

# Evaluation of quality of life after implantation of a new trifocal intraocular lens



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**Purpose:** To evaluate the vision-related quality of life (QOL) after implantation of a new trifocal intraocular lens (IOL), by using the National Eye Institute Visual Function Questionnaire-14 (VF-14 QOL questionnaire).

**Setting:** Baskent University Faculty of Medicine, Department of Ophthalmology, Ankara, Turkey.

**Design:** Prospective noncomparative case series.

**Methods:** Consecutive patients who had a new trifocal IOL (Pan-Optix) bilaterally implanted were included in the study. The vision-related QOL was assessed 3 months after the surgery in the second eye. The VF-14 QOL questionnaire was used, with a grading scale of 0, no difficulty; 1, a little difficulty; 2, moderate difficulty; 3, quite difficult; 4, impossible to perform. A subgroup of 14 patients, with an interval of at least 3 months between the surgery in the first eye and the surgery in the fellow eye, were also interviewed 3 months after the monocular IOL implantation.

In this subgroup, the QOL with monocular and binocular implantation was compared.

**Results:** The study comprised 48 patients. Reading small print, driving at night, and doing fine handwork were the most difficult tasks to perform, with the mean values of the VF-14 QOL questionnaire being  $0.94 \pm 0.81$  (SD),  $0.89 \pm 0.68$ , and  $0.64 \pm 0.67$ , respectively. Binocular implantation was associated with improvement in vision-related QOL when compared with monocular implantation, with significant differences in doing fine handwork such as sewing ( $P = .02$ ) and using a computer ( $P = .03$ ).

**Conclusions:** With mean values of 1.00 or lower for each question, the results of the VF-14 QOL questionnaire indicated that patients who have the new trifocal IOL bilaterally implanted have an overall high satisfaction rate and a high vision-related QOL.

*J Cataract Refract Surg 2019; 45:130–134 © 2018 ASCRS and ESCRS*

With the advances in intraocular lens (IOL) technology, cataract surgery has evolved to become a refractive procedure.<sup>1</sup> Multifocal IOLs were first presented in the late 1980s, and they provided spectacle independence by correcting near and distance vision.<sup>2,3</sup> However, tasks requiring intermediate vision, such as using computers and tablets, were difficult with these IOLs.<sup>4</sup> Trifocal IOLs with an additional focal point for intermediate vision were developed to reduce the limitations of bifocal IOLs. There are various commercially available multifocal IOLs with slightly different focal points for far, intermediate, and near activities.

The most frequent side effect of multifocal intraocular lenses is the development of unwanted photopic phenomena, most notably halos.<sup>2</sup> Although late generation multifocal IOLs have reduced those symptoms, they are still the

most frequent reason for dissatisfaction.<sup>5–8</sup> Vision-related quality-of-life (QOL) parameters might not correspond with visual acuity because acuity does not always reflect other aspects of vision, such as contrast issues and photopic symptoms such as halos or glare, as well as visual performance in daily activities. Even patients with better levels of acuity might perceive themselves to be disadvantaged.

Quality of life is a patient-reported experience measurement that can provide helpful multidimensional vision health information that is more comprehensive than traditional objective measurements. Accurate assessment of IOL outcomes can be obtained by evaluating QOL values through validated questionnaires such as the National Eye Institute Visual Function Questionnaire (NEI VFQ). Several QOL-based studies have shown that the most widely used multifocal IOLs could provide high patient

Submitted: August 13, 2018 | Final revision submitted: November 28, 2018 | Accepted: December 3, 2018

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Presented in part at the ASCRS•ASOA Annual Meeting, Washington, DC, USA, April 2018.

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satisfaction, with significant QOL improvement in a high percentage of patients.<sup>9–11</sup> In a recent study, the new trifocal IOL (AcrySof IQ PanOptix, Alcon Laboratories, Inc.) showed encouraging results for visual acuity, contrast sensitivity, and photopic symptoms as well as for quality of vision.<sup>12</sup>

The purpose of this study was to evaluate the vision-related QOL outcomes in patients who had the PanOptix IOL bilaterally implanted by using the National Eye Institute Visual Function Questionnaire-14 (VF-14 QOL questionnaire). The secondary aim was to compare vision-related QOL with monocular and binocular IOL implantation. Another aim was to report binocular uncorrected distance (UDVA), intermediate (UIVA), and near (UNVA) visual acuities and refractive changes 3 months after binocular implantation of this trifocal IOL.

