Visual outcomes after bilateral implantation of a new diffractive multifocal IOL: Preliminary results

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TITLE PAGE

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The study protocol was approved by the Ethics Committee of the Clinico San Carlos Hospital, Madrid, Spain. Declarations of interest: none

ABSTRACT

Background: The aim was to determine visual outcomes and patient satisfaction in patients undergoing cataract surgery after the binocular implant of multifocal difractive Intensity IOL

Methods: 21 patients were evaluated. Six weeks after surgery, uncorrected distance visual acuity(UDVA), corrected distance visual acuity(CDVA), distance corrected intermediate visual acuity at 60 cm(DCIVA) and distance corrected near visual acuity at 40cm (DCNVA) were determined using the ETDRS test. Defocus curves were produced both in photopic and mesopic conditions. Contrast sensitivity(CSF) was measured using the CSV-1000 test. Patients were shown pictures about dysphotopic phenomena and informed about their meaning with a likert scale from 0 (no problem) to 4 (overwhelming).

Results: Post implantation mean logMAR Binocular UDVA, CDVA, DCIVA and DCNVA were 0.07± 0.09, -0.01 ± 0.04, 0.08 ± 0.05 and 0.12 ± 0.06 respectively. Photopic defocus curve showed a extended range of good vision. Mesopic defocus curve results were better than previously reported with trifocal designs. Mean binocular CSF values for 4 spatial frequencies (3, 6, 12 and 18 cpd) were 1.55±0.29, 1.60±0.17, 1.29±0.26 and 0.81±0.15 log. units, respectively. Halos were more frequent than starburst and glare with a Likert scale mean value of 0.86±0.83.

Conclusions: The IOL provided a continuous range of vision from distance to near. Patients were not bothered or only slightly bothered in relation to the visual disturbances.

KEY WORDS

Cataract

Intraocular lens

Diffractive

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Patient satisfaction

Introduction

Intraocular lenses (IOL) used in modern cataract surgery have been designed to achieve a good quality of vision at near and intermediate distance as well as far dividing the incoming light to several foci. The new generation of multifocal IOLs attempts the patient satisfaction, which depends on the spectacle independence, a sufficient degree of contrast sensitivity and absence or low discomfort with visual disturbances such halos and glare[1, 2].

Intensity is a new generation of presbyopia correcting IOL. The material is Hydrophilic Acrylic (25% water content) with bonded UV absorber and refractive index of 1.46 including a natural Yellow Violet Filter. The optic design shows an aspheric-diffractive posterior surface and a spherical anterior surface with an induction of spherical aberration of -0.13μ and a power range from 10.0D to 30.0D in 0.50D steps.

The IOL profile is built of smooth shapes with a total of 12 steps with a central ring in 1mm diameter. Step heights vary along the lens radius with a maximum step height 3.6 microns. Center zone diameter from 0 to 4 mm is designed for photopic vision whereas the zone from 2.5 to 5.2 mm is designed for mesopic and scotopic vision. This pupil dependent profile attempt to reduce the energy lost in comparison to other diffractive lenses, potentially decreasing visual disturbances and intensifying vision. This contributes to the modulated transfer function (MTF) is increased in the area between far-intermediate and intermediate to near, enabling a continuous uninterrupted vision throughout the entire vision range. Intermediate focal points differ among different diffractive models. The design present a symmetric foci distribution around the zero order at 80cm (infinity, 133cm, 80cm, 60cm and 40cm).

The present study was designed to determine visual outcomes and patient satisfaction in patients undergoing cataract surgery after the binocular implant of Intensity IOL in both eyes. We evaluated Far, near and intermediate visual acuity, defocus curve both in photopic and mesopic conditions, contrast sensitivity function and visual disturbances. To the best of our knowledge there are no previous publications about this IOL.

