

Visual outcomes after progressive apodized diffractive intraocular lens implantation

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INTRODUCTION

Intraocular lens (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.

Recent progress in cataract surgery has been mainly made in the area of intraocular lenses (IOLs). The IOLs used in modern cataract surgery have been designed for a good quality of vision with minimal complications^{1,2}. Monofocal IOLs, which provide effective distance vision, currently account for most implanted IOLs. Depending on their visual demands, patients receiving a monofocal IOL will likely require spectacles to perform near-distance or intermediate-distance tasks. Trifocal IOLs still with a distance focus yet improved near and intermediate vision aim to reduce spectacle dependence³⁻⁷. However, halos and reduced contrast sensitivity related to multifocal IOLs (bifocal and trifocal IOLs) are common reasons for patient dissatisfaction^{6,8,9}.

Multifocal IOLs utilize a variety of optical designs to reduce visual disturbances and enhance visual acuity at multiple distances.

The BIFLEX M 677MY (Medicontur, Hungary) is an acrylic IOL manufactured from a long-time proven 25% water content copolymer material, with a sharp square edge all over 360° including the optic-haptic junction zone. This lens presents a high Abbe number value (58), intended to reduce the chromatic aberration which is a major

difficulty with diffractive optics than with refractive optics. The lens power range is from 0.00 D to 35.00 D (0.50 D steps).

The progressive apodized diffractive design (from 1.0 to 3.0 mm) to provide improved control of energy distribution whatever the pupil size. Shows 7 diffractive discontinuities or steps that have been incorporated in the anterior surface of the acrylic optic to provide the diffractive added power with an optimized progressive reduction in diffractive step heights from center to periphery (2.2-1.4 μ). The near power lens is +3.50D, equivalent to +2.7D in spectacle's plane.

This design procures to distribute the appropriate amounts of light to near, intermediate and distant focal points adaptive to any lighting situation and to minimize visual disturbances. Also shows an aspheric biconvex optic (6 mm diameter) with neutral approach to maintain depth of field.

The presents study was designed to determinate visual and refractive outcomes in patients undergoing cataract surgery and the implant of a BIFLEX IOL in both eyes. To our knowledge, this is the first study about this IOL.

PATIENTS AND METHODS

This prospective experimental study adhered to the tenets of the Declaration of Helsinki. The study protocol received institutional review board approval and written informed consent was obtained from all patients.

To qualify for the study, it was required that subjects had been diagnosed with cataract in both eyes and they had no other ocular disease and had not undergone prior ocular surgery. Inclusion criteria were an age between 55 and 80 years, an expressed desire to be independent of spectacles and a pre-surgery spherical equivalent of up to \pm 5.00 D and cylinder no more than 1.00D of corneal astigmatism.

After selecting 50 eyes of 25 patients meeting the inclusion/exclusion criteria, patients were implanted during cataract surgery with a Bi-Flex[®] M IOL.

All patients underwent cataract surgery by the same experienced surgeon (JMC) 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 6 weeks of the first.

Three months after the second surgery, all patients underwent an optometric examination in which objective refraction was assessed by the same optometrist, LogMAR visual acuity was measured using an ETDRS illumination cabinet (Precision Vision, USA) at high contrast (96%) and at a distance of 4 meters in photopic (85 cd/ m²) and mesopic (3 cd/ m²). Mesopic conditions were obtained using a large Mesopic filter (Precision Visión, USA) that reduced the normal cabinet lighting level. Furthermore the light of the room was turn off.

Next, near visual acuity were measured using the logarithmic Visual Acuity Chart ETDRS at 40 cm (Precision Vision, USA) under photopic conditions. Intermediate visual acuity was measured at 65 cm using the same chart and correcting the values obtained for the different distance.

Contrast Sensitivity (CS) were measured using the CSV-1000 test (Vector Vision, Greenville, OH) 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).

Once distance correction had been established using the ETDRS chart 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 uses 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^{10,11}. Defocus curve testing was performed in both photopic (85 cd/m²) and mesopic (3 cd/ m²) conditions.

