ARTICLE

Comparison of clinical outcomes of 3 trifocal IOLs

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Purpose: To compare the clinical outcomes obtained after implantation of 1 of 3 models of diffractive trifocal IOLs.

Setting: Hospital da Luz, Lisbon, Portugal.

Design: Prospective randomized comparative study.

Methods: Patients undergoing cataract surgery with bilateral implantation of 1 of 3 models of diffractive trifocal IOLs were enrolled. The IOL models implanted were the FineVision POD F, RayOne Trifocal, or the AcrySof IQ PanOptix IOL (30 eyes of 15 patients in each group). Visual acuity (VA), refraction, defocus curve, and contrast sensitivity outcomes were evaluated during a 3-month follow-up. Furthermore, the Quality of Vision questionnaire (QoV) was used to evaluate the frequency, severity, and discomfort of different visual symptoms.

Results: A total of 90 eyes of 45 patients were included. No statistically significant differences were found between groups in distance, intermediate, and near VA ($P \geq .112$) and postoperative refraction ($P \geq .059$). Postoperative binocular uncorrected intermediate VA of 0.10 logarithm of the minimum angle of resolution (logMAR) or better was found in 14 (93.33%) patients in the 3 groups. Postoperative binocular uncorrected near VA of 0.10 logMAR or better was found in 13 (86.67%), 14 (93.33%), and 13 (86.67%) patients in the POD F, RayOne, and PanOptix IOLs groups, respectively. No statistically significant differences were found between groups in scotopic contrast sensitivity with and without glare and in the QoV scores ($P \geq .057$), except for the difference between the POD F and RayOne IOLs groups in depth perception severity, which was less in the RayOne IOL group ($P = .019$).

Conclusions: The 3 trifocal IOLs evaluated provided a complete visual restoration with good visual quality outcomes.

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A variety of studies has demonstrated that diffractive trifocal IOLs can provide effective distance, intermediate, and near visual restoration after cataract surgery.[1–10] For this reason, these IOLs are currently considered a safe and effective option for presbyopia correction in cases of refractive lens exchange.[11,12] Indeed, high levels of spectacle independence and a significant positive impact on quality of life have been reported after cataract surgery with implantation of different models of trifocal IOLs in presbyopic and cataract eyes.[2,13–15]

With the advances in optics research, new designs of trifocal IOLs have continuously been developed by combining the effect of different diffractive orders and even some refractive components.[16–18] Comparative clinical studies with these new designs are necessary to evaluate their real benefit regarding visual acuity (VA), refractive predictability, contrast sensitivity, visual quality, photic phenomena perception, and patient satisfaction. These studies are crucial to learn about clinical outcome differences between the trifocal IOLs and to define clear indications for each IOL. The purpose of this study was to compare the clinical outcomes such as VA, refraction, contrast sensitivity, and visual quality of patients undergoing cataract surgery with implantation of 1 of 3 different models of diffractive trifocal IOLs: FineVision POD F (PhysIOL), RayOne Trifocal (Rayner IOL, Ltd.), or AcrySof IQ PanOptix (Alcon Laboratories, Inc.) IOL.

METHODS

Patients

This prospective randomized comparative study enrolled a total of 90 eyes of 45 patients undergoing cataract surgery with bilateral implantation of 1 of 3 models of diffractive trifocal IOL: the FineVision POD F (PhysIOL), RayOne Trifocal (Rayner IOL, Ltd.), or AcrySof IQ PanOptix (Alcon Laboratories, Inc.) IOL. All patients were informed about the surgery and provided informed consent to undergo the clinical examinations in accordance with the tenets of the Declaration of Helsinki. The study received the approval of the hospital ethics committee.

Each patient involved in the study was randomized to 1 of the 3 groups defined according to the IOL implanted (https://www.randomizer.org): POD F IOL group (30 eyes, 15 patients),

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RayOne IOL group (30 eyes, 15 patients), and PanOptix IOL group (30 eyes, 15 patients). In all patients, bilateral cataract surgery was performed.

Inclusion criteria for the study were the indication of bilateral refractive lens exchange or cataract surgery, age of 21 years or older, and signed informed consent preoperatively. Exclusion criteria included preoperative regular corneal astigmatism of more than 1.00 diopter (D) of magnitude; irregular corneal astigmatism; relevant concomitant ophthalmic diseases, such as pseudoexfoliation, glaucoma, traumatic cataract, and other comorbidities that could affect capsular bag stability (eg, Marfan syndrome); systemic disease with potential impact on visual outcome; previous ocular surgery; and patient inability to understand and/or fill in patient questionnaires.