Methods

This prospective experimental study adhered to the tenets of the Declaration of Helsinki. The study protocol was approved by the San Carlos Clinical Hospital review board and written informed consent was obtained from all patients. To qualify for the study, it was required that patients had been diagnosed with cataract in both eyes, had no other ocular disease, and had not undergone prior ocular surgery. Subjects were included if they were 60 to 80 years old, had expressed a desire to be independent of spectacles and their pre-surgery refraction was a sphere of up to ± 5.00D with an corneal astigmatism of equal or less than 1.00D.

All patients had cataract surgery by two experienced surgeons (JMC and JGB) under topical anesthesia through a 1.8 mm clear corneal incision. Phacoemulsification was performed using the Stellaris system (Bausch & Lomb Incorporated, Rochester, NY) and this was followed by irrigation and aspiration of the cortex and IOL implantation in the capsular bag. The second eye operation was performed within 2 weeks of the first. Axial Length (AL) was measured with IOL Master 700 (Carl Zeiss Meditec AG, Jena, Germany). The IOL power calculation was performed with Barret True-k formula. The chosen target was the closest value to emmetropia.

Six weeks after the second surgery, all patients underwent an optometric examination in which objective refraction and keratometry were conducted using the wavefront analyzer Topcon KR-1 W (Oakland, USA). Pupillometry in a dark room was assessed using the same instrument in both photopic and mesopic conditions to induce physiologically normal pupil sizes. Next, subjective refraction was performed with a trial frame and trial lens set. The relative power vector values of M, J0 and J45 were obtained. The method uses 3 fundamental vectors, including $M = S + C/2$, $J0 = (-C/2)\cos 2\alpha$, and $J45 = (-C/2)\sin 2\alpha$, where S is the sphere power, C is the cylinder power, α is the cylinder axis, and J is the Jackson astigmatic vector. M is the spherical lens equal to the spherical equivalent of the refractive error. J0 value is the cylinder power set at 90 and 180 degrees and J45 value refers to a cross-cylinder set at 45 and 135degrees.[3]

Postoperative far visual acuities were measured both monocularly and binocularly. Uncorrected distance visual acuity (UDVA) and corrected distance visual acuity with the subjective refraction (CDVA), were measured in logMAR notation in photopic (85 cd/m^2) luminance conditions using an ETDRS illumination cabinet with high contrast (96%) at a distance of 4 meters with the normal room lighting left on. Two different letter charts were used to prevent memorization of letters by participants. Subjects were required to identify each letter on the chart until they identified a full row of letters incorrectly, at which point the test was terminated and acuity calculated. Subjects were encouraged to guess letters if they were unsure. Next, given that the IOLs in our patients were implanted in both eyes to optimize vision, intermediate (distance corrected intermediate visual acuity at 60 cm, DCIVA) and near (distance corrected near visual acuity at 40cm, DCNVA) visual acuity were measured binocularly using the EDTRS scale with distance correction under the same photopic conditions. Then, using the ETDRS charts at 4 meters, two additional lenses of the same power were simultaneously introduced in front of both eyes to produce defocus and then measure visual acuity. The range of lenses used was −4.00D to +1.50D in 0.50D steps. This method has been validated as a repeatable and reliable procedure to measure the amplitude of accommodation.[4] Given the Intensity IOL was designed to work in conjunction with pupil aperture, defocus curve testing was performed in both photopic (85 cd/m^2) and mesopic ($\leq$3 cd/m^2) conditions. For the mesopic luminance level required, illumination was reduced by using a large filter designed for use in the ETDRS cabinet with the room lighting turned off.

Monocular and binocular contrast sensitivity function (CSF) were measured using the CSV-1000 test (Vector Vision, USA) at 2.50 meters for 4 frequencies in cycles per degree (cpd) (A: 3 cpd, B: 6 cpd, C:12 cpd and D: 18 cpd). The chart was retroilluminated with an 85cd/m^2 fluorescent light and the normal room lighting was left on. As sensitivity is the inverse of contrast values, the log unit was used, and therefore, higher log values indicate better sensitivity.