Pacients were shown pictures (Figure 2) representing dysphotopic phenomena (halos, halos+ring, halos+line or combined) 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 Marques et al (*).

Pupil diameter was measured in each subject using a wavefront analyzer Topcon KR-1 W (Oakland, USA).

STATISTICAL ANALYSIS

Quantitative data are provided as ranges, means and standard deviations. The Student t-test for paired data was used to compare normally distributed data as confirmed using the Kolmogorov-Smirnov test, and the Wilcoxon rank-sum test was used for non-normally distributed data. All statistical tests were performed using the software package SPSS Statistics v18.0 (SPSS Inc., Chicago, USA). Significance was set at a $p \leq 0.05$. Pearson regression analysis was used to look for possible association between mesopic pupil diameter and Likert scale values.

RESULTS

The final study sample was comprised of 50 eyes of 25 patients (5 men, 10 women). Mean age was $66,3 \pm 7,7$ years (range 55 to 75 years). Table 1 shows monocular mean spherical and cylindrical refraction preoperatively and postoperatively. Table 2 shows monocular and binocular UDVA, DCVA, DCIVA and DCNVA for the study participants at the end of the follow up period. Also monocular and binocular CS recorded at the end of the using the CSV-1000 test.

	Mean \pm SD	range
Pre RE:	Sph: 1.92 ± 1.65 D	(-2.50 / +4.25 D)
	Cyl: -0.83 ± 0.62 D	(-1.75 / -0.25 D)
Pre LE:	Sph: 1.72 ± 1.92 D	(-4.00 / +4.25 D)
	Cyl: -0.95 ± 0.67 D	(-1.75 / -0.25 D)
Post RE:	Sph: $+0.40 \pm 0.57$ D	(-0.50 / +1.25 D)
	Cyl: -0.63 ± 0.55 D	(-1.25 / 0.00 D)
Post LE:	Sph: $+0.40 \pm 0.40$ D	(-0.50 / +0.75 D)
	Cyl: -0.65 ± 0.53 D	(-1.25 / 0.00 D)

TABLE I - Monocular spherical (Sph) and cylindrical refraction (Cyl) preoperatively and postoperatively

Lente Biflex		
	Mean \pm SD	range
PosAV _L RE: UDVA	0.12 \pm 0.14	(-0.10/0.40)
PosAV _L LE: UDVA	0.14 \pm 0.13	(-0.10/0.40)
PosAV _L bino: (12)	0.03 \pm 0.09	(-0.1/0.32)
PosAV _{LMC} RE: CDVA	-0.01 \pm 0.07	(-0.10/0.22)
PosAV _{LMC} LE: CDVA	0.01 \pm 0.08	(-0.14/0.22)
PosAV _{LMC} bino: CDVA	-0.05 \pm 0.06	(-0.20/0.04)

TABLE II: Monocular and binocular uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA)

PosAV _C RE: DCIVA	0.28 \pm 0.09	(0.10/0.54)
PosAV _C LE: DCIVA	0.29 \pm 0.12	(0.12/0.60)
PosAV _C bino: DCIVA	0.20 \pm 0.07	(0.08/0.36)

Table III: monocular and binocular DCIVA

PosAV _c RE: DCNVA	0.13 ± 0.08	(0.00/0.30)
PosAV _c LE: DCNVA	0.14 ± 0.14	(0.00/0.50)
PosAV _c bino:	0.11 ± 0.08	(0.00/0.3)

Table IV: monocular UDVA and binocular DCVA, DCIVA and DCNVA

Lente Biflex CSV (log units)		
	Mean ±SD	range
PosCSV A bino:	1.66 ± 0.16	(1.34/1.93)
PosCSV B bino:	1.75 ± 0.14	(1.55/2.14)
PosCSV C bino:	1.39 ± 0.22	(1.08/1.69)
PosCSV D bino:	0.96 ± 0.19	(0.64/1.25)

TABLE V: Contrast sensitivity measured with CSV-1000

Figure 1 shows the post-surgery results of the CSV-1000 test under photopic (85 cd/m²) conditions for 4 spatial frequencies (A: 3 cpd, B: 6 cpd, C:12 cpd and D: 18 cpd). Post implantation mean binocular CS for the 4 frequencies examined (3, 6, 12 and 18 cpd) were 1.66±0.16 (range 1.34-1.93), 1.75±0.14 (range 1.55-2.14), 1.39±0.22 (range 1.08-1.69) and 0.96±0.19 (range 0.64-1.25) log units, respectively.