## PATIENTS AND METHODS

This study was performed at Baskent University Faculty of Medicine, Department of Ophthalmology, Ankara, Turkey. The conduct of the study conformed to the Declaration of Helsinki. The university's ethics committee approved the study design and protocol. The participants were fully informed about the purpose of the study after which they provided informed consent. All surgeries were performed by the same experienced surgeon (A.A.). A sample size calculation was performed using the online G\*Power3 software.<sup>13</sup> The required sample size with a 95% confidence interval was determined as 45. The first 48 consecutive cataract patients who were bilaterally implanted with the new trifocal IOL (AcrySof IQ PanOptix IOL TFNT00, Alcon Laboratories, Inc.) at the university's clinic between January 2017 and January 2018 were included in the study. This new trifocal IOL is an aspheric, hydrophobic IOL with a blue filter and a 6.0 mm optical zone composed of a 4.5 mm large diffractive area with 15 diffractive zones and an outer refractive rim. It has three focal points from distance to intermediate and near ranges, dividing the incoming light to create intermediate and near add powers of +2.17 diopters (D) and +3.25 D, respectively. Therefore, it provides optimal close reading distances at 60 cm and 42 cm.

Preoperatively, all patients had a full ophthalmologic examination, including the evaluation of the refractive status, the distance and near visual acuities, slitlamp evaluation, tonometry, and fundoscopy. Corneal topography with Scheimpflug imaging (WaveLight Oculyzer II, WaveLight Laser Technologie AG) and biometry (IOLMaster 700, Carl Zeiss Meditec AG) were performed as well. Patients with a history of ocular surgery and those with coexisting ocular pathologies such as glaucoma, macular degeneration, and severe dry eye for whom vision-related QOL might be affected by these pathologies, were excluded from the study. All participants had corneal astigmatism of 1.0 D or lower as confirmed by biometry and corneal topography. No complications were observed during the cataract surgery or the postoperative follow-up. Binocular UNVA (40 cm), UIVA (60 cm), and UDVA (6 m) were measured preoperatively and postoperatively under photopic light conditions. UDVA testing was performed with the Snellen chart and the visual acuity at 60 cm was measured by means of the 40 cm chart. The results were converted to logarithm of the minimum angle of resolution (logMAR) to make the results comparable to other studies. The visual acuity at 40 cm was performed with a standardized logMAR chart specifically designed for this distance.

The postoperative subjective refraction at the third month was recorded and the mean absolute error (MAE) was calculated to assess deviation from the target refraction. The MAE was calculated as the mean of the absolute value of the differences between the actual and predicted spherical equivalences of the postoperative refractive error. The predicted postoperative mean spherical

equivalent was obtained from the Holladay 2 formula<sup>14</sup> calculations by the IOLMaster 700 biometer.

The vision-related QOL was assessed 3 months after the surgery of the second eye. The questionnaire was administered by a trained researcher (C.Ö.) who administered the questionnaire in a face-to-face manner. It was ensured that each question was fully understood, and special care was taken not to influence the patients. The VF-14 QOL questionnaire with a grading scale: 0, no difficulty; 1, a little difficulty; 2, moderate difficulty; 3, quite difficult; 4, impossible to perform; was used for evaluation of the QOL 3 months after binocular IOL implantation. Four additional questions were asked to evaluate certain issues that are important when evaluating the outcomes of trifocal IOLs, such as difficulty in using a personal computer.

