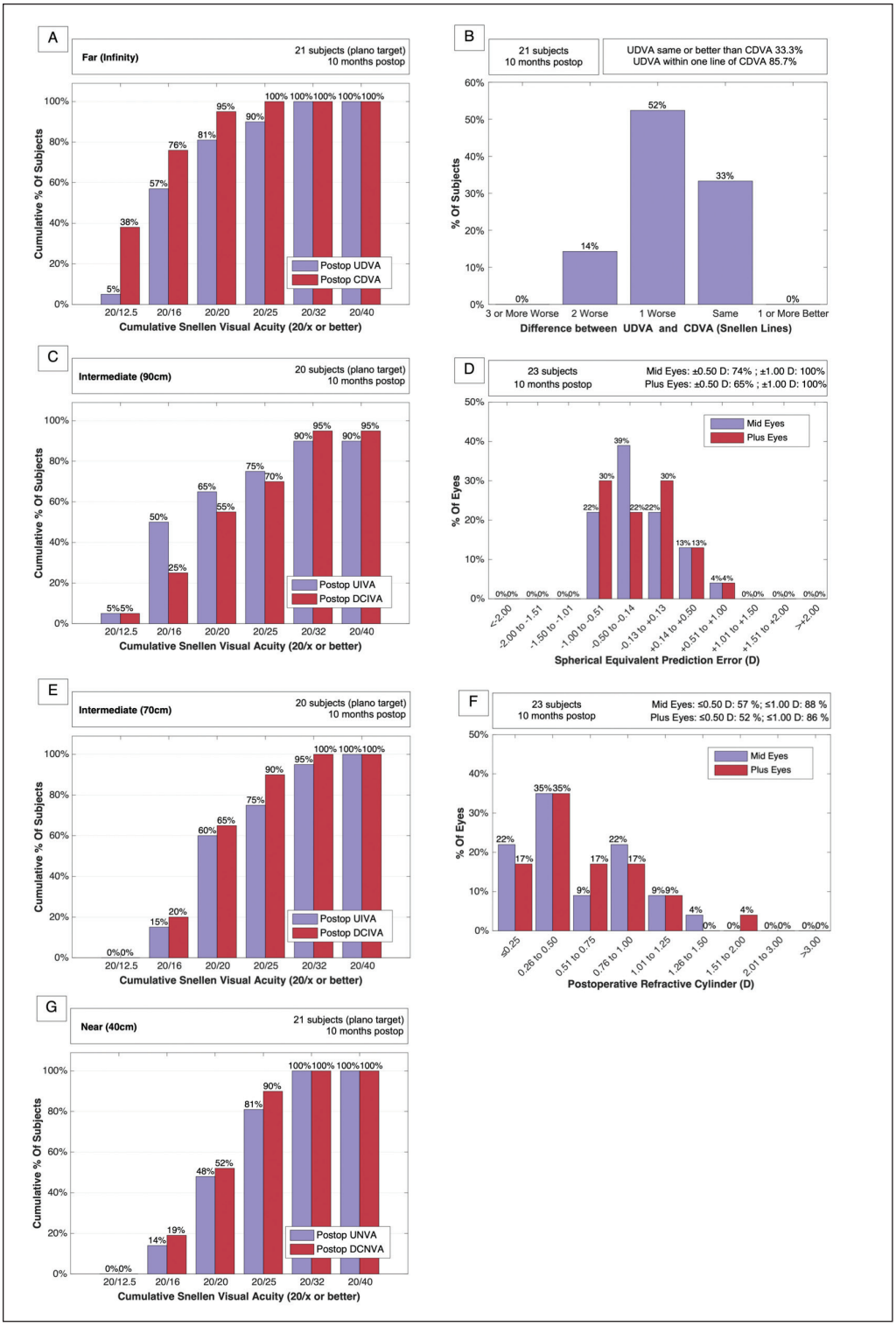

Figure 3. Standard graphs for intraocular lens (IOL)–based cataract surgery. Binocular visual acuity at different distances and monocular refractive outcomes of eyes implanted with Artis Symbiose Mid or Plus IOLs (Cristalens Industrie). CDVA = corrected distance visual acuity; D = diopters; DCIVA = distance-corrected intermediate visual acuity; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; UNVA = uncorrected near visual acuity

was a surprise finding given that these multifocal IOLs distribute the light energy between distinct foci, providing less light energy at far distance than monofocal IOLs. The binocular contrast sensitivity was slightly higher than the monocular contrast sensitivity, also supporting the idea that patients retained their binocular summation.

