Original Article

Comparison of Two Presbyopia-Correcting Trifocal Intraocular Lenses: A Prospective Study

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Abstract

Objectives: To evaluate the clinical results of a new trifocal intraocular lens (IOL) with sinusoidal design by comparing with a traditional trifocal IOL.

Materials and Methods: A total of 79 patients undergoing uneventful microincisional cataract surgery with bilateral implantation of one of two types of trifocal IOLs, the Acriva Trinova IOL (VSY) or Acrysof IQ PanOptix IOL (Alcon), were enrolled in this prospective study. Visual and refractive outcomes, contrast sensitivity (CS), and defocus curve were assessed at 3 months after surgery. Patient satisfaction and incidence of photic phenomena were also evaluated.

Results: The number of patients/eyes were 48/96 in the Trinova group and 31/62 in the PanOptix group. There were no significant differences between the groups for monocular and binocular corrected/uncorrected distance or intermediate (at 60 cm) and near visual acuities (VA) postoperatively. The Trinova group had statistically significantly better intermediate VA at 80 cm than the PanOptix group ($p<0.05$). The CS results of both groups were within the normal limits. In the binocular defocus curve of both IOLs, we observed a peak of good VA at 0.0 diopters defocus and a useful wide range for intermediate distances. The incidence of photic phenomena in the Trinova group was lower at postoperative 1 month ($p<0.05$) but this difference disappeared at 3 months. A total of 47 patients (97.9%) in the Trinova group and 30 patients (96.7%) in the PanOptix group stated that they would recommend the same IOL.

Conclusion: Both trifocal IOLs provide good visual quality outcomes and patient satisfaction.

Keywords: Trifocal intraocular lens, sinusoidal, presbyopia

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Introduction

Today, cataract surgeons should aim not only for removal of the cataractous lens but also for satisfactory refractive and clinical outcomes of surgery. Thus, the goals of an ideal cataract surgery are to achieve a vision-related quality-of-life that is equal to pre-presbyopic levels and to maintain this state throughout the remaining life of the patient without any further intervention.

Studies of multifocal intraocular lenses (IOLs) providing both distance and near visual acuity have been available since the late 1980s.[1] Reasonable spectacle independence was reported with the initial multifocal IOL optics.[2] However, potential for halos and glare, loss of contrast sensitivity (CS), and poorer results for intermediate-distance tasks performed at arm's length, such as cooking or viewing computer monitors, led to the development of newer IOL designs.[3,4,5] Hence, trifocal diffractive IOLs of different models were designed to address this limitation.[6]

Trifocal IOLs separate light into three different foci in order to provide unaided near, intermediate, and far vision. Part of the light is also dispersed during this process.[4] Though multifocal/trifocal IOLs increased spectacle independence, some patients may be dissatisfied and report symptoms of photic phenomena and blurred vision.[6,7] Traditional trifocal IOLs have a diffractive overlapping pattern with differences in the amount of energy allocated to each focus and in the proportion of the energy loss.[8] It is known that photic phenomena are reported more with diffractive IOLs than monofocal IOLs and have even necessitate IOL exchange in some cases.[9,10]

A next-generation trifocal IOL has recently been introduced, the Acriva Trinova IOL (VSY Biotechnology, Netherlands). The shape of the Trinova IOL is derived from sinusoidal functions. This sinusoidal pattern was designed to provide an IOL optical surface with no sharp edges. Clinical studies evaluating this new trifocal IOL model and pattern are crucial because the results might suggest a course of action in trifocal technology and IOL designs in the future.

The aim of the current study was to assess the clinical performance of the new sinusoidal trifocal IOL (Acriva Trinova, VSY Biotechnology) and compare its performance with a well-known, previously studied diffractive trifocal IOL (Acrysof IQ PanOptix, Alcon Laboratories). To the best of our knowledge, this is the first study evaluating the clinical outcomes of the Acriva Trinova trifocal IOL with its unique sinusoidal profile.