Intraocular Lenses

The FineVision POD F IOL is a hydrophilic acrylic IOL with an aspheric optic (spherical aberration [SA] −0.11) with 26 diffractive steps, a +3.50 D near add and +1.75 D intermediate add, and a light split of 42% for distance, 15% for intermediate, and 29% for near. The RayOe Trifocal IOL is a hydrophilic acrylic IOL with an aspheric optic (neutral SA) with 16 diffractive steps, a +3.50 D near add and +1.75 D intermediate add, and a light split of 52% for distance, 22% for intermediate, and 26% for near. The PanOptix IOL is a hydrophobic acrylic IOL with an aspheric optic (SA −0.20) with 15 diffractive steps, a +3.25 D near add and +2.17 D intermediate add, and a light split of 42% for distance, 24% for intermediate, and 22% for near.

Preoperative Examination

All patients underwent a complete eye examination preoperatively, including subjective refraction, corrected distance visual acuity (CDVA) using logarithm of the minimum angle of resolution (logMAR) acuity charts under photopic conditions (lighting levels of 85 Candelas [cd)/m^2], optical biometry using the Lenstar LS900 system (Haag-Streit AG), corneal topographic evaluation with the Cassini system (i-Optics), anterior segment analysis by slitlamp biomicroscopy, and fundus evaluation under pupil dilation. The IOL power was selected using the Hill-RBF formula, considering emmetropia or the closest myopic value to emmetropia as the postoperative target.[19]

Surgical Procedure

All surgical procedures were performed by 2 experienced surgeons (F.R., T.B.F.) using topical anesthesia and microcoaxial phacoemulsification with a sutureless incision of 2.2 mm. The sequence followed in the surgical procedure was as follows: creation of a clear corneal self-sealing incision in the steepest meridian to reduce postoperative astigmatism, injection of ophthalmic viscosurgical device, creation of the capsulorhexis, phacoemulsification, irrigation/aspiration of cortical material, and IOL implantation in the capsular bag by docking the cartridge onto the incision. The Accuject 2.0 (Medicel AG) injector was used to preload and implant the FineVision POD F IOL and the Monarch injector (Alcon) to implant the AcrySof IQ PanOptix IOL, whereas the preloaded RayOne Trifocal IOL was inserted using its ready-to-use injection system.

Postoperative Examinations

Postoperative ocular examinations were performed at 1 week and 1 month and 3 months postoperatively. At the last postoperative visit, the following clinical tests were performed: subjective refraction; measurement of monocular and binocular uncorrected distance visual acuity (UDVA); CDVA; uncorrected intermediate visual acuity (UIVA) and distance-corrected intermediate VA (measured at 66 cm); uncorrected near visual acuity (UNVA) and distance-corrected near VA (measured at 40 cm); slitlamp examination; measurement of the binocular defocus curve under photopic conditions (85 cd/m^2) using defocusing lenses from +1.00 to −4.00 D in 0.50 D steps of blur; and measurement of contrast sensitivity with and without glare at luminance levels of 85 and 3.0 cd/m^2 using the Optec 6500 device (Stereo Optical, Inc.). Distance, near, and intermediate VAs were assessed by logMAR acuity charts under photopic conditions (85 cd/m^2).

Furthermore, the Quality of Vision questionnaire (QoV) was evaluated at the last postoperative visit using the questionnaire developed by McAlinden et al.[20] The following visual symptoms were captured: glare, halos, starbursts, hazy/blurred/double vision, distortion, focusing difficulties, fluctuation, and depth perception. This 30-item QoV is separated into 3 scales according to the frequency of visual symptoms (never = 0; occasionally = 1; quite often = 2; and very often = 3), severity of the symptoms (not at all = 0; mild = 1; moderate = 2; and severe = 3), and how bothered the patient is by the symptoms (not at all = 0; a little = 1; quite = 2; and very = 3).[20]

Statistical Analysis

The sample size was calculated for an alpha of 0.05 and a power of 0.80. A standard deviation in VA of 0.10 logMAR units was presumed in addition to a minimum detectable difference of 1 line of VA (0.1 logMAR), based on previous data analyses for a similar study.[1] This calculation recommended the inclusion of 13 eyes per group.