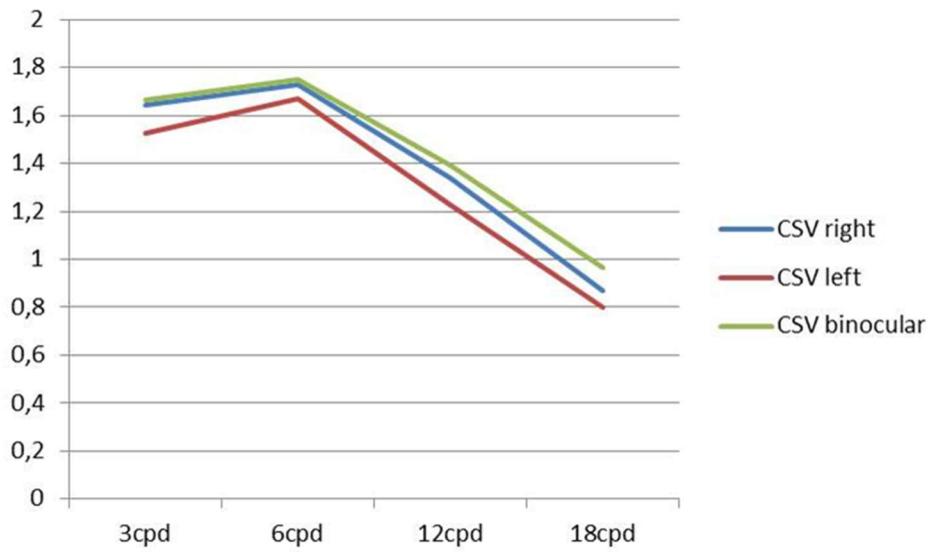


Figure 1: Monocular and binocular contrast sensitivity using CSV-1000

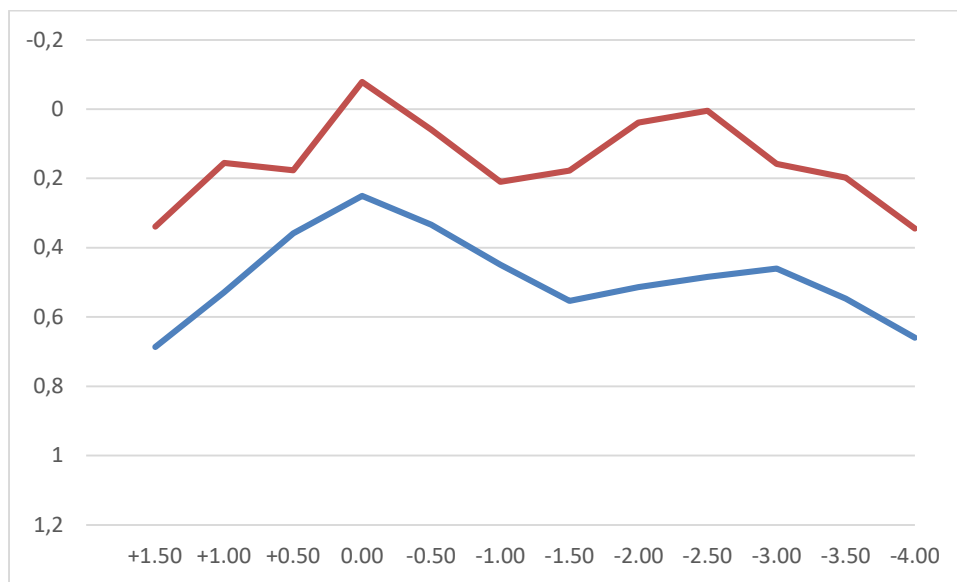


Figure 2. Defocus curves in mesopic and photopic conditions

Halo tipo	%	Likert scale
Type 1 (halo)	35.71%	0.2 ± 0.44
Type 2 (halo+ring)	42.86%	2.75 ± 0.75
Type 3 (halo+line)	14.29%	1.00 ± 0.02
Type 4 (combined)	13.28%	2.02 ± 0,34
Type 5 (Combined)	7,14%	2,50 ± 0.05

TABLE VI: Percentage of patients with dysphotopic phenomena and values in the Likert Scale

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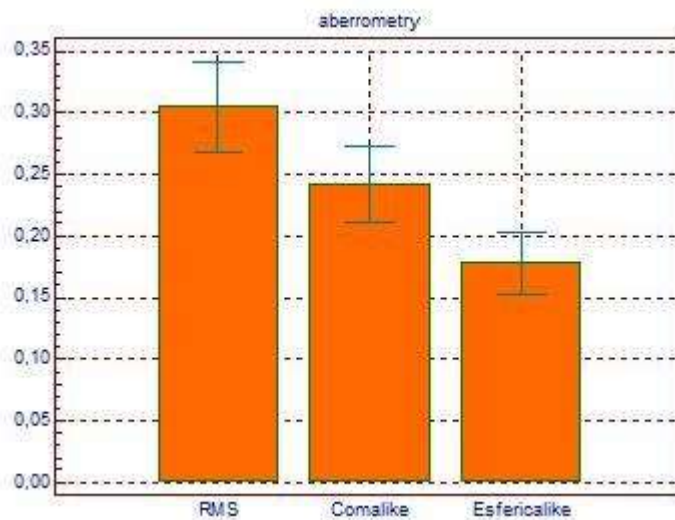


Figure 3: Aberrometry outcomes

Figure 2 shows photopic and mesopic postoperative through-focus corrected binMean value for the 50 eyes of pupil diameter was 3.25 ± 0.69 mm in photopic conditions and 4.58 ± 0.73 mm in mesopic conditions. There was no statistically significant difference between right and left eyes.

In photopic conditions, significant differences were detected between the far and intermediate focus ($p < 0.00019$) and between the far and near focus ($p = 0.03$).

In far vision, no significant difference was found between 0.00 D and +0.50 D focuses ($p = 0.09$). In intermediate vision, no statistically significant difference was found between -1.00D and -1.50 D focus. Also in near vision, there was no difference between -2.00 D, -2.50 D, and -3.00 D.