A subgroup of 14 patients, with an interval of at least 3 months between the surgery in the first eye and the surgery in the fellow eye, were also interviewed 3 months after the monocular IOL implantation. In this subgroup, the QOL with monocular and binocular implantation was compared using the Wilcoxon signed-rank test because Shapiro-Wilks significance testing demonstrated the data were not normally distributed. A paired-sample *t* test was used for comparison of preoperative and postoperative visual acuities and refraction, after confirmation of the normal distribution of data. The statistical analysis was performed with SPSS for Windows software (version 20.0, IBM Corp.). For all statistical tests, the same level of significance was used ( $P < .05$ ).

## RESULTS

The study comprised 48 patients (17 men, 31 women). The mean age of the patients was  $65.1 \pm 8.4$  years. Table 1 shows the mean preoperative and postoperative binocular UNVA, UIVA, and UDVA as well as refractive changes. The postoperative mean refractive spherical equivalent was  $0.73 \pm 0.31$  D and the MAE was  $0.31 \pm 0.17$  D.

The mean values of the VF-14 QOL questionnaire items at 3 months postoperatively after binocular implantation were as follows: Reading small print,  $0.94 \pm 0.81$ ; reading a newspaper or a book,  $0.33 \pm 0.52$ ; reading a large-print book or numbers on a telephone,  $0.08 \pm 0.35$ ; recognizing people when they are close to you,  $0.06 \pm 0.32$ ; seeing steps, stairs, or curbs,  $0.14 \pm 0.36$ ; reading traffic, street, or store signs,  $0.13 \pm 0.39$ ; doing fine handwork like sewing,  $0.64 \pm 0.67$ ; writing checks or filling out forms,  $0.60 \pm 0.61$ ; cooking,  $0.02 \pm 0.14$ ; watching television,  $0.13 \pm 0.39$ ; driving during the day,  $0.23 \pm 0.43$ ; driving at night,  $0.89 \pm 0.68$ ; recognizing people from a distance,  $0.10 \pm 0.37$ ; using a personal computer,  $0.38 \pm 0.57$ ; shaving, styling hair, or putting on makeup,  $0.58 \pm 0.65$ ; and difficulty in going out to see movies, theater, plays, or sports events,  $0.17 \pm 0.52$ . Reading small print, driving at night, and doing fine handwork were the most difficult tasks to perform.

Table 2 shows a comparison of the mean values of the VF-14 QOL questionnaire items at the third postoperative month after monocular and binocular implantation of the new trifocal IOL in the 14-patient subgroup. Binocular implantation was associated with improvement in vision-related QOL, with significant differences in doing fine handwork such as sewing ( $P = .02$ ) and using a personal computer ( $P = .03$ ), when compared with monocular implantation.

**Table 1. The mean preoperative and postoperative binocular UDVA, UIVA, and UNVA and refractive changes for all 48 patients 3 months after binocular implantation of the new trifocal intraocular lens.\***

Parameter	Mean $\pm$ SD		P Value
	Preop	Postop	
Binocular UDVA (6 m) (logMAR)	0.35 $\pm$ 0.07	0.05 $\pm$ 0.04	.01
Binocular UIVA (60 Cm) (logMAR)	0.74 $\pm$ 0.27	0.11 $\pm$ 0.08	.01
Binocular UNVA (40 Cm) (logMAR)	0.79 $\pm$ 0.21	0.09 $\pm$ 0.04	.01
Refractive sphere (D)	0.49 $\pm$ 2.24	-0.08 $\pm$ 0.42	.01
Refractive cylinder (D)	-0.28 $\pm$ 0.51	-0.32 $\pm$ 0.18	.06

logMAR = logarithm of the minimum angle of resolution; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity

\*AcrySof IQ PanOptix, Alcon Laboratories, Inc

## DISCUSSION

Multifocal IOLs provide good near and distance vision for patients undergoing cataract surgery; however, good intermediate vision is crucial for daily activities such as using a computer, tablet, or smartphone. Therefore, trifocal IOLs are becoming increasingly popular, and published reports indicate high levels of both spectacle freedom and patient satisfaction.<sup>9,11,12,15-17</sup> The PanOptix IOL has a novel diffractive structure that allows a higher light utilization, transmitting 88% of light to the retina at a simulated 3.0 mm pupil size. The PanOptix is equivalent to bifocal IOLs in photopic

near and distance performance while providing an optimal intermediate focus at 60 cm.<sup>18</sup> Recently, visual outcomes of the PanOptix in daily clinical practice have been reported.<sup>12,15-17</sup> In addition to clinical outcomes, some of these reports also analyzed visual quality,<sup>12</sup> effect of vision on life-style activities,<sup>15</sup> and visual satisfaction<sup>17</sup> of the participants.