All statistical analyses were performed using IBM SPSS Statistics for Mac (version 22.0, IBM Corp.). Normality of data samples was evaluated by means of the Kolmogorov-Smirnov test. Because most of the samples were not normally distributed, nonparametric statistical tests were used. Differences between IOL groups were evaluated using the Kruskal-Wallis test, with the use of the Mann-Whitney test with the Bonferroni adjustment for the post hoc comparative analysis by pairs. The results were expressed as the mean ± SD, and a P value of less than 0.05 was considered statistically significant.

RESULTS

A total of 30 eyes of 15 patients ranging in age from 55 to 79 years were included in each group (POD F, RayOne, and PanOptix IOLs). Table 1 displays the mean preoperative clinical data obtained in each group and the statistical significance of differences between groups for each parameter evaluated. Statistically significant differences between groups were detected in only preoperative manifest sphere (P = .005) and spherical equivalent (P = .006).

Table 2 summarizes the 3-month postoperative data obtained in the 3 groups and the statistical significance of differences between groups for each parameter evaluated. Statistically significant differences were not found between groups in any of the VA parameters evaluated ($P \geq .112$). A total of 14 patients (93.33%) in all 3 groups achieved a postoperative binocular UIVA of 0.10 logMAR or better (Figure 1). Furthermore, 13 (86.67%), 14 (93.33%), and 13 (86.67%) patients achieved a postoperative binocular UNVA of 0.10 logMAR or better in the POD F, RayOne, and PanOptix IOLs groups, respectively (Figure 1). Concerning postoperative refractive data, no statistically significant differences were found between groups ($P \geq .059$). A total of 22 (73.33%), 29 (96.67%), and 23 (76.67%) eyes had a postoperative spherical equivalent within ±0.50 D in the POD F, RayOne, and PanOptix IOLs groups, respectively (Figure 2).

Table 1. Mean preoperative clinical data and statistical significance of differences for each parameter evaluated between groups.

Parameters	POD F IOL Group		RayOne IOL Group		PanOptix IOL Group		*P* Value
	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range	
Eyes (n)	30		30		30		—
Patients (n)	15		15		15		—
Age (y)	68 ± 8	55, 79	66 ± 6	58, 77	64 ± 6	55, 72	.434
Manifest sphere (D)	0.86 ± 1.84	−3.00, 4.00	−0.39 ± 1.67	−3.00, 3.00	1.04 ± 2.83	−7.75, 5.00	.005
PODFT IOL vs RayOne IOL							.036
PODFT IOL vs PanOptix IOL							.534
RayOne IOL vs PanOptixIOL							.006
Manifest cylinder (D)	−0.48 ± 0.40	−1.25, 0.00	−0.53 ± 0.39	−1.50, 0.00	−0.64 ± 0.45	−1.25, 0.00	.133
Manifest SE (D)	0.62 ± 1.94	−3.50, 3.75	−0.66 ± 1.78	−3.62, 2.88	0.72 ± 2.86	−8.25, 4.62	.006
PODFT IOL vs RayOne IOL							.045
PODFT IOL vs PanOptix IOL							.574
RayOne IOL vs PanOptix IOL							.009
Axial length (mm)	23.79 ± 0.97	21.22, 25.55	23.21 ± 0.41	22.66, 24.30	23.86 ± 1.71	21.25, 28.01	.124
PODFT IOL vs RayOne IOL							.093
PODFT IOL vs PanOptix IOL							.621
RayOne IOL vs PanOptix IOL							.081
IOL power (D)	21.82 ± 2.63	16.00, 30.00	22.30 ± 1.15	20.00, 24.50	21.35 ± 4.54	8.00, 29.50	.522

IOL = intraocular lens; SE = spherical equivalent

Figure 3 displays the mean 3-month postoperative binocular defocus curve obtained in the 3 groups. No statistically significant differences were found between groups in the VA measurements obtained with the different levels of defocus ($P \geq .555$). Contrast sensitivity results in the 3 groups are shown in Figure 4. No statistically significant differences were found between groups in low mesopic contrast sensitivity with and without glare for any of the spatial frequencies evaluated ($P > .05$). Contrast sensitivity tended to be slightly worse in the PanOptix IOL

Table 2. Mean 3-month postoperative visual acuity and refractive data and statistical significance of differences for each parameter evaluated between groups.