Materials and Methods

Study Design

This prospective, comparative study included a total of 79 patients (158 eyes) undergoing uneventful microincisional cataract surgery with bilateral implantation of either the Acriva Trinova (VSY Biotechnology) or Acrysof IQ PanOptix (Alcon Laboratories) trifocal IOL. All surgeries were performed by three experienced surgeons (H.A.B., T.T., İ.C.) in three different centers. The same study protocol and devices were used in all centers during the study.

All subjects enrolled in the study agreed to participate, met the inclusion criteria, and signed an informed consent agreement before any procedures were performed. The study was approved by a Yozgat Bozok University Clinical Research Ethics Committee (protocol number: 2017-KAEK-189_2020.02.26_26, date: 26.02.2020) and was performed in accordance with the ethical principles described in the Declaration of Helsinki.

Inclusion criteria were an interest in spectacle/contact lens independence and a diagnosis of bilateral grade 2-3 age-related cataract according to Lens Opacities Classification System III staging system.[11] Patients who had any ocular disease that could affect postoperative visual acuity (e.g., amblyopia, pathologic miosis, glaucoma, uveitis, corneal or retinal abnormalities), a history of previous ocular surgery, preoperative corneal astigmatism >0.75 diopters (D), axial length over 25 mm or shorter than 22 mm, or intraoperative complications were excluded.

Each patient was implanted with the same IOL model in both eyes and the patients were divided into two groups according to the type of IOL implanted (the Trinova and PanOptix groups). In all patients, there was an average interval of one week between the surgeries on the first eye and fellow eye.

Preoperative Evaluation

Before surgery, all patients underwent a detailed ophthalmologic examination that included corrected distance visual acuity measurement, anterior segment biomicroscopy, dilated fundus examination, optical biometry (Lenstar LS 900, Haag-Streit AG, Switzerland), and corneal topography (Sirius, CSO, Italy). IOL power was based on optical biometry targeting emmetropia and calculated using the Barrett Universal II formula.

Intraocular Lenses

Ninety-six eyes received the Trinova trifocal IOL (VSY Biotechnology, Netherlands) with plate haptic design. This aspheric trifocal IOL is made of hydrophilic acrylic with a hydrophobic surface. The total length is 11.0 mm and the optic diameter is 6.0 mm. The optic has unique sinusoidal pattern with twelve ridges that, according to the manufacturer, was designed to provide ideal continuous vision and reduce halo and glare by eliminating sharp edges. It also has a 360-degree continuous square optic and haptic edge to reduce posterior capsule opacification formation.

The other 62 eyes in the study received the Acrysof IQ PanOptix trifocal IOL (Alcon Laboratories, USA). This IOL has a central nonapodized diffractive zone of 4.5 mm with 15 diffractive rings and a peripheral refractive zone from 4.5 to 6.0 mm. The lens has a negative asphericity of -0.10 µm and its overall diameter is 13.0 mm.

At 3 months after the second eye surgery, binocular performance on the curve of defocus and CS chart was evaluated. Defocus curve testing was performed under photopic conditions starting from -3.0 D to 0.0 D with 0.5-D increments. CS was assessed with a standardized CS chart (CSV 1000, Vector Vision Co., Ohio, USA).

For evaluation of symptoms, participants completed the National Eye Institute Visual Function Questionnaire (NEI VFQ-25) at postoperative 3 months. The NEI VFQ-25 includes primary patient-reported outcome measures, which are subdivided into 12 subscales: general vision, near vision, distance vision and driving, peripheral vision, color vision, ocular pain, general health, vision-related role limitations, dependency, social function, and mental health. The highest score is 100 and represents the best functional state. In the current study, the patients were also asked additional questions about the presence of halo (rings around a light), glare (trouble seeing street signs due to bright light or oncoming headlights), double vision, and ghosting at 1 month and 3 months after the second eye surgery. Particular emphasis was placed on driving at night, and the examiner showed standard photographs demonstrating examples of these photic phenomena. If the answer was yes, the type of symptom was noted and the patients were asked to rate the impact of these symptoms on their daily lives. The patients were also questioned about spectacle independence for near, intermediate, and far vision, and whether they would recommend the same IOL and procedure to their family and friends. The answers to these additional questions were assessed independently of the NEI VFQ-25.