Patients were shown pictures about dysphotopic phenomena representing glare, halo, starbust or combined (figure 1) and informed about their presence and meaning. The pictures were shown and patients were asked to classify each of these 3 visual symptoms according to a 5-point Likert scale (0 = no trouble; 1 = minimal trouble; 2 = moderate trouble; 3 = considerable trouble; 4 = overwhelming trouble). A similar procedure was described by Kretz et al. [5]

Statistical analysis

Quantitative data are provided as means and standard deviations. The Student t-test for paired data was used to compare normally distributed data as confirmed using the Shapiro-Wilks test, and the Wilcoxon rank-sum test was used for non-normally distributed data. The comparison between the visual acuity values obtained in the defocus curve was realized with a repeated measured ANOVA with a Greenhouse-Geisser correction following by Bonferroni´s post hoc test. All statistical tests were performed using Statgraphics-19 (Statgraphics Technologies, USA). Significance was set at a $p < 0.05$.

Results

The final study sample comprised 42 eyes of 21 patients (13 women, 8 men). Mean age was 70.3 ± 5.8 years (range 61-81). Table 1 shows the refractive values expressed as relative powers vectors. Also, keratometric values, the axial length and the pupil diameters assessed in photopic and mesopic conditions. No statistically significant differences were found between both eyes in any case. Regarding the predictability, 30 of 42 eyes showed a M value equal or less than ± 0.50D and 38 of 42 eyes within ± 1.00D.

Table 2 shows visual acuity outcomes after IOL implantation. No statistically significant differences were found between both eyes in any case. When the binocular far visual acuity was compared without and with correction, there was found a statistically but not clinically significant difference of 4 logMAR letters ($p<0.001$). When the corrected far, intermediate and near binocular visual acuity results were compared, there was found a statistically significant difference (Greenhouse-Geisser; $p<0.001$). The Bonferroni post hoc comparison showed a statistically but not clinically significant mean difference of 4 logMAR letters between far and intermediate vision, and a statistically significant mean difference of 1 line and 3 logMAR letters between far and near vision. Moreover, there was found a statistically but not clinically significant mean difference between intermediate and near vision of 4 logMAR letters.

Figure 2 shows the photopic and mesopic defocus curves after IOL implantation. In photopic conditions, a statistically significant difference was found between the visual acuity outcomes (Greenhouse-Geisser; $p<0.001$). No statistically significant differences were found between the obtained values from 0.00D to -2.50D. There was found a statistical but not clinically significant difference between 0.00D and +0.50D ($p=0.009$) with a mean difference of 3 logMAR letters. Finally, there was found a statistically significant difference between 0.00D and the rest of powers (-3.00D,-3.50D,-4.00D, +1.00D and +1.50D; $p<0.001$). In mesopic conditions, the defocus curve consisted of one peak of maximum vision located at the far focus without statistically significant differences between the obtained values from +0.50D to -0.50D. There were found statistical but not clinically significant differences between the values obtained with 0.00D and -1.00D ($p=0.003$); -1.50D ($p=0.003$) and -2.00D ($p= 0.001$), with a mean difference lower than 1 logMAR line in all cases. Finally, there was found a statistically significant difference between 0.00D and the rest of powers ($p<0.001$) When photopic and mesopic defocus curves were compared, statistically significant differences between all foci were found ($p<0.001$).

Monocular and binocular contrast sensitivity functions are represented in figure 3. There was no statistically significant difference between both eyes. Post implantation mean binocular values for 4 spatial frequencies (3, 6, 12 and 18 cpd) were 1.55 ± 0.29, 1.60 ± 0.17, 1.29 ± 0.26 and 0.81 ± 0.15 log. units, respectively.