In mesopic conditions, the defocus curve consisted of one peak of maximum vision located at the far focus, corresponding to 0.00 D. Significant differences were detected

between the far and intermediate (-1.50 D) focus ($p < 0.0001$) and between the far and near (-3.00 D) focus ($p < 0.0005$). A slightly significant difference between the intermediate (-1.50 D) and near (-3.00 D) foci ($p < 0.003$) was found.

A statistically significant difference between photopic and mesopic defocus curves in far ($p < 0.001$), intermediate ($p < 0.001$), and near focus ($p < 0.001$) was found.

Table VI shows the percentage of patients with each type of dysphotopic phenomena and the mean value in the Likert scale. In the whole sample, the mean value was 1.72 ± 1.15 . A statistically significant correlation between the mesopic pupil diameter and the Likert scale ($r = 0.62$, $p = 0.017$) was found.

Figure 3 shows the aberrometry outcomes obtained after IOL implantation. Mean outcomes, for a mean measured mesopic pupil diameter of 4.58 ± 0.73 , were as follows: high-order root mean square $0.30 \pm 0.14 \mu\text{m}$, coma-like $0.24 \pm 0.12 \mu\text{m}$, and spherical-like aberration $0.18 \pm 0.10 \mu\text{m}$.

DISCUSSION

This study was designed to assess visual outcomes with best distance correction in patients implanted with progressive apodized diffractive Bi-Flex® M 677MY IOL.

This study examines the outcome of bilateral implantation of this IOL and provides far, intermediate, and near visual acuities determined with best distance correction in photopic conditions, defocus curves for photopic and mesopic conditions, CS values assessed with CSV-1000 test, and the presence and disturbance of dysphotopic phenomena valued with Likert scale.

This IOL offered satisfactory logMAR visual acuity at any distance when subjectively tested. Our far vision CDVA results were similar to those obtained by Sheppard et al (13) 2 months after FineVision® implantation (0.08 ± 0.08) and Mojzis et al (14) 3 months after trifocal AT LISA® tri 839 MP implantation (0.06 ± 0.07).

Regarding intermediate logMAR CDVA, our results were similar to those found at 70 cm distance by Jonker et al (15) 6 months after surgery with AcrySof IQ Restor® +3 D bifocal (0.24 ± 0.08) and FineVision® trifocal IOLs (0.31 ± 0.11).

However, our results were slightly worse than those reported at 66 cm distance in the Mojzis et al (14) study, 3 months after surgery, trifocal AT LISA® tri 839 MP (0.05 ± 0.05), and Carballo-Alvarez et al (3) at 60 cm distance 3 months after FineVision® trifocal IOL implantation (0.15 ± 0.10).

In relation to near CDVA, our results were similar to those found at the same distance (40 cm) by Jonker et al (15) 6 months after surgery with AcrySof IQ Restor® +3 D bifocal (0.11 ± 0.08) and FineVision® trifocal IOLs (0.08 ± 0.08) and Mojzis et al (7) 3 months after surgery, trifocal AT LISA® tri 839 MP (0.06 ± 0.07) and bifocal AT LISA® 801 (0.16 ± 0.11), and to Carballo-Alvarez et al (3) 3 months after FineVision® trifocal IOL implantation (0.06 ± 0.10).

Our defocus curves obtained lacked the classic double-hump pattern characteristic of bifocal IOLs and showed a less pronounced reduction in intermediate vision. In photopic conditions, we agree with the study of Marques and Ferreira (4); decrease in visual acuity was often produced in the intermediate range of the defocus curve (from -1 D to -2 D) for bifocal lenses. Thus, the defocus curves provided by de Vries et al (16) (monocular) for AcrySof Restor® +4 D and +3 D, by Toto et al (17) for Tecnis® +4 D, by Blaylock et al (18) for AcrySof Restor®+4 D, and by Alfonso et al (1) (binocular) for AcrySof Restor®+4 D, +3 D, and Acri LISA® all revealed a loss of visual acuity between -1 D and -1.5 D (from logMAR 0.2 to 0.4).

Our mesopic and photopic defocus curves varied significantly, indicating worse mesopic far, intermediate, and near vision. Furthermore, in mesopic conditions, the difference between intermediate and near focus was lower than in photopic curves.

Differently from us, Sheppard et al (13) did not find a statistically significant difference between photopic and mesopic defocus curves with a sample of 15 patients implanted with trifocal Fine Vision® Micro F IOL, probably owing to the different VA test used, with our mesopic conditions being more demanding.

Our CS results were in the expected range for older subjects (13). We agree with the study of Carballo-Alvarez et al (3) 3 months after FineVision® trifocal IOL implantation, the study by Sheppard et al (13) 2 months after implantation of the same lens, and with

the study of Jonker et al (15) 6 months after surgery with AcrySof IQ Restor® +3 D bifocal and FineVision® trifocal IOLs. Marques and Ferreira (4) found similar results when comparing AT LISA® tri 839 MP and the FineVision® trifocal IOLs with 2 samples of 15 patients. Approximately 2 out of 3 patients referred dysphotopic phenomena type 2, 3, or combined. A total of 21% referred a Likert scale value equal to or higher than 3.

In conclusion, our findings indicate that Bi-Flex® M 677MY IOL provides effective restoration of visual function in far and near vision distance with an adequate intermediate visual quality between -1.00 and -1.50 focus.

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