Statistical Analysis

All data were analyzed using SPSS software (version 22.0, IBM Corp., Armonk, NY, USA). The chi-square (χ^2) test was used to make comparisons of categorical data and the independent samples t-test was used for comparisons of continuous data. Evaluations were made at a 95% confidence level, and a p value <0.05 was considered statistically significant.

Results

The final number of patients/eyes was 48/96 in the Trinova group and 31/62 in the PanOptix group. All patients (n=79) included in the statistical analysis completed the 3-month

follow-up. Table 1 shows the patient demographics and preoperative characteristics. There was no statistically significant difference between groups in any preoperative or intraoperative parameter.

At postoperative 3 months, the mean spherical equivalent was -0.10±0.28 D in the Trinova group and -0.16±0.31 D in the PanOptix group (p=0.218).

There were no significant differences between the groups in corrected/uncorrected distance and near and intermediate (at 60 cm) visual acuities 3 months after surgery. The Trinova group had a statistically significantly better visual acuity performance at 80 cm than the PanOptix group (Table 2). Binocular uncorrected intermediate visual acuity (UIVA) at 60 cm was 0.0 logarithm of the minimum angle of resolution (logMAR) or better in 32 patients (66.6%) in the Trinova group and 22 patients (70.9%) in the PanOptix group. Binocular UIVA at 80 cm was 0.0 logMAR or better in 36 patients (75%) in the Trinova group and 11 patients (35.4%) in the PanOptix group and was 0.15 logMAR or better in 47 patients (97.9%) in the Trinova group and 27 patients (87%) in the PanOptix group.

With respect to photic symptoms, 33 of 48 patients (68%) in the Trinova group and 27 of 31 patients (87%) perceived optical phenomena at 1 month after surgery (p=0.028). On the other hand, the difference in the incidence of photic phenomena between groups was not statistically significant at postoperative 3 months (Trinova: 64.5% vs. PanOptix: 67.7%, p>0.05). Halo was the most frequent dysphotopic phenomena in both groups. None of the patients reported double vision in any visit, whereas two patients in the PanOptix group reported mildly bothersome ghosting at 1 month that disappeared at 3 months after surgery. Table 3 summarizes the patients' subjective evaluation of halo and glare during follow-up.

According to the binocular defocus curve results, the best visual acuity in the Trinova group and PanOptix group was at 0.0 D defocus (-0.07 logMAR and -0.08 logMAR, respectively), which simulates far distance. The binocular defocus curve of both IOLs showed a useful wide range for intermediate distances. From -2.50 D defocus to -3.0 D defocus, there was a decrease of the curve in both IOL groups (Figure 1).

CS measurements of the groups are shown in Table 4. CS measurements (with and without glare) at any spatial frequencies were within the normal range for normal subjects of similar age in both IOL groups.

As regards spectacle use, 47 patients (97.9%) in the Trinova group, and 29 patients (93.5 %) in the PanOptix group reported that they never needed glasses/contact lenses (in the last month)

Table 1. Patient demographics and preoperative data

Parameter	Trinova group	PanOptix group	p value
Mean age (years)	63.58±7.86	63.16±8.22	0.828
Sex (n female/male)	23/25	15/16	0.575
Mean CDVA (logMAR)	0.58±0.26	0.54±0.21	0.632
Mean corneal toricity (D)	0.36±0.29	0.33±0.23	0.784
Angle kappa (mm)	0.25±0.13	0.26±0.16	0.328
Axial length (mm)	23.32±1.06	23.26±1.12	0.416

CDVA: Corrected distance visual acuity, logMAR: Logarithm of the minimum angle of resolution, D: Diopters

Table 2. Comparison of visual outcomes (in logMAR) between the groups at postoperative 3 months