Table 3 shows the percentage of patients with each type of dysphotopic phenomena and the mean value in the Likert scale. The halos were more frequent than starburst and glare. The 52.38% of patients reported a Likert scale value equal or less than 1. The worst assessment was reported by 2 patients who perceived Halo + starburst which had spontaneous complaints about visual disturbances. In any case, they only reported a moderate trouble (likert scale=2). In the whole sample, the mean value was 0.86 ± 0.83

Discussion

This prospective study introduces the results of a new IOL with an aspheric-diffractive posterior surface and a spherical anterior surface (Intensity IOL). This IOL offered satisfactory logMAR visual acuity at far, intermediate and near distances under both photopic and mesopic conditions.

Regarding the predictability, 71,42% of eyes showed a M value equal or less than ± 0.50D and 90.47% within ± 1.00D. Due to only 3 eyes had an AL ≤ 22mm and other 3 had a AL ≥ 24.5mm, it was not possible analyze the relation between short/long eyes and predictability reported by other authors[6]. Previous studies with trifocal designs reported a predictability from 85 to 100%[7-9] within ±0.50, although the results can be influenced by the characteristics of the sample and the differents equation used[10]. The lower predictability in this study can be explained because 18 of 42 eyes had a corneal astigmatism from 0.75 to 1.00 of which 11 eyes presented a refractive cylinder from 0.75D to 1.00D.

The high levels of visual acuity at different distances confirm that the multifocality generated by this IOL does not induce deterioration in visual quality in terms of corrected visual acuity. The binocular far vision results (0.07 logMAR for UDVA and 0.00 logMAR for CDVA) were similar to the logMAR visual acuity reported by previous studies with diffractive IOLs. Previous authors reported that the mean UDVA from 5 studies after AcrySof IQ PanOptix TNFT00 implantation[11-15] was 0.036 logMAR (range -0.02, 0.07), mean UDVA from 6 studies with AT LISAtri 839 MP[7, 11-13, 16, 17] was 0.02 logMAR (-0.03 , 0.08) and mean UDVA from 5 studies with Finevision microF[7, 12, 17-19] was 0.07 logMAR (0.03, 0.18). Regarding CDVA, the mean CDVA from 5 studies after Panoptyx IOL implantion[11-14, 20] was 0.00 logMAR(-0.06, 0.01), mean CDVA from 6 studies with AT LISAtri 839 MP was 0.00 logMAR (-0.04, 0.04) [7, 11-13, 16, 17] and mean CDVA from 5 studies with Finevision MicroF was 0.02 (-0.02, 0.05)[7, 12, 17, 19, 21] .

Intermediate focal points differ among different diffractive models. One of the 5 distributed foci in the Intensity IOL is designed at 60cm. AT LISA tri 839MP has the intermediate focus at 80 cm, whereas PanOptix and Finevision have a focus at 60cm. As 60 cm is around the standard arm length, this might provide a more comfortable intermediate vision. With respect to the obtained mean binocular visual acuity in this study at 60cm (0.08 logMAR), is in line with the logMAR mean value found at the same distance after PanOptix implantación by Mencucci et al.[13] (0.06 ± 0.05) and by Kohnen et al. (0.01 ± 0.12)[22]. Also, our result is agree with the logMAR mean values reported at 66cm by Modi et al. after PanOptix implantation (-0.007 ± 0.08)[20], Fernandez et al. with the low addition trifocal IOL Versario3F (0.08 ± 0.09)[6] , Auffarth et al. with the enhaced monofocal ICB00 IOL (0.09 0.11)[23] and Ribeiro et al. with Tecnis Synergy ZFR00V IOL, which combines EDOF and multifocal profiles (0.03 0.10)[24]. Regarding binocular CNVA at 40 cm, the mean value found in this study (0.12 logMAR) is agree with the VA reported at the same distance in previous studies: mean binocular CNVA from 4 studies after PanOptix IOL implantation was 0.10 logMAR (0.04,0.13)[11-13, 20], whereas mean binocular CNVA from 6 studies with AT LISAtri 839 MP was 0.10 logMAR (0.06, 0.13)[7, 11-13, 16, 17] and Binocular Mean CNVA from 4 studies with Finevision microF was 0.09 logMAR (0.03, 0.16)[7, 12, 17, 19].