Parameters	POD F IOL Group		RayOne IOL Group		PanOptix IOL Group		*P* Value
	Mean ± SD	Range	Mean ± SD	Range	Mean ± SD	Range	
UDVA (logMAR)							
Monocular	0.04 ± 0.08	−0.12, 0.30	0.03 ± 0.11	−0.18, 0.30	0.05 ± 0.09	−0.10, 0.20	.419
Binocular	−0.01 ± 0.06	−0.12, 0.10	−0.02 ± 0.08	−0.20, 0.10	−0.02 ± 0.09	−0.10, 0.20	.854
CDVA (logMAR)							
Monocular	−0.01 ± 0.08	−0.16, 0.10	−0.01 ± 0.08	−0.18, 0.20	−0.01 ± 0.07	−0.10, 0.12	.981
Binocular	−0.02 ± 0.06	−0.14, 0.05	−0.04 ± 0.10	−0.20, 0.10	−0.01 ± 0.07	−0.10, 0.10	.963
UIVA (logMAR)							
Monocular	0.09 ± 0.11	−0.10, 0.36	0.06 ± 0.10	−0.18, 0.28	0.11 ± 0.13	−0.10, 0.36	.311
Binocular	0.04 ± 0.07	−0.08, 0.20	0.00 ± 0.10	−0.20, 0.20	0.06 ± 0.06	−0.05, 0.20	.112
DCIVA (logMAR)							
Monocular	0.04 ± 0.10	−0.10, 0.30	0.04 ± 0.13	−0.20, 0.30	0.05 ± 0.09	−0.10, 0.40	.960
Binocular	0.02 ± 0.08	−0.10, 0.20	−0.02 ± 0.13	−0.20, 0.30	0.01 ± 0.07	−0.10, 0.20	.269
UNVA (logMAR)							
Monocular	0.05 ± 0.12	−0.20, 0.30	0.04 ± 0.13	−0.18, 0.20	0.05 ± 0.11	−0.10, 0.24	.898
Binocular	0.02 ± 0.11	−0.20, 0.20	0.01 ± 0.12	−0.20, 0.20	0.03 ± 0.09	−0.10, 0.20	.781
DCNVA (logMAR)							
Monocular	0.03 ± 0.11	−0.20, 0.20	0.02 ± 0.12	−0.18, 0.30	0.02 ± 0.10	−0.18, 0.18	.666
Binocular	0.00 ± 0.07	−0.10, 0.10	0.00 ± 0.09	−0.18, 0.10	0.00 ± 0.10	−0.18, 0.18	.997
MS (D)	−0.07 ± 0.44	−1.00, 1.00	0.02 ± 0.28	−0.50, 0.75	−0.04 ± 0.43	−0.75, 0.75	.716
MC (D)	−0.39 ± 0.27	−1.00, 0.00	−0.37 ± 0.31	−1.00, 0.00	−0.24 ± 0.32	−1.00, 0.00	.059
Manifest SE (D)	−0.26 ± 0.39	−1.00, 0.50	−0.17 ± 0.28	−0.62, 0.50	−0.16 ± 0.48	−1.25, 0.75	.509

CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; logMAR = logarithm of the minimum angle of resolution; MC = manifest cylinder; MS = manifest sphere; SE = spherical equivalent; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity

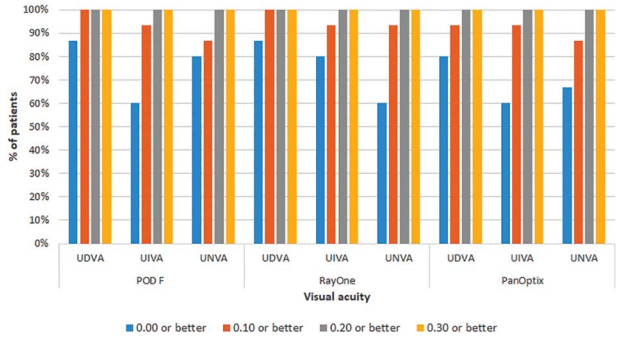

Figure 1. The 3-month postoperative binocular UDVA, UIVA, and UNVA (UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity).