Parameter (mean)	Trinova group	PanOptix group	p value
Monocular UDVA	0.04±0.12	0.05±0.13	0.702
Binocular UDVA	-0.02±0.09	0.00±0.10	0.643
Monocular CDVA	-0.07±0.06	-0.07±0.07	0.831
Monocular UIVA (60 cm)	0. 07±0.15	0.06±0.12	0.722
Binocular UIVA (60 cm)	0.05±0.12	0.04±0.10	0.686
Monocular DCIVA (60 cm)	0.04±0.11	0.04±0.08	0.852
Monocular UIVA (80 cm)	0.06±0.12	0.14±0.13	0.02
Binocular UIVA (80 cm)	0.00±0.11	0.08±0.11	0.02
Monocular DCIVA (80 cm)	0.00±0.10	0.07±0.13	0.01
Monocular UNVA	0.06±0.13	0.05±0.11	0.513
Binocular UNVA	0.01±0.09	0.00±0.10	0.786
Monocular DCNVA	0.05±0.07	0.05±0.10	0.658

logMAR: Logarithm of the minimum angle of resolution, CDVA: Corrected distance visual acuity, DCIVA: Distance-corrected intermediate visual acuity, DCNVA: Distance-corrected near visual acuity, UDVA: Uncorrected distance visual acuity, UIVA: Uncorrected intermediate visual acuity, UNVA: Uncorrected near visual acuity

to correct their vision. For near vision, one patient in the Trinova group and one patient in the PanOptix group sometimes used spectacles. One patient in the PanOptix group reported using spectacles sometimes for intermediate vision. None of the patients in either group needed spectacles for far vision. The difference in the spectacle independency between groups was not statistically significant (p>0.05).

The assessment of VFQ-25 showed very high scores in both groups (sum score: PanOptix group=88.3±8.6, Trinova group=87.9±11.8). The difference between groups was not statistically significant (p>0.05). A total of 47 patients (97.9%) in the Trinova group and 30 patients (96.7%) in the PanOptix group stated that they would recommend the same IOL and procedure to their family and friends.

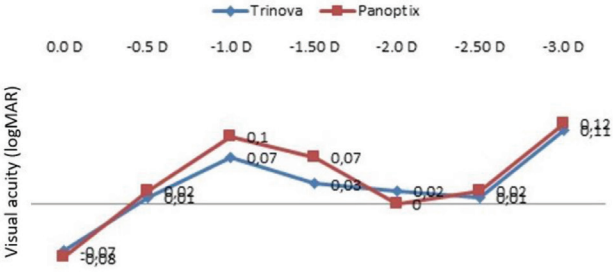

Figure 1. Binocular distance-corrected defocus curves at postoperative 3 months
D: Diopters, logMAR: Logarithm of the minimum angle of resolution

At the 3-month follow-up, none of the eyes in either group had developed posterior capsule opacification. All IOLs in both groups were well positioned, with no change in IOL position up to 3 months postoperatively, and no complications were reported during the follow-up.

Discussion

Presbyopia is an age-related reduction in the accommodative ability of the eye that affects more than a billion people.[12] This study evaluated the presbyopia correction and patient satisfaction results of two different types of trifocal IOLs.

The analysis of the visual outcomes demonstrated that both IOLs provided very good mean visual acuities at near, intermediate, and far distances. Distance vision, intermediate vision at 60 cm, and near vision showed comparable visual acuity between the two study groups. However, the Trinova group had a significantly better UIVA at 80 cm than the PanOptix group. Mencucci et al.[13] reported that the PanOptix IOL had worse intermediate visual outcomes at 80 cm than the Zeiss AT LISA tri 839MP IOL and TECNIS Symfony IOL, whereas the performance of the PanOptix IOL at 60 cm was similar to that of the AT LISA tri at 80 cm in photopic conditions. Kohnen et al.[14] also reported that the PanOptix IOL has an intermediate focal point shift from 80 cm to 60 cm and the intermediate performance of the IOL is slightly better at 60 cm compared to 80 cm. In our study, though there was a difference