Binocular defocus testing was consistent with the visual acuity results. The Intensity IOL maintained a mean visual acuity of 0.1 logMAR or better at the photopic defocus range of +0.50D to -2.50 D. Interestingly, in this study, the curve analysis showed a horizontal extended range of good vision without the marked peak in the intermediate distance reported with bifocal designs or the less marked peak found with trifocal IOLs[7, 12, 16, 17, 25]. This photopic curve is in line with the recently published outcomes by Poyales et al. after Finevision POD F and POD F GF[26]. Under mesopic conditions, the obtained values for all the powers were better than those found in a previous study with FineVision Micro F and AT LISA tri 839MP performed with the same setting, with a difference near to 2 logMAR lines from -1.50D to -3.00D[21].

In agreement with previous publications with trifocal and bifocal designs, the incoming light distribution between foci reduced contrast sensitivity. Our CS results showed a reduction with respect to the normal values reported by Pomerance and Evans (1.55 ± 0.15, 1.76 ± 0.18, 1.49 ± 0.22 and 0.91 ± 0.30 log units for 3, 6, 12 and 10 cyc/deg, respectively) for a normally sighted group of 63.9 ± 12.17 years. [27] However, results are in concordance with those reported by Poyales et al. after Finevision POD F and POD G implantation[26]. Also, they are agree with the results found by Alio et al. 1 month after implantation of AT Lisa 809 MP, AT LISA tri 939MP and RESTOR SN6ADI [11].

Perception of photic phenomena and subjective complaints is considered a major concern after multifocal IOLs implantation[28]. De Vries et al. reported that the major complaint of 38.2% of dissatisfied patients was the perception of photic phenomena and subjective complaints included glare and halos.[28] Previous reports showed than phenomena decrease with time which might be attributed to neural adaptation and lower pupil diameters.[8, 29] Moreover, as previous authors suggested, the personality characteristics of the patients conditions the impact on subjective disturbance including the difference in age-related visual need that could explain the different subjective perception of halos and glares.[30] Alba-bueno et al. analized a bifocal design with 3 differents additions and 2 trifocals. When the assessment was carried out with a subjective method, individuals with trifocal IOLs were less bothered by halos than those with bifocals.[31] Despite the short time since the second surgery in this study (6 weeks), patients were not bothered or only slightly bothered, which was in accordance with previous studies with a longer period after surgery[8, 22, 32].

This study had some limitations; a relatively small study size and a short follow-up period. In conclusion, this study demonstrated that the Intensity IOL provides a continuous range of vision from distance to near, with spectacle independence and patient satisfaction. Despite the short time since the surgery of the second eye (6 weeks), patients were not bothered or only slightly bothered in relation to the visual disturbances.

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Figure Legends

Figure 1: Dysphotopic phenomena image presented to the patients. Designed by the authors.

Figure 2: Binocular defocus curves measured in photopic and mesopic conditions.

Figure 3: Monocular and binocular contrast sensitivity function using CSV-1000 test.