Because the real success of a medical intervention can be measured by its effect on the QOL, with this study we specifically aimed to evaluate QOL in patients who had the PanOptix IOL implanted bilaterally, using a validated questionnaire. For this purpose, we used the NEI VF-14 QOL questionnaire, one of the most commonly used vision-related functional questionnaires.<sup>19</sup> Initially, it was designed and validated to assess vision-related functioning in patients undergoing cataract surgery; however, it has also been validated for use with other eye conditions such as glaucoma,<sup>20-22</sup> retinal disorders,<sup>23,24</sup> and corneal diseases.<sup>25</sup> The VF-14 QOL questionnaire, which has a format that makes it easy to administer, has a high rate of patient compliance. This is important because patient-reported outcomes can be affected by many variables, including psychosocial and environmental factors.<sup>26</sup> Meanwhile, work remains to test the validity, reliability, and cultural relevancy of this questionnaire within the Turkish population because some of the activities questioned were not performed by the participants in this study.

Alió et al.<sup>12</sup> evaluated visual acuity, defocus curve, contrast sensitivity, near activity visual questionnaire results, and internal aberrations in 26 patients who had the AcrySof IQ PanOptix IOL bilaterally implanted. They

**Table 2. Comparison of mean values of the VF-14 QOL questionnaire items 3 months after monocular and binocular implantation of the new trifocal intraocular lens\* in a subgroup of 14 patients, with an interval of at least 3 months between the surgery in the first eye and the surgery in the fellow eye.**

VF-14 QOL Value <sup>†</sup>	Mean $\pm$ SD		P Value
	Monocular Implantation	Binocular Implantation	
Reading small print	1.07 $\pm$ 0.83	0.80 $\pm$ 0.81	.35
Reading a newspaper or a book	0.22 $\pm$ 0.45	0.20 $\pm$ 0.44	.76
Reading a large-print book or numbers on a telephone	0.26 $\pm$ 0.07	0.00 $\pm$ 0.00	.18
Recognizing people when they are close to you	0.06 $\pm$ 0.32	0.00 $\pm$ 0.00	.32
Seeing steps, stairs, or curbs	0.14 $\pm$ 0.36	0.00 $\pm$ 0.00	.05
Reading traffic, street, or store signs	0.14 $\pm$ 0.36	0.00 $\pm$ 0.00	.26
Doing fine handwork like sewing	0.93 $\pm$ 0.47	0.20 $\pm$ 0.45	.02 <sup>‡</sup>
Writing checks or filling out forms	0.71 $\pm$ 0.47	0.60 $\pm$ 0.55	.69
Playing games such as bingo, dominos, card games, mahjong	— <sup>§</sup>	— <sup>§</sup>	— <sup>§</sup>
Taking part in sports like bowling, handball, tennis, golf	— <sup>§</sup>	— <sup>§</sup>	— <sup>§</sup>
Cooking	0.00 $\pm$ 0.00	0.00 $\pm$ 0.00	
Watching television	0.21 $\pm$ 0.43	0.00 $\pm$ 0.00	.08
Driving during the day	0.40 $\pm$ 0.55	0.23 $\pm$ 0.43	.52
Driving at night	0.86 $\pm$ 0.66	0.80 $\pm$ 0.83	.90
Recognizing people from a distance	0.14 $\pm$ 0.36	0.00 $\pm$ 0.00	.17
Using a personal computer	0.50 $\pm$ 0.52	0.00 $\pm$ 0.00	.03 <sup>‡</sup>
Shaving, styling hair, or putting on makeup	0.60 $\pm$ 0.55	0.57 $\pm$ 0.51	.92
Difficulty in going out to see movies, theater, plays, sports events	0.07 $\pm$ 0.27	0.00 $\pm$ 0.00	.34

QOL = quality of life; VF-14 = National Eye Institute Visual Function-14 Questionnaire

\*AcrySof IQ PanOptix, Alcon Laboratories, Inc.