Table 3. Subjective evaluation of photic phenomena during follow-up

Parameter		1 month		3 months	
		Trinova	PanOptix	Trinova	PanOptix
Halo	None, n (%)	17 (35.4)	6 (19)	24 (50.0)	13 (41.9)
	Mildly bothersome, n (%)	22 (45.8)	16 (51.6)	23 (47.9)	18 (58.1)
	Moderately bothersome, n (%)	9 (18.7)	9 (29.0)	1 (2.1)	0 (0.0)
	Very bothersome, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Glare	None, n (%)	31 (64.5)	15 (48.3)	36 (75)	24 (77.4)
	Mildly bothersome, n (%)	12 (25.0)	10 (32.2)	11 (22.9)	6 (19.4)
	Moderately bothersome, n (%)	5 (10.4)	6 (19.4)	1 (2.1)	1 (3.2)
	Very bothersome, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Table 4. Contrast sensitivity measurements (in logCS) of the groups 3 months postoperatively

Spatial frequencies		Trinova group	PanOptix group
Without glare	3 cpd	1.62±0.16	1.59±0.19
	6 cpd	1.73±0.22	1.70±0.26
	12 cpd	1.44±0.17	1.40±0.19
	18 cpd	1.10±0.25	1.08±0.23
With glare	3 cpd	1.59±0.19	1.57±0.18
	6 cpd	1.62±0.24	1.60±0.21
	12 cpd	1.38±0.22	1.35±0.19
	18 cpd	1.07±0.27	1.05±0.26

cpd: Cycles per degree

in intermediate visual performance of the IOLs at 80 cm, both IOLs performed well binocularly and most patients achieved a binocular UIVA of 0.15 logMAR or better at 80 cm and better than 0.10 logMAR at 60 cm. Because most tasks are performed at arm's length (60 to 70 cm), both IOLs had high acceptance and patient satisfaction by making near and intermediate vision very comfortable, and almost all patients achieved good functional state levels in the VFQ-25 questionnaire with both IOLs. We also found no statistically significant differences in uncorrected distance, corrected distance, and uncorrected near visual acuity values with the Trinova IOL and PanOptix IOL. When compared with previous studies, the high visual performance of the Trinova IOL and PanOptix IOL are consistent with results obtained with the PanOptix IOL in a previous study and better than the near visual performance of the various types of multifocal IOLs.[14,15,16] The Trinova IOL has +3.0 D near addition and +1.50 D intermediate addition that theoretically provides up to 80 cm reading distance. The preferred reading distance for the Trinova IOL is 38 cm, which is similar to the preferred reading distance of the PanOptix IOL. Very good visual acuities for near and preferred reading distance were achieved with both the Trinova and PanOptix IOLs in the current study. Another previous study comparing the PanOptix and Trinova IOLs suggested that the PanOptix IOL provides better intermediate and near vision results and may be a good choice for patients who want to be independent of glasses.[17] Contrary to that study, we observed no significant difference in spectacle independence between the two IOLs in our study. At postoperative 3 months, this rate was 97.9% and 93.5% in the Trinova and PanOptix groups, respectively. Compared to bifocal IOLs and a low-near-add asymmetric IOL (+1.50 D) and a diffractive IOL (+1.75 D), both trifocal IOLs implanted in this study provided equivalent or better visual acuity and spectacle independence at near, intermediate, and distance.[18,19,20] This alleviates concerns that the addition of an intermediate focus will result in a reduction in performance at near and distance foci.

Multifocal IOLs are based on a non-physiological optical method to achieve near and intermediate vision, because light dispersion to different foci and subsequently at the level of the retina is not present in the natural human visual system. Also, traditional overlapping of the different foci in diffractive trifocal IOLs is neither normal nor physiological.[4] The optical surface of the Trinova IOL does not have any sharp edges. Vega et al.[21] experimentally assessed the through focus energy efficiency of the Acriva Trinova lens and demonstrated a smooth distribution with slightly more energy allocated to the distance focus. The smoothly transitioning surface profile of the lens is a unique patent-pending technology called sinusoidal vision technology. This optical surface pattern provides up to 92% light transmission to the retina, the highest value among all available trifocal IOLs. Thus, reduced light scattering by the stepless diffractive zones of the Trinova IOL might have a mitigating effect on dysphotopsia symptoms.