Overall, the Artis Symbiose performed excellently in terms of visual acuity with the binocular visual acuities better than 0.1 logMAR at all tested distances. Moreover, 81% of the patients achieved a binocular UDVA of 20/20 or better, 65% reached uncorrected intermediate visual acuity at 90 cm, 60% attained uncorrected

TABLE 2
Adverse Events Found During the Study Follow-up

Adverse Event	No. of Eyes	Secondary Intervention
Refractive surprise	2 (4%)	Yes[a]
Posterior vitreous detachment	4 (8%)	No
Macular edema	2 (4%)	No
Dry eye syndrome	2 (4%)	No
Age-related macular degeneration	1 (2%)	No

[a]*Photorefractive keratectomy enhancement*

intermediate visual acuity at 70 cm, and 48% achieved a binocular visual acuity of 20/20 or better in uncorrected near visual acuity. Of note, surgeries were planned to achieve a residual astigmatism of 0.75 D or less, using incisions on the steep meridians when necessary, but 13% of the Mid eyes and 13% of the Plus eyes had a residual astigmatism of greater than 1.00 D, which contributed to the reduction of the uncorrected visual acuity at all distances. We believe that the corneal astigmatism orientation provided by the biometer was not accurate in some cases, and this led to some refractive errors, which in this study were corrected with photorefractive keratectomy surgery in 2 eyes (4%).

The appearance of a photic phenomenon is a recognized limitation with multifocal IOLs[20] and is a reason for IOL exchange.[21] Artis Symbiose IOLs are apodized, whereby the diffractive steps height decreases from the center to the periphery of the optical zone to change the energy distribution between foci, endeavoring to reduce the photic phenomena. In this study, we assessed photic phenomena semi-objectively with a new device, the Light Distortion Analyzer, which reports the size of these phenomena. The LDIs were 12.57% (range: 7.64% to 23.71%) for the Mid eyes and 14.99% (range: 7.24% to 28.65%) in the Plus eyes. There was no difference in the distribution of the LDI between Mid and Plus eyes, which surprised us because we expected a higher LDI in the latter group, given that it is recognized that the amount of addition power of multifocal IOLs is a factor influencing the size of photic phenomena.[22] The small sample of this study is likely to explain the lack of a significant difference in the LDI between Mid and Plus eyes. If the LDI is analyzed binocularly, this reduces to 10.36% (range: 3.82% to 22.76%), again supporting the idea of a retained binocular summation.

Other researchers have used the same device for assessing the photic phenomena of patients implanted with multifocal and EDOF IOLs. Escandón-García et al[23] measured the monocular LDI in patients implanted with the FineVision (PhysIOL), the AcrySof IQ PanOptix IOL, and the Tecnis Symfony (Johnson & Johnson Vision) IOLs, reporting LDI values of 28.60%, 26.10%, and 34.60%, respectively. Guarro et al[24] also evaluated the LDI of three EDOF IOLs, AcrySof IQ Vivity (Alcon Laboratories, Inc), AT Lara (Carl Zeiss Meditec AG), and Tecnis Symfony, and a monofocal IOL, AcrySof IQ (Alcon Laboratories, Inc), reporting monocular values of 14.36%, 29.18%, 23.54%, and 13.03%, respectively. It can be seen that our results with both Mid and Plus IOLs seem to produce milder photic phenomena than the other evaluated multifocal IOLs and comparable to the refractive EDOF and monofocal IOLs. One should be cautious with these comparisons between studies because the LDI relies heavily on the illuminance conditions and is patient dependent. A prospective comparative study would be necessary to prove definitively these differences and similarities between the IOLs.

We incorporated the patients' subjective experience into our results by using the Spanish version of the Visual Function Index (VF-14) questionnaire.[25] The score of this questionnaire ranges from 0 (complete disability in performing any tasks due to vision) to 100 (complete absence of any limitation). The score at 6 months was 95.99 (8.92), denoting high patient satisfaction, with 100% of patients reporting not wearing glasses regularly and only 2 patients (7%) reporting wearing near glasses specifically for a single task (sewing).

The main limitation of this study was the lack of a systematic follow-up of some patients due to the coronavirus disease 2019 pandemic. Nevertheless, this study was not designed to be a longitudinal study, and the time frame of the follow-up visits was longer than designed, providing longer term outcomes. A further limitation is the low sample size, also affected by the coronavirus disease 2019 pandemic, which led to some patients being lost to follow-up. However, the sample was large enough to analyze and compare the monocular defocus curves, as shown by the effect sizes, reported by the Cohen's d values, which were always either medium (> 0.5) or large (> 0.8). On the other hand, the sample size does not seem enough to find differences between both IOLs in the LDI.