<sup>†</sup>Grading scale: 0, no difficulty; 1, a little difficulty; 2, moderate difficulty; 3, quite difficult; 4, impossible to perform

<sup>‡</sup>Statistically significant

<sup>§</sup>The questioned activities were not performed by any of the participants

found good visual rehabilitation for near, intermediate, and far distances with acceptable contrast sensitivity and significant improvement in the near activity visual questionnaire results.

In a prospective noncomparative case series comprising 27 patients, Kohnen et al.<sup>15</sup> reported good visual acuity at all distances—in particular, good intermediate visual acuity (logMAR > 0.1) with the best visual acuity at 60 cm—and high patient satisfaction and spectacle independence at the third postoperative month. Binocular UDVA, UIVA (80 cm), UIVA (60 cm), and UNVA were  $0.00 \pm 0.094$  logMAR,  $0.09 \pm 0.107$  logMAR,  $0.00 \pm 0.111$  logMAR, and  $0.01 \pm 0.087$  logMAR, respectively. Lawless et al.<sup>16</sup> reported a mean UDVA, UIVA, and UNVA of  $0.01 \pm 0.10$  logMAR,  $0.30 \pm 0.14$  logMAR, and  $0.18 \pm 0.10$  logMAR, respectively. García-Pérez et al.<sup>17</sup> found binocular UDVA (4 m), UIVA (60 cm), and UNVA (33 cm) of  $0.03 \pm 0.046$  logMAR,  $0.12 \pm 0.143$  logMAR, and  $0.02 \pm 0.099$  logMAR. The visual acuity results obtained in our study are comparable to these as well as to similar previous studies with the same model and different models of trifocal IOLs.<sup>9–12,15–17</sup>

Kohnen et al.<sup>15</sup> also performed a short quality-of-vision questionnaire that included the following 9 visual lifestyle activities: driving during the day, driving at night, watching TV, theatre/concert, cooking, using a computer/musical instrument, domestic work, and reading a newspaper. The questions were based on a survey distributed in the U.S. Food and Drug Administration clinical trials and subscales of the NEI VFQ-25. The NEI VFQ-25 contains 3 items for evaluating near vision. These items question difficulty in reading ordinary print in newspapers, performing work or hobbies requiring near vision, and finding something on a crowded shelf. On a scale of 1 (very good) to 6 (very bad) patients rated their quality of uncorrected vision for daily life tasks with a mean score of  $2.0 \pm 0.42$ . The mean score for far distance activities was  $2.1 \pm 0.54$  and for near and intermediate distance,  $1.8 \pm 0.10$ . Different from our results, patients reported slightly better scores in tasks requiring near vision when compared with distance vision in this study. This might be related to the absence of questions evaluating fine near activities, such as reading small print and doing fine handwork, which the participants included in our study reported as the most difficult tasks to perform.

We observed that one of the tasks with the highest reported difficulty was driving at night. This might be related to the perception of halos and glare in photopic conditions with multifocal IOLs. Kohnen et al.<sup>15</sup> reported that 93% of the patients perceived optical phenomena such as halos (89%), glare (11%), double vision (7%), ghosting (4%), and distorted vision (4%); whereas, 7% did not report any optical phenomena with the PanOptix IOL. Lawless et al.<sup>16</sup> reported a lower rate of photopic phenomena with the same IOL in 5 (15%) of 33 patients. All patients in this study reported the phenomena diminishing by the subsequent postoperative visits (between 4 weeks to 3 months), likely indicating the neuroadaptation process. It is known that a visual neuroadaptation process is necessary for the brain to adapt to the different images that are provided

by multifocal optics. Failure in this neuroadaptation could cause the perception of glare, confusion, distortion, and the feeling of poor vision. The typical neuroadaptation process after multifocal IOL implantation involves a minimum of 3 months, and improvement continues reaching its maximum 1 year after surgery.<sup>4</sup> In our study, the duration of follow-up was 3 months, at which time the neuroadaptation process was probably incomplete. This might be the reason for relatively high mean scores for driving at night in our study population.