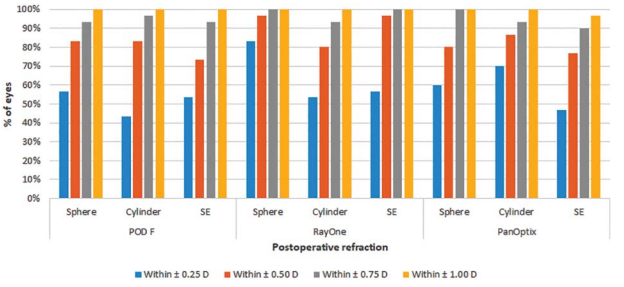

Figure 2. The 3-month postoperative refractive data (SE = spherical equivalent).

group for the highest spatial frequency compared with the other 2 groups, but differences did not reach statistical significance ($P > .05$) (Figure 4). Finally, visual quality was also evaluated using the questionnaire by McAlinden et al. No statistically significant differences between groups were found in the QoV scores for frequency ($P \geq .145$) and discomfort ($P \geq 0.057$) of the visual symptoms evaluated (Figure 5). Regarding severity, statistically significant differences between groups were found only in limited depth perception ($P = .019$), with more severity of this visual symptom in the POD F IOL group compared with that in the RayOne IOL group ($P = .048$) (Figure 5).

DISCUSSION

In this study, a comparison of the clinical outcomes obtained with 3 models of commercially available diffractive trifocal IOLs has been performed. Regarding distance, intermediate, and near visual outcomes, no statistically significant differences have been found between these 3 IOL models, despite the theoretical differences in preferred working distances given by the different additions for near and intermediate vision in the 3 IOLs. The mean 3-month postoperative binocular logMAR UDVA was −0.01 ± 0.06, −0.02 ± 0.08, and −0.02 ± 0.09 in the POD F, RayOne, and PanOptix IOLs groups, respectively. These results are consistent with those reported previously for a variety of diffractive trifocal IOLs.[1–10] Similarly, as in previous series, good levels of intermediate vision were found in this study, with the 3-month postoperative binocular UIVA values of 0.04 ± 0.07, 0.00 ± 0.10, and 0.06 ± 0.06 in the POD F, RayOne, and PanOptix IOLs groups, respectively.[1–6,9,10] Sezgin Asena recently reported the results of a comparative study of 2 different types of diffractive trifocal IOLs, showing good results but with more limited intermediate visual outcome for a hydrophilic trifocal IOL (AT LISA tri 839MP; Carl Zeiss Meditec AG).[2] Similar outcomes have been reported in other studies evaluating this modality of hydrophilic trifocal IOL.[7,8] In our series, no clear trend of a more limited intermediate visual outcome was observed with any of the 3IOLs evaluated. This result was contradictory to that obtained in previous studies showing evidence of a slight but statistically significant difference between POD F and PanOptix IOLs in intermediate vision. Indeed, Carson et al. confirmed in an experimental study that better intermediate vision at 60 cm was expected to be obtained with the PanOptix IOL compared with the FineVision trifocal IOL, whereas the trend should be the opposite at 80 cm.[18] Several factors might have accounted for this apparently contradictory finding, which might be contributed to the experimental setting of the study by Carson et al. and our clinical setting.

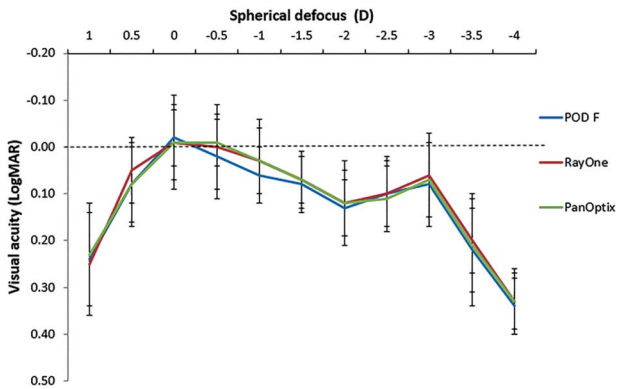

Figure 3. The mean 3-month postoperative binocular defocus curve (logMAR= logarithm of the minimum angle of resolution).