This pilot study describes the clinical outcomes with the combination of Artis Symbiose IOLs. We have shown that both types of Artis Symbiose IOLs work synergistically, evidenced by their monocular defocus curves, and the retained binocular summation of the image of both eyes as extracted from the binocular defocus curve. The Artis Symbiose IOLs were an effective and safe treatment for our patients with cataract, able to restore a continuous range of vision by using binocularity, thus compensating for presbyopia.

AUTHOR CONTRIBUTIONS

Study concept and design (JL-B, JFZ-D); data collection (JL-B, MAR-I, MRGO-G); analysis and interpretation of data (JL-B, MAR-I, LV-S-L, GJ); writing the manuscript (JL-B, MAR-I); critical revision of the manuscript (JL-B, MAR-I, LV-S-L, GJ, MRGO-G, JFZ-D); statistical expertise (MAR-I, GJ); administrative, technical, or material support (JL-B, MAR-I, LV-S-L, JFZ-D); supervision (JL-B, JFZ-D)

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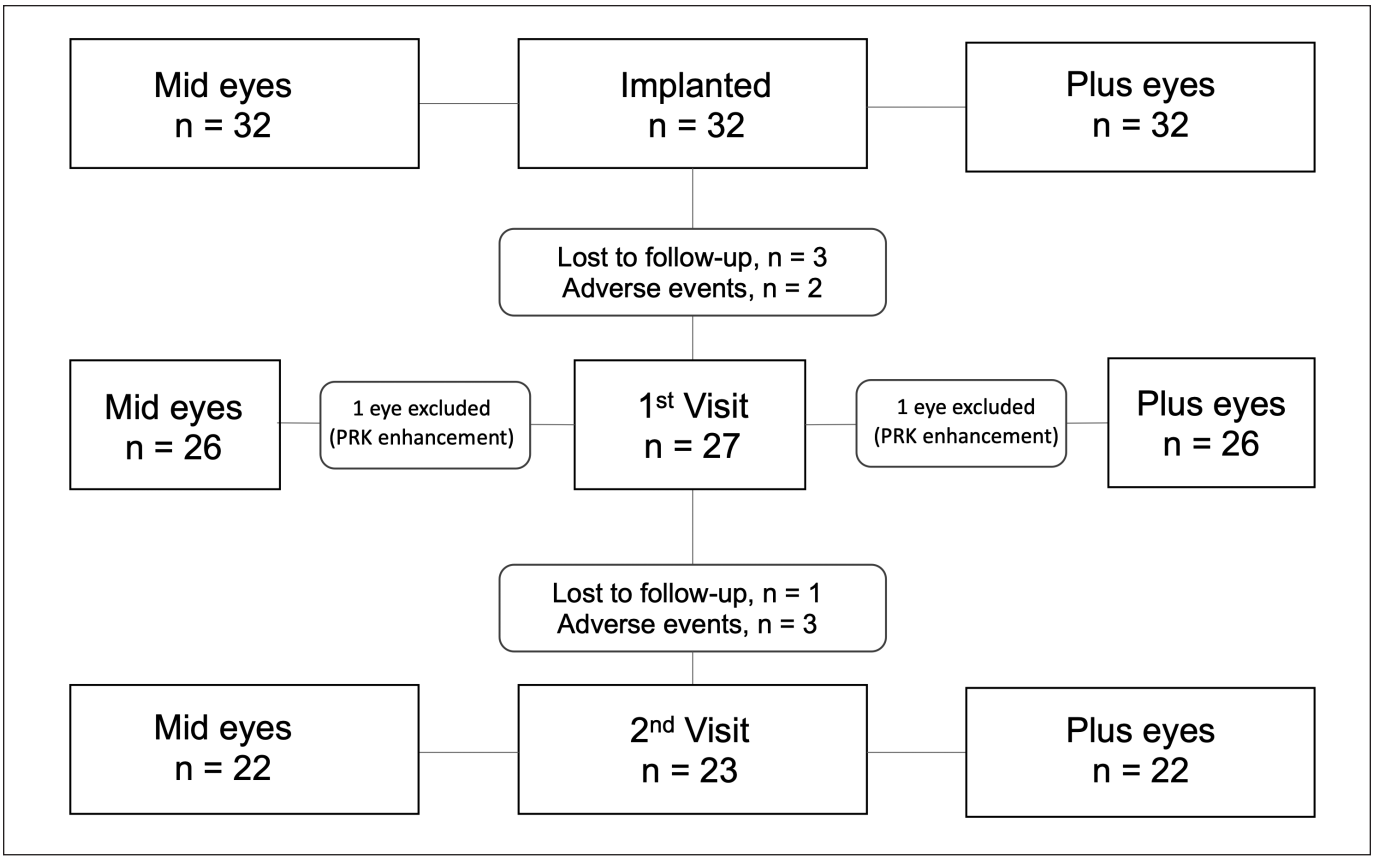

Figure A. Distribution of patients and eyes at each of the study follow-up visits. The Artis Symbiose Mid and Plus are manufactured by Cristalens Industrie.