In another recent study evaluating clinical outcomes in 58 patients with bilateral PanOptix lens implantation, a visual satisfaction questionnaire was administered between 9 and 12 months after surgery.<sup>17</sup> That study used a modified version of the Catquest 9-SF questionnaire, and most patients reported little or no difficulty with the activities included in the questionnaire. In this study, driving at night was observed to be the most challenging activity with 25.9% of the patients reporting difficulties occasionally or often. In our study, driving at night was the second most difficult task to perform after reading small print. Although these were the items with the highest mean values we obtained from the respective VF-14 QOL questions, the scores were lower than 1.00, which indicates there was either only a little or no difficulty during these activities.

Optical bench comparisons between trifocal and multifocal IOLs confirm that compared with a single out-of-focus image, the presence of two out-of-focus images, as in case with trifocal IOLs, increases the likelihood of halos.<sup>18,27</sup> Therefore, discussing the possible postoperative symptoms, including glare or halos, is essential before implantation of trifocal IOLs because they might have a significant effect on vision-related QOL.

With mean values of 1.00 or lower for each question, the results of the VF-14 QOL questionnaire indicate that patients who had the new PanOptix trifocal IOL implanted have an overall high satisfaction rate and a high vision-related QOL. Spectacle independence can be obtained for near activities, such as reading books or newspapers, as well as activities requiring intermediate and distance vision. A little difficulty might be described for reading very small print such as medicine leaflets, even in the absence of residual refraction or posterior capsule opacification. We also observed that when patients are informed about the correct use of illumination during near activities, they report performing much better. Patients should be informed about possible photopic phenomena while driving at night and the neuroadaptation process.

Improvement in QOL is usually observed after binocular implantation of the same IOL when compared with monocular implantation. According to the results of our study, this improvement was more apparent in tasks requiring near and intermediate vision. Although best results are obtained with binocular implantation, some patients in our cohort preferred a relatively longer interval between the surgeries of the 2 eyes because of socioeconomic reasons or unilateral cataract. Unilateral implantation of multifocal IOLs might also provide patients with high levels of spectacle



independence without compromising contrast sensitivity, especially in young patients.<sup>28</sup> Nevertheless, the possible disadvantages of a long waiting period should be discussed with patients when there is a planned interval between the surgery of both eyes.

Limitations of this study are the lack of comparative nature, relatively small sample size, short duration of follow-up, and the lack of objective measurement results evaluating contrast sensitivity and glare. However, our primary aim was to evaluate QOL in a questionnaire-based study.

### WHAT WAS KNOWN

- The most widely used multifocal intraocular lenses (IOLs) might provide high patient satisfaction with significant quality-of-life (QOL) improvement in a high percentage of patients.
- The new trifocal IOL (AcrySof IQ PanOptix, Alcon Laboratories, Inc.) showed encouraging results for visual acuity, contrast sensitivity, and photopic symptoms as well as quality of vision.

### WHAT THIS PAPER ADDS

- With mean values of 1.00 or lower for each question, the results of the National Eye Institute Visual Function Questionnaire-14 (VF-14 QOL questionnaire) indicated that patients who had the new trifocal IOL implanted had an overall high satisfaction rate and high vision-related QOL values.
- Reading small print, driving at night, and doing fine handwork were the most difficult tasks to perform. Although these were the items with the highest mean values obtained from the respective VF-14 QOL questions, the scores were lower than 1.00, which indicates there was either only a little difficulty or no difficulty during these activities.
- Binocular IOL implantation was associated with improvement in vision-related QOL, with significant differences in tasks requiring near and intermediate vision such as doing fine handwork and using a personal computer, when compared with monocular IOL implantation.

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**Disclosures:** None of the authors has a financial or proprietary interest in any material or method mentioned.



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