Concerning near vision, mean binocular logMAR UNVA values of 0.02 ± 0.11, 0.01 ± 0.12, and 0.03 ± 0.09 were obtained in the POD F, RayOne, and PanOptix IOLs groups, respectively. These near visual outcomes were consistent with those reported in previous clinical studies evaluating the POD F, RayOne, and PanOptix IOLs.[1,2,4,6,8–10] Bilbao-Calabuig et al. evaluated in a sample of 5,802 eyes the visual results obtained with a previous version of the POD F IOL with binocular UDVA and UNVA values of 0.01 ± 0.05 and 0.05 ± 0.08 logMAR, respectively.[21] The near visual outcomes obtained in the current comparative study with the 3 models of trifocal IOLs were better than those reported in previous studies with low-addition designs of diffractive trifocal IOLs.[3,5] All these outcomes are consistent with the profile of the binocular defocus curve obtained with the 3 IOLs in our study with no significant differences between IOLs. For the 3 trifocal IOLs evaluated, there was no loss of VA for defocus levels simulating intermediate vision, with the best

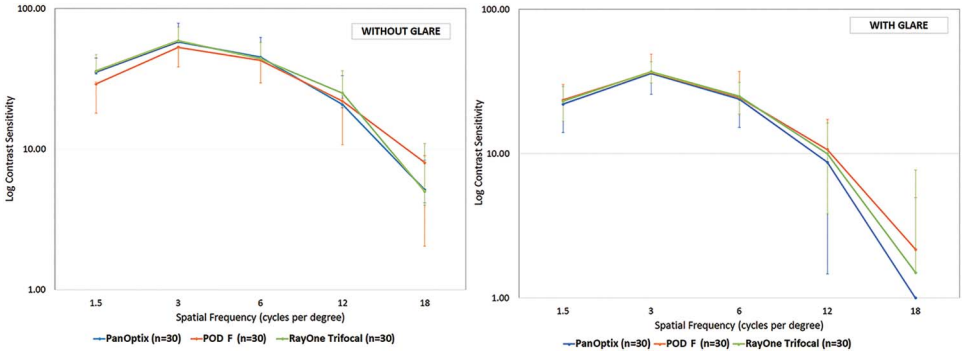

Figure 4. Contrast sensitivity functions measured under photopic conditions without glare (*left*) and mesopic conditions with glare (*right*).

level of VA achieved at 4 m (0.00 D of defocus) and for near vision at 33 cm (−3.00 D of defocus). These findings are consistent with other series reporting defocus curves for these specific models of trifocal IOLs.[1,2,6,8,10,21,22] A trend of lower VA values for defocus levels of −0.5 to −1.5 D was observed in the POD F IOL group compared with the other 2 IOLs groups, but these differences did not reach statistical significance.