Figures

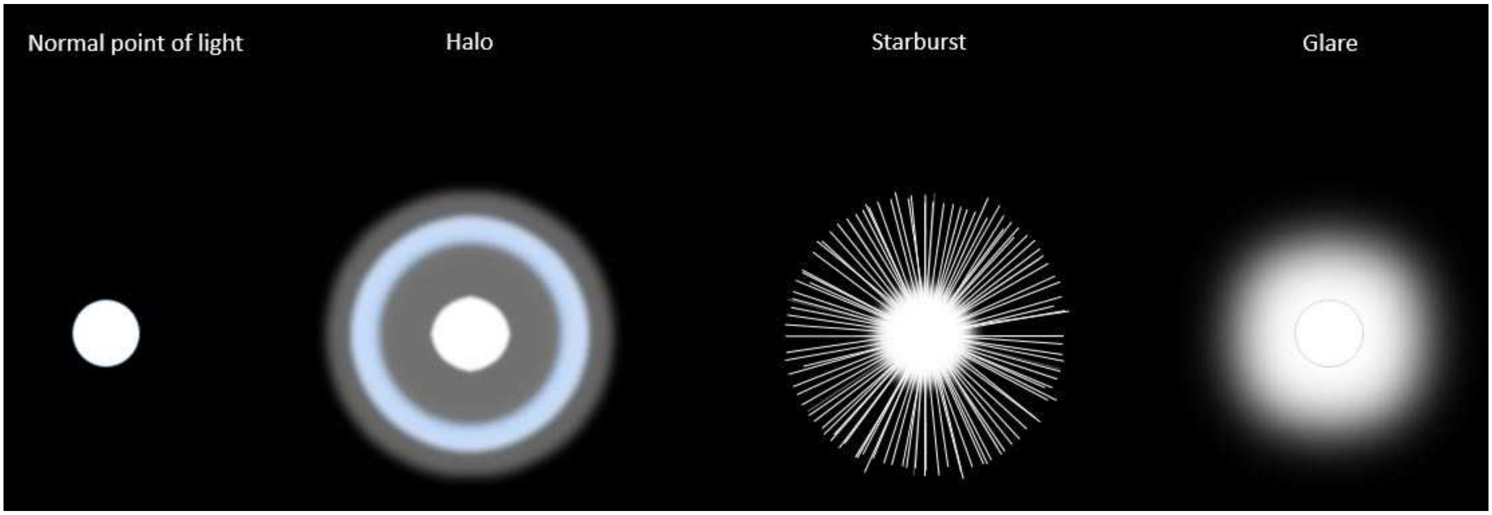

Figure 1

Dysphotopic phenomena image presented to the patients. Designed by the authors.

Figure 2

Binocular defocus curves measured in photopic and mesopic conditions.

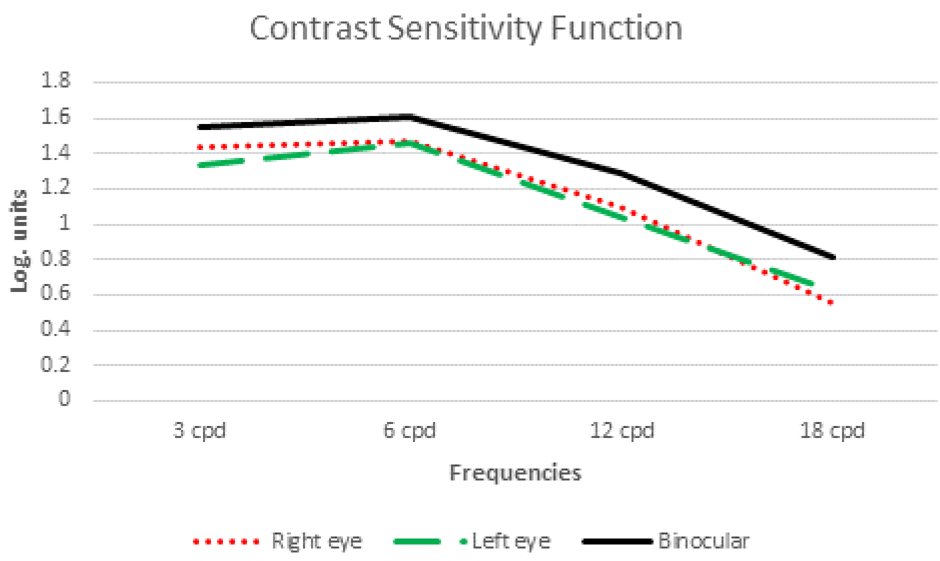

Figure 3

Monocular and binocular contrast sensitivity function using CSV-1000 test

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Intensitytable1220518.docx
- IntensityTable22205181.docx
- Intensitytable32205181.docx