Angle kappa, the difference between the visual axis and pupillary axis, should also be kept in mind when evaluating pseudophakic photic phenomena. Prakash et al.[22] reported that large angle kappa values correlated with patients' photic complaints after multifocal IOL implantation. Additionally, a large angle kappa is thought to cause functional decentration of multifocal IOLs. It is noticed that if a patient has an angle kappa greater than half of the diameter of the central optical zone of the implanted multifocal IOL, then light may pass through one of the multifocal rings instead of the central optical zone of the lens. This leads to photic phenomena and an unacceptable multifocal IOL.[23] The PanOptix IOL has 15 overlapping diffractive rings surrounding a ~1.16-mm refractive zone, whereas the Trinova IOL has 12 sinusoidal diffractive zones surrounding a 1.4-mm central ring. Since the central ring diameter of the Trinova IOL is slightly larger than that of the PanOptix, greater tolerance to kappa angle and minimal decentration are expected. This might also have an influence on the difference in photic symptoms between the two study IOLs in the early period (1 month).

Despite the difference in the first month, there was no significant difference in photic symptoms between the two IOLs at postoperative 3 months. A functional magnetic resonance imaging study showed that multifocal IOL implantation is followed by a change in visual input, modification of the cortical circuitry, and increased activity in the caudate nucleus (cortical area of planning of adaptive behaviors). These processes, likely representing the beginning of neuroadaptation, are more pronounced in patients with more photic complaints.[24] Alió et al.[3] reported that at postoperative 1 month, significantly more patients in the AT LISA and RESTOR groups expressed that they would choose the same IOL again compared to the AT LISA tri group, whereas this difference in patient satisfaction disappeared at postoperative 6 months. The authors speculated that a longer period of neuroadaptation is needed for the trifocal lens.[3] In the present study, neural processing and neuroadaptation to pseudophakic optical patterns might play a role in the equalization of photic symptom rates in the two groups at 3 months after surgery.

The defocus curve illustrates vision quality at each dioptric level of spectacle defocus and would be linear at 0.0 logMAR from plano all the way through 3.0 D defocus in an ideal eye.[25] In the current study, regarding the continuous range of visual acuity, both IOLs provided a visual acuity of 0.10 logMAR or better for binocular defocus levels from 0.0 D to -2.50 D defocus. This result shows that both IOLs provide good functionality and sufficient visual acuity levels from near to distance. Similar to our results, Galvis et al.[26] also reported an absence of distinct peaks throughout the defocus curve with the PanOptix IOL.

Study Limitations

The lack of 6-month results is one of the limitations of our study. However, our study is the first comprehensive study in the literature to evaluate the Trinova and PanOptix IOLs together with many important parameters related to multifocal IOLs, including visual acuity, CS, defocus curve results, the VFQ-25 questionnaire, and spectacle independence.

Conclusion

The new sinusoidal trifocal IOL Trinova provided good visual outcomes, with uncorrected monocular and binocular visual acuities for all distances consistent with those of the PanOptix IOL. The defocus curve and CS results of the Trinova IOL suggest that an aspheric optic and smooth sinusoidal surface profile provide satisfactory, high-quality vision. The Trinova IOL had significantly better subjective dysphotopsia ratings than the PanOptix IOL at postoperative 1 month, whereas photic phenomena were reported to be mild and not disabling for both IOLs at 3 months.

Ethics

Ethics Committee Approval: Yozgat Bozok University Clinical Research Ethics Committee (protocol number: 2017-KAEK-189_2020.02.26_26, date: 26.02.2020).

Informed Consent: Obtained.

Authorship Contributions

Surgical and Medical Practices: H.A.B., T.T., İ.C., Concept: H.A.B., Y.Y.T., S.A.B., T.T., İ.C., Design: H.A.B., Y.Y.T., S.A.B., T.T., İ.C., Data Collection or Processing: H.A.B., Y.Y.T., S.A.B., T.T., İ.C., Analysis or Interpretation: H.A.B., Y.Y.T., S.A.B., T.T., İ.C., Literature Search: H.A.B., Y.Y.T., S.A.B., T.T., İ.C., Writing: H.A.B., Y.Y.T., S.A.B., T.T., İ.C.

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