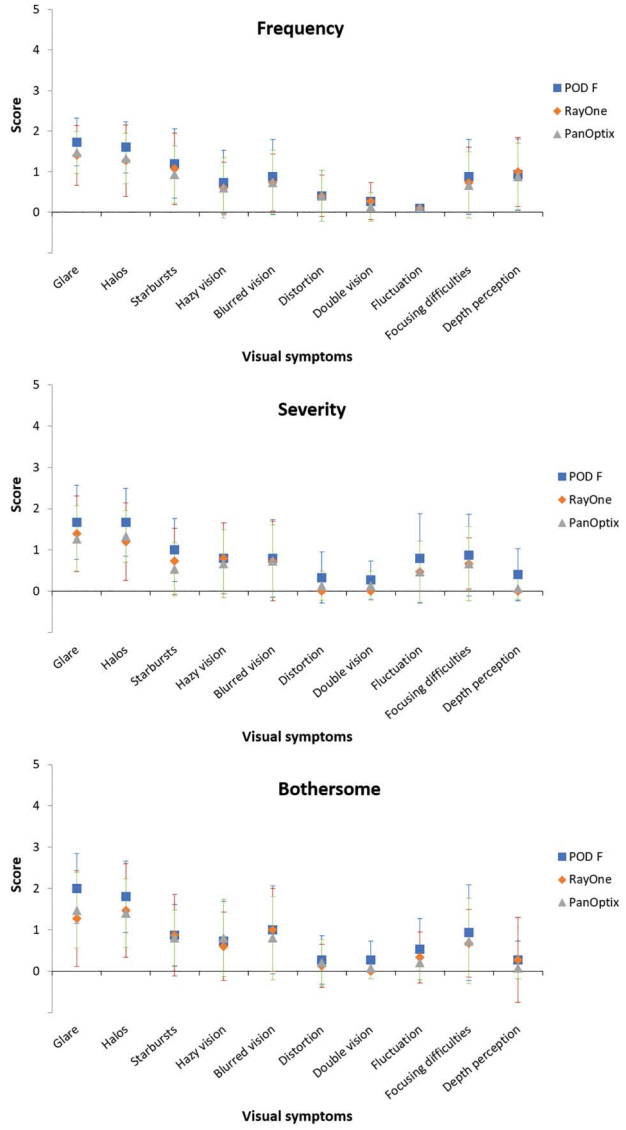

Figure 5. Quality of vision scores obtained with the questionnaire by McAlinden et al. for frequency (*up*), severity (*middle*), and discomfort (*down*) of different visual symptoms.

The predictability of the refractive correction was good for all 3 types of IOLs evaluated, although a statistically nonsignificant trend to a more predictable outcome of spherical equivalent was observed in the RayOne IOL group. One of the main factors potentially contributing to this might be a better optimization of the IOL constants required for IOL power calculations with this specific trifocal design. Indeed, a similar outcome was obtained in a previous comparative study conducted by our research group in a different population implanted with the RayOne Trifocal and POD F IOLs.[1] However, other studies showed higher levels of predictability for spherical equivalent with the PanOptix and POD F IOLs, with similar percentages of eyes with postoperative values within ±0.50 D than that obtained in this series in the RayOne IOL group.[8] These differences among studies might be attributed to differences in the surgical procedure (manual phacoemulsification vs femtosecond assisted), the optical biometer used, and even the method to obtain subjective refraction. In any case, despite these differences in the percentage of eyes with a spherical equivalent within ±0.50 D, no significant differences between groups were observed for monocular and binocular distance, intermediate, and near visual outcomes.

Besides VA and refraction, visual quality outcomes were also evaluated in our series for distance low mesopic contrast sensitivity outcomes and subjective complaint scores on photic phenomena and other visual disturbances, which were assessed with a validated questionnaire. Although a trend of a slightly worse contrast sensitivity for the highest spatial frequency was observed in the PanOptix IOL group, differences between groups did not reach statistical significance for any of the spatial frequencies evaluated. Furthermore, the contrast sensitivity data are consistent with those obtained in previous series evaluating the POD F, RayOne, and PanOptix IOLs.[1,6,10] Concerning the perception of visual disturbances evaluated with the questionnaire by McAlinden et al., no statistically significant differences were found between groups in the QoV score associated with the frequency and discomfort of the visual symptoms. Regarding severity, the significant difference

between groups was found only for limited depth perception, with slightly more severity of this visual symptom in the POD F IOL group compared with that in the RayOne IOL group. Our research group reported a similar finding when comparing in another sample of patients the severity scores of visual symptoms observed with RayOne Trifocal and POD F IOLs, with less severity of limited depth perception with the RayOne IOL.[1] This might be due to the difference in the diffractive design of the 2 IOLs, with less diffractive rings in the RayOne Trifocal IOL, being something that should be investigated further in future studies. In general, the scores associated with disturbing visual symptoms were low, as in previous series, and comparable between IOLs. Monaco et al demonstrated that similar QoV scores were obtained with an extended depth-of-focus IOL compared with the PanOptix trifocal IOL.[1,2,6,22,23]

In conclusion, the POD F, RayOne, and PanOptix trifocal IOLs allowed a complete visual restoration, with good visual quality outcomes and a low incidence of photic phenomena. This confirmed the suitability of these IOLs as an effective option for visual restoration in presbyopia.

WHAT WAS KNOWN

- Commercially available diffractive trifocal IOLs can provide functional levels of distance, intermediate, and near visual acuity and a predictable correction.
- These IOLs provide high levels of spectacle independence and induce a significant positive impact on quality of life.

WHAT THIS PAPER ADDS

- The POD F, RayOne, and PanOptix trifocal IOLs provided similar levels of distance, intermediate, and near visual restoration and quality of vision.
- The frequency, severity, and discomfort of photic phenomena were comparable between these 3 IOL models, with only a trend of a more severely limited depth perception with the POD F IOL compared with the RayOne IOL.

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