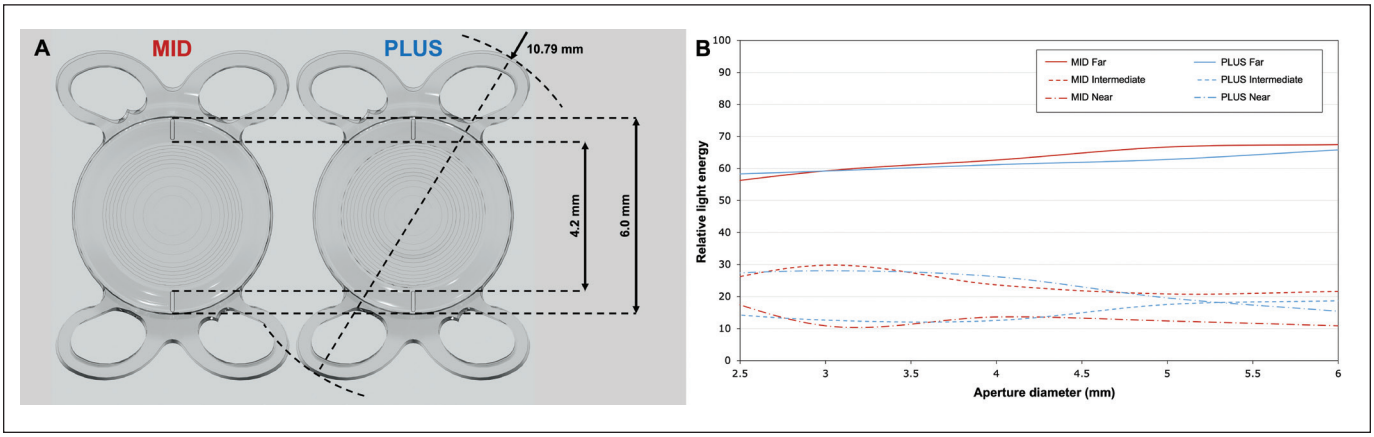

Figure B. (A) Front-side view (not to scale) of the Artis Symbiose (Cristalens Industrie) intraocular lenses (IOLs), Mid (left) and Plus (right), showing the dimensions of the lenses. (B) Graph of the energy distribution of the study IOLs against the aperture diameter. The red lines represent the energy distribution at the different ranges (far, intermediate, and near) of the Mid IOL, whereas the blue lines represent the Plus IOL. Images created using data from Cristalens Industrie.

TABLE A

Description of Assessments Performed at All Follow-up Visits

	Preop	Day 1	Day 7	V1	V2
Anamnesis	X				
Anterior Segment Evaluation and Fundoscopy	X	X	X	X	X
Anterior Segment OCT	X				
Endothelial Cell Count	X				
Tonometry	X	X	X	X	X
UDVA and CDVA	X			X	X
Manifest Refraction	X			X	X
Ocular Dominance	X				
Biometry	X				
Corneal Tomography	X			X	X
Tear Film Evaluation	X				
Defocus Curves				X	
Contrast Sensitivity				X	
UNVA and DCNVA				X	X
UIVA90 and DCIVA90					X
UIVA70 and DCIVA70					X
Photic Phenomena Evaluation				X	
Stereopsis					X
Quality of Life					X

V1 = first study follow-up; V2 = second study follow-up; UIVA90 = uncorrected intermediate visual acuity at 90cm; DCIVA90 = distance corrected intermediate visual acuity at 90cm; UIVA70 = uncorrected intermediate visual acuity 70cm; DCIVA70 = distance corrected intermediate visual acuity at 70cm. Devices used were: OCT (Cirrus, Carl Zeiss Meditec AG, Germany); Biometry (IOL Master v5.4, Carl Zeiss Meditec AG, Germany); Corneal Tomography (Pentacam, Oculus, Germany) Tear Film Evaluation (LipiView II, TearScience, USA & Ocular Surface Analyzer, SBM Sistemi, Italy); Contrast sensitivity (CSV-1000, VectorVision, USA); Photic Phenomena (Light Distortion Analyzer, Binary Target, Portugal); Stereopsis (Titmus test, circles, StereoOptical, USA); Quality of Life (Spanish version of the VF-14 questionnaire)