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Original Article

Comparision of a Novel Trifocal Intraocular Lens and a Monofocal Enhanced Depth of Focus Intraocular Lens in Visual Performance and Quality of Life Scores

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Abstract

Objectives: The aim of this study was to investigate the effects of trifocal and monofocal intraocular lens with enhanced depth of focus implantations.

Methods: Forty patients who had bilateral implantation of the trifocal or monofocal extended depth of focus (EDOF) intraocular lenses after phacoemulsification were included in the study. The pre-operative and post-operative examination findings were analyzed. At the 6th post-operative month, binocular defocus curves, contrast sensitivity measurements, subjective complaints, spectacles independence, and the quality of life questionnaire results of the visual function 14 questionnaire (VF-14) questionnaire were also examined.

Results: While distance and intermediate visual acuities were similar at 6 months postoperatively, near visual acuities were found to be statistically significantly better in the trifocal group. The contrast sensitivity values were found to be statistically better in the EDOF group. In the trifocal group, 25% of the patients had low-intensity and 5% of the patients had moderate-intensity of photopic complaints, respectively, while 10% of the patients in the EDOF group had low-intensity photopic complaints. While spectacles independence could be achieved in all patients in the trifocal group, in the EDOF group, 80% of patients needed spectacles. When examining VF-14 test values without spectacles, it was found that the values of the trifocal group were significantly higher.

Conclusion: Trifocal group performed better at near, although far and intermediate vision was comparable between the groups. On the other hand, a higher rate of photic phenomena was observed in the trifocal group.

Keywords: Cataract, Extended depth of focus, presbyopia, trifocal intraocular lens

Introduction

Thanks to advancements and technological developments in the technique of phacoemulsification, expectations have surpassed complication-free surgery, aiming for low post-operative residual refractive error, rapid visual rehabilitation, and routine independence from glasses at all distances (1). The most commonly implanted intraocular lenses (IOLs) in cataract surgeries are still monofocal IOLs due to their low cost, satisfactory visual function for distance vision, suitability for patients with comorbidities such as corneal and retinal diseases, and lesser occurrence of photic phenomena (2). However, these IOLs still fall short in intermediate and near activities, leading to a need for glasses (3).

To provide clear vision simultaneously at near and far, bifocal refractive IOLs were first introduced in 1986 (4). However, these IOLs did not provide sufficient correction for intermediate functions (5). In addition, the multiple focal points of light refraction caused a decrease in contrast sensitivity and resulted in photic phenomena such as halos and glare (6,7). The discovery of multifocal diffractive IOLs has relatively reduced dysphotopsia complaints and improved vision at far, intermediate, and near (8).

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Trifocal IOLs create three different focal points to provide vision at different distances, while extended depth of focus (EDOF) IOLs, whose fundamental principle is to create a longitudinal focal plane, have been introduced to increase the range of vision (9,10). This extended focal plane can be achieved through the modification of spherical aberrations, diffractive optical designs, pinhole effect, or bio-analogical technologies (11). Nowadays, to achieve better visual performance, one or more of the available IOL technologies in the market can be combined (12).

In this study, we aimed to investigate the effects of newly designed AcrivaUD Trinova Pro C® lenses, which utilize the principle of diffractive trifocal IOLs, and Tecnis Eyhance® lenses, which utilize the principle of EDOF, on distance, intermediate, and near visual acuity, contrast sensitivity, photic phenomena, and quality of life. The absence of studies reported in the literature with Trinova Pro IOLs makes our research significant.

Methods

Patients who underwent phacoemulsification and IOL implantation at a tertiary-level university hospital between January 2021 and December 2021 were retrospectively screened. The pre-operative and post-operative examination findings of patients implanted with Trinova Pro C and Tecnis Eyhance following bilateral uncomplicated phacoemulsification were analyzed.

All included patients were provided with detailed information about cataract surgery and the implanted IOLs during pre-operative visits. In accordance with the principles and ethical rules of the Helsinki Declaration, patients participating in the study were informed that their medical records would be used for the performed surgery and follow-up visits, and their written consent was obtained. Ethical approval for this study was obtained from Kartal Dr. Lütfi Kırdar City Hospital Ethics Committee on April 13, 2022 (Approval Number: 2022/514/223/3).

Patient Selection

Twenty patients with a total of 40 eyes who were literate and aged 40 years and above, and who received uncomplicated bilateral phacoemulsification followed by Trinova Pro C implantation, as well as 20 patients with a total of 40 eyes who received Tecnis Eyhance implantation, were included in the study.

Patients with a need for high contrast sensitivity due to their profession or unrealistic expectations were not included. Patients with severe dry eye symptoms or ocular surface irregularities, corneal pathology, uveitis, pseudoexfoliation syndrome, glaucoma, retinopathy, and other additional eye diseases, as well as patients with neuro-ophthalmologic pathologies, were not included in the study. Patients who had undergone any previous eye surgery had a mesopic pupil diameter above 6 mm or a photopic pupil diameter below 2 mm, had hyperopia or myopia >5 D, had corneal astigmatism of 1 D or higher, or had axial length below 22 mm or above 26 mm were not included in the study.

Pre-operative Assessments

The patients' complaints and expectations, as well as their ophthalmological and systemic medical history, were thoroughly evaluated. Their educational status, occupations, daily activities, and hobbies were questioned. Autorefraction measurements of the patients were taken using an autorefractor/keratometer (NIDEK ARK-1a®, Japan). Intraocular pressure (IOP) measurements were performed using applanation tonometry. Light reflexes and relative afferent pupillary defect examinations were evaluated. Keratometry values and pupil diameters under photopic and mesopic conditions were measured (Sirius®, CSO, Italy). Monocular uncorrected and best-corrected distance (at 4 m) visual acuity were measured and converted to logMAR units (monocular uncorrected distance visual acuity [MUDVA] and monocular best-corrected distance visual acuity [MBCDVA]) using Snellen equivalents. Detailed anterior segment and dilated fundus examinations were performed. Central macular morphology was evaluated using optic coherence tomography (OCT) (TOPCON DRI OCT TRITON®, Japan). Axial lengths were measured using optical biometry (Haag-Streit Lenstar LS900®, Switzerland) and confirmed using A-scan mode ultrasound (Sonomed Escalon E-Z AB5500+®, U.S.A). Biometric measurements were performed targeting emmetropia in both eyes using the SRK/T formula.

Surgical Technique

All cases were performed by the same experienced surgeon (AP) using the standard small incision phacoemulsification technique with a continuous curvilinear capsulorhexis of 5–5. 5 mm diameter created with micro forceps. The preplanned IOLs were implanted into the capsular bag. IOL centration was checked using Purkinje reflexes. The same phacoemulsification machine (Bausch and Lomb, Stellaris®, USA) and microscope (Zeiss, OPMI LUMERA T S88®, Germany) were used in all surgeries. In all cases, the eye causing more complaints was operated on first, followed by the other eye approximately 1–4 weeks later.

The IOLs Used in Our Study

According to the company data, Trinova Pro C is a trifocal IOL that features a sinusoidal design and a smooth transition diffractive surface area. Unlike traditional overlapping design trifocal IOLs, this smooth transition sinusoidal design aims to increase light distribution efficiency and minimize post-operative photic phenomena. With its enhanced pupil adaptive feature, Trinova Pro C maintains visual quality under different lighting conditions. Approximately 93% of the light entering the eye reaches the retina with Trinova Pro C (13). With +1.8

D intermediate and +3.6 D near additions, Trinova Pro C provides a clear vision for activities such as phone usage, reading, and computer use at intermediate and near.

Tecnis Eyhance is a single-piece hydrophobic acrylic posterior chamber lens. With a modified aspheric front surface, this monofocal IOL aims to expand the depth of focus and increase the range of vision. The modified aspheric front surface provides a continuous power profile that increases from the periphery to the center. As a result, it offers better vision at intermediate distances compared to a standard monofocal IOL. Based on the modification of spherical aberrations, this design does not include refractive or diffractive zones and cannot be distinguished from a standard monofocal IOL macroscopically (2,3). The increased range of vision provided by this design, along with the depth of field created, is less affected by photic phenomena caused by multifocal IOLs that create multiple focal points.

Post-operative Evaluations

All patients were prescribed dexamethasone sodium phosphate 0.1% and moxifloxacin 0.5% eye drops for the post-operative period. Dexamethasone sodium phosphate 0.1% was gradually discontinued.

During the post-operative 1st day and 1st week examinations, IOP, MUDVA, detailed anterior segment examinations, and dilated fundus examinations were evaluated. In addition, at the 1st and 3rd-month follow-up visits, MBCDVA and binocular uncorrected distance visual acuity were measured using Snellen charts and converted to the logMAR unit. Monocular and binocular uncorrected intermediate (60 cm) visual acuity (BUIVA) (monocular uncorrected intermediate (60 cm) visual acuity [MUIVA], BUIVA), along with monocular distance-corrected intermediate visual acuity (MDCIVA), and monocular and binocular uncorrected near (40 cm) visual acuity (BUNVA) (monocular uncorrected near (40 cm) visual acuity [MUNVA] and BUNVA) were measured and recorded using a Turkish reading chart prepared according to the international standards of Bailey-Lovie and early treatment diabetic retinopathy study reading charts (2).

At the 6th-month post-operative evaluation, in addition to the aforementioned assessments, posterior capsule opacity (PCO) was evaluated during biomicroscopic examination and scored as follows: 0 = none, 1 = transparent, and only assessable with retroillumination, 2 = distinct fibrosis visible during retroillumination, 3 = intense white fibrosis with Elschnig pearls (14). Monocular glare and glare-free photopic contrast sensitivity values were examined using CSV-1000E® (VectorVision, USA) after correcting any existing refractive errors. Moreover, binocular defocus curves were generated with 0.50 D increments within the range of +2.0 D–−5.0 D. Patients were also questioned about photopic symptoms such as halos, glare, sunbursts, and dark areas, and they were asked to rate the severity of their symptoms on a scale of 1 = none, 2 = mild, 3 = moderate, 4 = severe. The visual function 14 questionnaire (VF-14), consisting of 14 questions, was conducted to evaluate patients' visual satisfaction and quality of life (15). In contrast to the original version of the questionnaire, responses were also noted without glasses to assess patients' functional ability to perform activities without glasses.

Statistical Analysis

Statistical analysis was performed using R version 2.15.3 software (R Core Team, 2013). The study data were reported using measures such as minimum, maximum, mean, standard deviation, median, frequency, and percentage. The normality of quantitative data was evaluated using the Shapiro-Wilk test and graphical examinations. Between-group comparisons of normally distributed quantitative variables were performed using independent samples t-test. Within-group comparisons of normally distributed quantitative variables were analyzed using dependent samples t-test, repeated measure analysis of variance, and pairwise comparison with Bonferroni correction. The comparison of qualitative data was conducted using Pearson's Chi-square test. A $p<0.05$ was considered statistically significant.

Results

During post-operative follow-ups, all cases exhibited round and light-sensitive pupils and a centralized IOL position. Demographic characteristics and pre-operative evaluations are summarized in Table 1.

Upon examining visual acuity values, it was observed that at the post-operative 1st month, the MUDVA and MBCDVA values of the Trinova Pro C group were significantly higher compared to the Tecnis Eyhance group ($p=0.001$, $p=0.003$). However, near visual acuity values were significantly lower in the Trinova Pro C group at all visits ($p<0.001$). The visual acuity values for each group are summarized in Table 2. The cumulative binocular uncorrected visual acuity at 6 months postoperatively is shown in Figure 1. Defocus curves evaluated between the groups are displayed in Figure 2.

At the post-operative 6th month, spherical equivalent values were significantly more myopic in the Trinova Pro C group compared to the Tecnis Eyhance group ($p<0.001$). However, no significant difference was observed in cylindrical values ($p>0.05$). In the Trinova Pro C group, contrast sensitivity values at 12 cpd and 18 cpd in glare-free photopic conditions, as well as at 12 cpd in glare conditions, were significantly lower ($p=0.004$, $p=0.031$, $p=0.007$). The contrast sensitivity graph is shown in Figure 3.

There was no significant difference in PCO scoring between the groups at 6 months ($p>0.05$). Weak posterior capsule opacification, assessable with retroillumination, was

Table 1. Pre-operative characteristics of patients in both groups

	Trinova pro C group (%)	Tecnis eyhance group (%)	p
Patients/eyes (n)	20/40	20/40	
Gender (n/%)			
Female	9/45	10/50	
Male	11/55	10/50	
Age (y)	60.65±10.83	61.50±8.32	0.694
Manifest spherical equivalent (D)	-0.23±1.96	-0.44±1.8	0.615
Cylindrical power (D)	-0.44±0.15	-0.46±0.15	0.714
IOP (mm/hg)	13.53±1.74	13.52±1.45	0.899
MUDVA (Logmar)	0.59±0.28	0.58±0.26	0.953
MBCDVA (Logmar)	-0.29±0.11	-0.3±0.12	0.685
Axial length	23.50±0.55	23.51±0.65	0.917
Photopic pupil diameter	3.56±0.21	3.53±0.26	0.476
Mesopic pupil diameter	4.86±0.20	4.83±0.18	0.465

MUDVA: Monocular uncorrected distance visual acuity, MBCDVA: Monocular best-corrected distance visual acuity.

Table 2. Post-operative parameters of patients in both groups

	Trinova Pro C group	Tecnis eyhance group	p
1 Month			
MUDVA LogMAR	0.07±0.04	0.03±0.06	0.001*
MBCDVA logMAR	0.06±0.04	0.03±0.04	0.003*
BUDVA LogMAR	-0.02±0.03	-0.04±0.04	0.276
MUIVA LogMAR	0.22±0.06	0.23±0.06	0.452
MDCIVA LogMAR	0.22±0.05	0.22±0.06	0.962
BUIVA LogMAR	0.11±0.04	0.13±0.04	0.165
MUNVA LogMAR	0.22±0.07	0.44±0.06	<0.001*
BUNVA LogMAR	0.13±0.06	0.36±0.07	<0.001*
3 Months			
MUDVA LogMAR	0.04±0.04	0.02±0.05	0.053
MBCDVA logMAR	0.04±0.04	0.02±0.04	0.074
BUDVA LogMAR	-0.03±0.04	-0.04±0.05	0.540
MUIVA LogMAR	0.17±0.06	0.19±0.05	0.234
MDCIVA LogMAR	0.17±0.05	0.19±0.06	0.392
BUIVA LogMAR	0.09±0.05	0.10±0.04	0.503
MUNVA LogMAR	0.17±0.06	0.43±0.06	<0.001*
BUNVA LogMAR	0.12±0.05	0.36±0.06	<0.001*
6 Months			
Spherical equivalent(D)	-1.06±0.36	-0.14±0.35	<0.001*
Cylindrical value (D)	-0.43±0.15	-0.43±0.14	0.999
MUDVA LogMAR	0.03±0.04	0.02±0.05	0.058
MBCDVA logMAR	0.03±0.03	0.01±0.05	0.087
BUDVA LogMAR	-0.03±0.06	-0.05±0.05	0.438
MUIVA LogMAR	0.16±0.06	0.17±0.05	0.495
MDCIVA LogMAR	0.16±0.05	0.17±0.07	0.512
BUIVA LogMAR	0.08±0.05	0.10±0.05	0.179
MUNVA LogMAR	0.13±0.06	0.43±0.06	<0.001*
BUNVA LogMAR	0.12±0.05	0.35±0.06	<0.001*

MUDVA: Monocular uncorrected distance visual acuity; MBCDVA: Monocular best corrected distance visual acuity; BUDVA: Binocular uncorrected distance visual acuity; MUIVA: Monocular uncorrected intermediate (60 cm) visual acuity; BUIVA: Monocular and binocular uncorrected intermediate (60 cm) visual acuity; MDCIVA: Monocular distance-corrected intermediate visual acuity; MUNVA: Monocular uncorrected near (40 cm) visual acuity; BUNVA: Monocular and binocular uncorrected near (40 cm) visual acuity; *p<0.05.

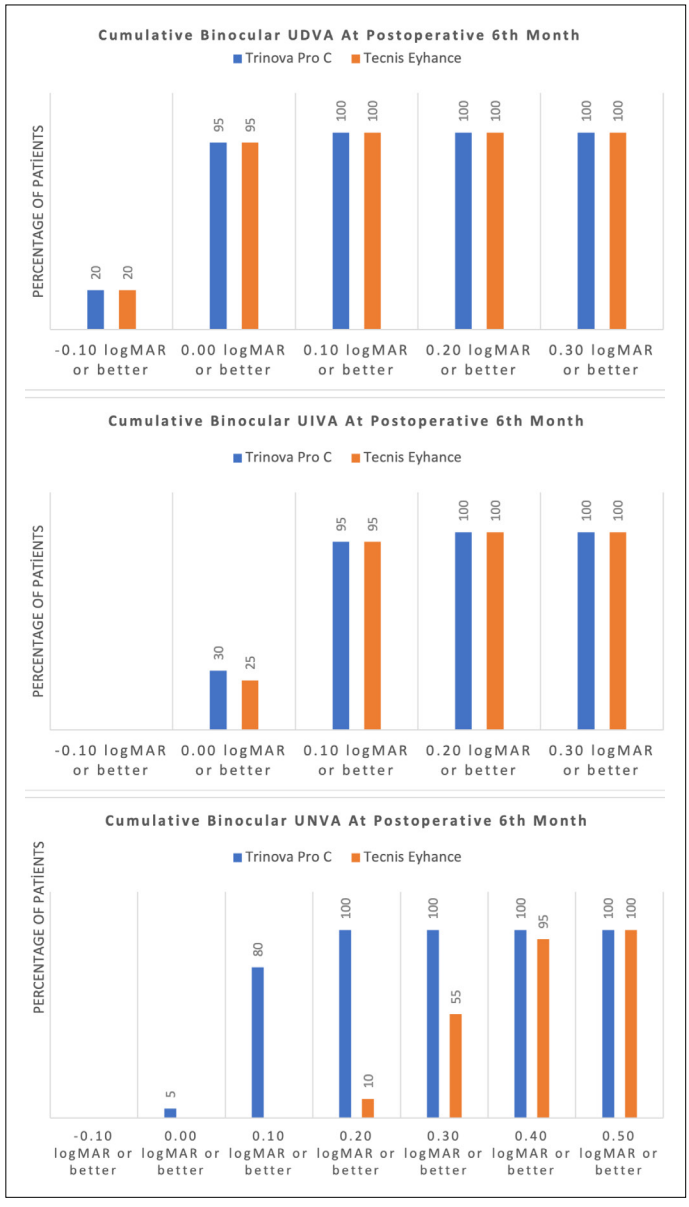

Figure 1. The cumulative binocular uncorrected visual acuities of patients. *UDVA: Uncorrected distance visual acuities; UIVA: Uncorrected intermediate visual acuities; UNVA: Uncorrected near visual acuities; logMAR: logarithm of the minimum angle of resolution*

observed in 4 eyes (10%) in the Trinova Pro C group and in 3 eyes (7.5%) in the Tecnis Eyhance group.

Subjective photic complaints were significantly higher in the Trinova Pro C group at 6 months postoperatively (p=0.034). In the Trinova Pro C group, 14 patients (70%) reported no complaints, 5 patients (25%) reported mild complaints, and 1 patient (5%) reported moderate complaints. No patients reported severe complaints. In the Tecnis Eyhance group, 18 patients (90%) reported no complaints, and 2 patients (10%) reported mild complaints.

When examining VF-14 test values, it was found that the values of the Trinova Pro C group were significantly higher

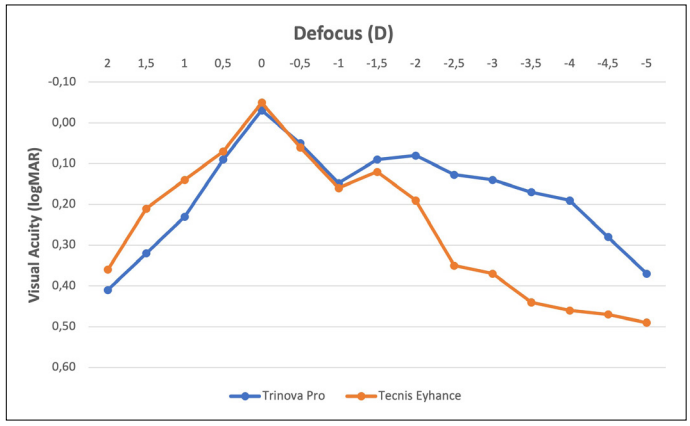

Figure 2. Mean uncorrected binocular defocus curves of the patients in both groups at post-operative 6th months

(p<0.001). For near visual activities (questions 1, 2, 7, 8, and 9), the values of the Trinova Pro C group were significantly higher than those of the Tecnis Eyhance group (p<0.001). No significant difference was found in VF-14 test values for other activities and questionnaire questions repeated with the presence of glasses (p>0.05).

In our study, all patients in the Trinova Pro C group achieved spectacle independence in distance, intermediate, and near visual functions. In the Tecnis Eyhance group, 16 patients (80%) used near glasses. Among these 16 patients, 12 always used glasses, three frequently used glasses, and one occasionally used glasses for near activities. Finally, 95% of patients in the Trinova Pro C group and 90% of patients in the Tecnis Eyhance group reported that they would recommend the implanted IOL to others.

Discussion

The high rates of patient satisfaction and recommendations for both IOLs suggest that they are well-received by patients. In a study conducted with Trinova, the first diffractive IOL that the manufacturer produced using a sinusoidal design, MUDVA results similar to those of Trinova Pro C were obtained at our post-operative 6th month (16). Another study compared Trinova and FineVision Micro F® (PhysIOL SA, Belgium), both trifocal diffractive IOLs, finding similar DVA values (17). In the study, when comparing the DVA values obtained with Trinova and those obtained with Trinova Pro C better results were found. According to data obtained from the producer, Trinova Pro C showed a slight increase in light transmission from 92% to 93%, possibly contributing to the observed improvement in DVA values. Our study's DVA values aligned with those of other trifocal IOL studies (18-20). Similarly, studies comparing Tecnis Eyhance with standard monofocal IOLs found no significant difference in UDVA (2,21).

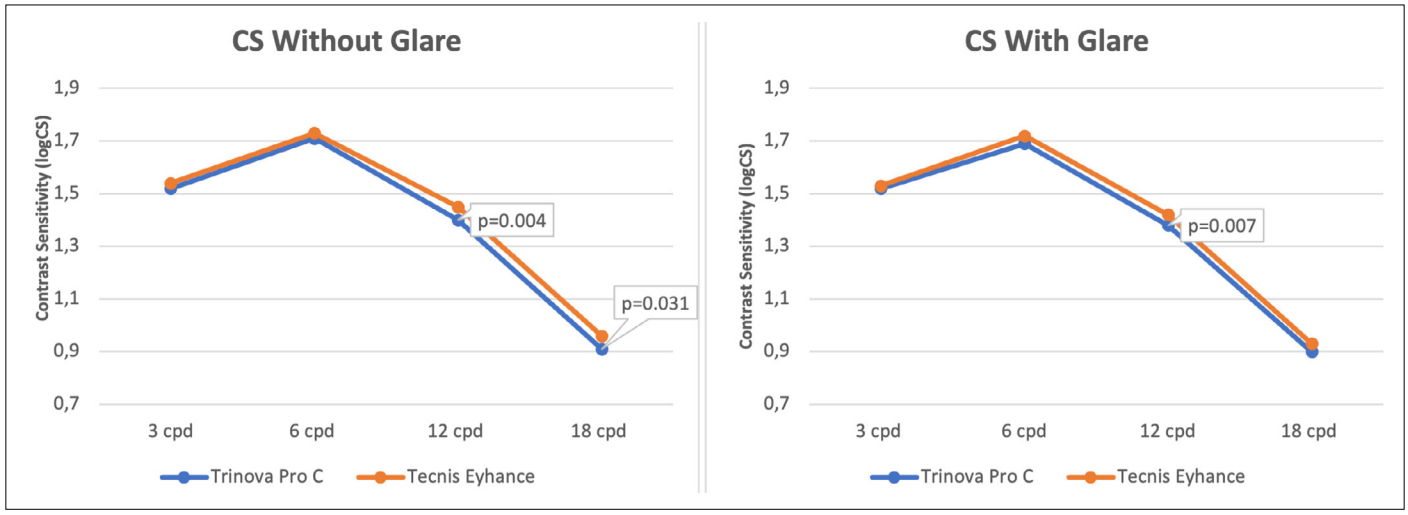

Figure 3. Contrast sensitivity values glare in both groups.
CS: Contrast Sensitivity; logMAR: logarithm of the minimum angle of the resolution.

The variability in tests assessing near and intermediate visual performance complicates study design and comparisons (22). Amigo et al. (17) found no statistically significant difference in intermediate visual acuity between Trinova and FineVision Micro F 3 months post-surgery. Trinova Pro C, utilized in our study, increased Trinova's +1.50 D intermediate vision addition to +1.80 D. Alió et al. (18) reported higher intermediate visual levels with AcrySof IQ Panoptix® 6 months post-surgery compared to our findings. Ünsal and Sabur achieved results similar to our MUIVA values with Tecnis Eyhance, (21) while Mencucci et al. (2) reported lower MUIVA and MDCIVA values than our Eyhance study.

In our study, Trinova Pro C achieved better results in near visual acuity. Amigo et al. (17) found the MUNVA and BUNVA values to be statistically better with FineVision Micro F compared to Trinova. The Trinova near additional strength is 3.0 D, which value was raised to 3,6 D in Trinova Pro that we used in our study. Alió et al. (18) reported lower near-vision MUNVA levels with Panoptix compared to those we obtained with Trinova Pro C.

Mencucci et al. (2) found similar MUNVA values for Tecnis Eyhance at 6 months compared to our findings. In a study evaluating Mini Well® as a monofocal EDOF lens, Bellucci et al. (23) reported better MUNVA values than those obtained with Tecnis Eyhance. In this study, the mean spherical equivalent measured by post-operative autorefraction was −0.59±0.58 D, which was more negative than the values obtained in our study.

At 6 months post-surgery, Trinova Pro C yielded significantly more myopic spherical equivalent values. The absence of a distinct focal plane complicates precise determination of patients' objective or subjective refraction (24). Moreover, the similarity in MUDVA and MBCDVA values at 6 months, coupled with no observed change in visual acuity during examinations with myopic corrections, suggests that autorefraction-derived values may not accurately reflect the true refractive error.

Both IOLs used in our study are hydrophobic and have sharp-edge designs. Shah et al. (25) compared the rates of Nd:YAG laser capsulotomy for multifocal and monofocal IOLs and reported a higher rate of posterior capsulotomy in the multifocal group. Dönmez et al. (26) reported that the rate of PCO at 6 months postoperatively with Panoptix IOL was 10%. Çınar et al. (27) noted no instances of PCO development in patients who received Tecnis Eyhance IOL implantation during a follow-up period averaging 3.02±1.3 months. The incidence of PCO development can vary over time. Further clinical studies with longer follow-up periods are needed to evaluate both lens groups used in our study.

In our study, subjective photic complaints were more frequently observed in Trinova Pro C cases. