EJO
ISSN 1120-6721

Eur J Ophthalmol 2017; 00 (00): 000-000
DOI: 10.5301/ejo.5001030

ORIGINAL RESEARCH ARTICLE

Visual outcomes after progressive apodized diffractive intraocular lens implantation

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ABSTRACT

Purpose: To assess photopic and mesopic vision in patients implanted with the Bi-Flex® M 677 MY bifocal intraocular lens (IOL).

Methods: In this prospective clinical study, 25 patients with cataract in both eyes were subjected to cataract surgery and bilateral implantation of the Bi-Flex® M 677MY (Medicontur, Hungary) IOL. Three months after surgery, high-contrast photopic uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) were determined. Intermediate at 65 cm (DCIVA) and near at 40 cm (DCNVA) visual acuity were also measured, both with best distance correction. The CSV-1000 test chart was used to assess contrast sensitivity (CS). Defocus curves were constructed under photopic and mesopic conditions, determining binocular best-corrected visual acuity over the range +1.50 D to -4.00 D in 0.50-D steps. A KR-1W Wavefront Analyzer was used to measure pupil size and aberrometric outcomes. Presence and type of dysphotopsia were evaluated with the Likert scale.

Results: Mesopic mean pupil diameter was 4.58 ± 0.73 mm. The mean values at 3 months were UDVA 0.03 ± 0.09, CDVA -0.05 ± 0.06, DCIVA 0.20 ± 0.07, and DCNVA 0.11 ± 0.08. Mean CS for the 4 frequencies examined were 1.66 ± 0.16, 1.75 ± 0.14, 1.39 ± 0.22, and 0.96 ± 0.19. Significant differences were observed in defocus curves for photopic and mesopic conditions. A significant correlation between pupil diameter and the dysphotopic photopic was found (r = 0.62; p = 0.02).

Conclusions: The evaluated progressive apodized diffractive design 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.

Keywords: Bi-Flex®, Intraocular lens, Multifocal, Outcomes, Visual

Introduction

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 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. Bifocal IOLs have only 2 foci, which might be insufficient to obtain satisfactory vision in all distances. Trifocal IOLs with a distance focus yet improved near and intermediate vision aim to reduce spectacle dependence (3-7). However, halos and reduced contrast sensitivity (CS) related to multifocal IOLs (bifocal and trifocal IOLs) are common reasons for patient dissatisfaction (6, 8, 9).

The Bi-Flex® M 677MY (Medicontur) is an acrylic IOL that presents a high Abbe number value (58), intended to reduce the chromatic aberration that is a major difficulty with diffractive optics vs with refractive optics.

The progressive apodized diffractive design (from 1.0 to 3.0 mm) is intended to provide improved control of energy distribution whatever the pupil size. It 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 µm). The near lens power is +3.50 D, equivalent to +2.70 D in the

Accepted: August 22, 2017
Published online: September 11, 2017

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spectacle plane. This design procures to distribute the appropriate amounts of light to near and intermediate (60%) and far focal (40%) points to minimize visual disturbances.

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

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 presurgery spherical equivalent of up to ±5.00 D and cylinder no more than 1.00 D 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) 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 Early Treatment Diabetic Retinopathy Study (ETDRS) illumination cabinet (Precision Vision) at high contrast (96%) and at a distance of 4 meters in photopic (85 cd/m^2) and mesopic (3 cd/m^2) conditions. Mesopic conditions were obtained using a large mesopic filter (Precision Vision) that reduced the normal cabinet lighting level. The room light was turned off.

Next, near visual acuity was measured using the ETDRS logarithmic visual acuity chart at 40 cm (Precision Vision) 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 was measured using the CSV-1000 test (Vector Vision) 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, 2 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 -4.00 D to +1.50 D in 0.50 D 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/m^2) and mesopic (3 cd/m^2) conditions.

Patients were shown pictures 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 Kretz et al (12).

Corneal and internal aberrations were measured in each subject in a dark room in both photopic and mesopic conditions to induce physiologically normal pupil sizes, using a wavefront analyzer Topcon KR-1 W.

Statistical analysis

Quantitative data are provided as ranges, means, and SD. 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.). Significance was set at $p \leq 0.05$. Pearson regression analysis was used to look for possible association between mesopic pupil diameter and Likert scale values.

Results

The final study sample comprised 50 eyes of 25 patients (8 men, 17 women). Mean age was 66.3 ± 7.7 years (range 55-75 years). Table I shows monocular mean spherical and cylindrical refraction preoperatively and postoperatively. Table II shows monocular and binocular uncorrected distance visual acuity and corrected visual acuity (CDVA). Table III shows distance-corrected intermediate visual acuity and Table IV shows distance-corrected near visual acuity for the study participants at the end of the follow-up period. Monocular and binocular CS were recorded at the end using the CSV-1000 test (Tab. V).

Figure 1 shows the postsurgery results of the CSV-1000 test under photopic (85 cd/m^2) conditions for 4 spatial frequencies (A: 3 cpd, B: 6 cpd, C: 12 cpd, and D: 18 cpd). Postimplantation mean binocular CS was 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.

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

	D, mean ± SD	D, range
Presurgery, RE	Sph: 1.92 ± 1.65	-2.00 ± 4.50
	Cyl: -0.83 ± 0.62	-2.25 ± 0.00
Presurgery, LE	Sph: 1.72 ± 1.92	-4.00 ± 4.25
	Cyl: -0.95 ± 0.67	-2.50 ± 0.00
Postsurgery, RE	Sph: +0.40 ± 0.57	-0.50 ± +1.75
	Cyl: -0.63 ± 0.55	-1.75 ± 0.00
Postsurgery, LE	Sph: +0.40 ± 0.40	-0.50 ± +1.00
	Cyl: -0.65 ± 0.53	-2.50 ± 0.00

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

	LogMAR, mean ± SD	LogMAR, range
UDVA (RE)	0.12 ± 0.14	-0.10 to 0.40
UDVA (LE)	0.14 ± 0.13	-0.10 to 0.40
UDVA (binocular)	0.03 ± 0.09	-0.10 to 0.32
CDVA (RE)	-0.01 ± 0.07	-0.10 to 0.22
CDVA (LE)	0.01 ± 0.08	-0.14 to 0.22
CDVA (binocular)	-0.05 ± 0.06	-0.20 to 0.04

TABLE III - Monocular and binocular distance-corrected intermediate visual acuity (DCIVA)

	LogMAR, mean ± SD	Range
DCIVA (RE)	0.28 ± 0.09	0.10-0.54
DCIVA (LE)	0.29 ± 0.12	0.12-0.60
DCIVA (binocular)	0.20 ± 0.07	0.08-0.36

TABLE IV - Monocular and binocular distance-corrected near visual acuity (DCNVA)

	LogMAR, mean ± SD	Range
DCNVA (RE)	0.13 ± 0.08	0.00-0.30
DCNVA (LE)	0.14 ± 0.14	0.00-0.50
DCNVA (binocular)	0.11 ± 0.08	0.00-0.30

TABLE V - Contrast sensitivity measured with CSV-1000

Frequency	Mean ± SD	Range
A	1.66 ± 0.16	1.34-1.93
B	1.75 ± 0.14	1.55-2.14
C	1.39 ± 0.22	1.08-1.69
D	0.96 ± 0.19	0.64-1.25

Values in logarithmic scale.

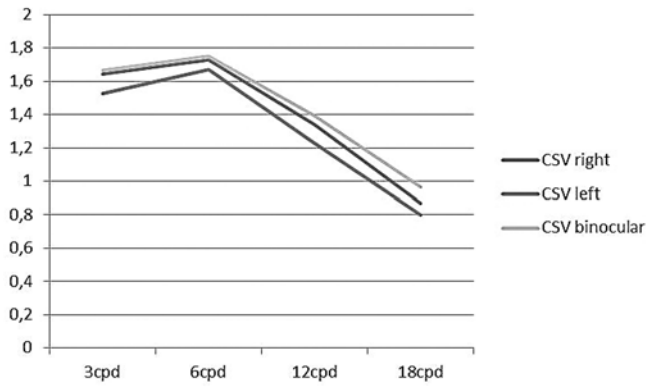

Fig. 1 - Monocular and binocular contrast sensitivity using CSV-1000.

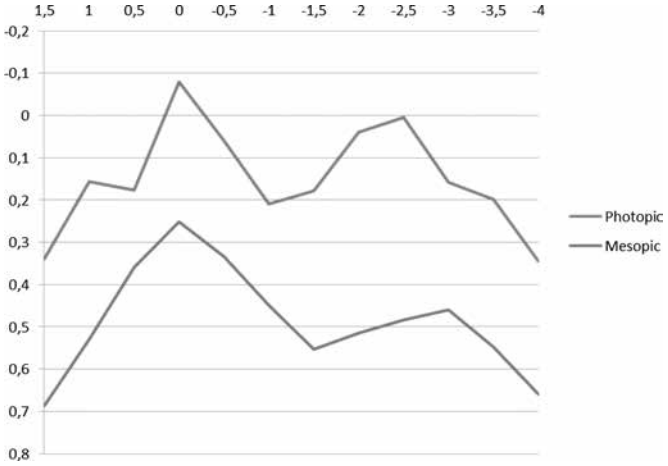

Fig. 2 - Defocus curve in mesopic and photopic conditions.

Figure 2 shows photopic and mesopic postoperative through-focus corrected binocular logMAR visual acuity.

Mean 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 ($p<0.0001$) 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 -1.00 D 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 ± 0.14 µm, coma-like 0.24 ± 0.12 µm, and spherical-like aberration 0.18 ± 0.10 µm.

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

	Percentage of patients	Likert scale
Type 1 (halo)	35.71	0.20 ± 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

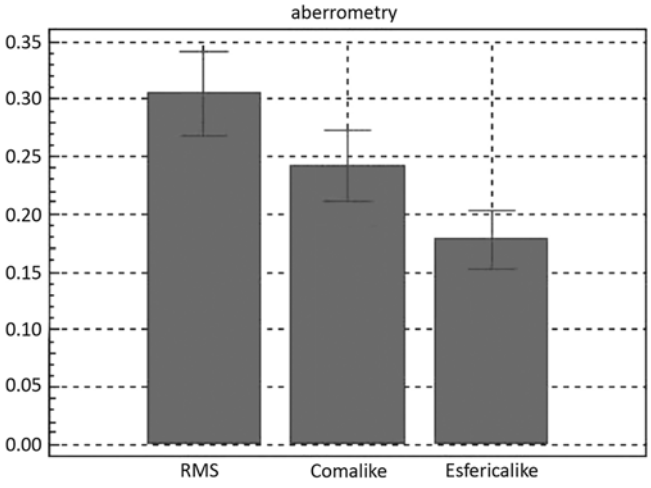

Fig. 3 - Aberrometry outcomes.

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.

Acknowledgments

The authors thank the Optometry Faculty, Complutense University of Madrid.

Disclosures

Financial support: No financial support was received for this submission.
Conflict of interest: None of the authors has conflict of interest with this submission.

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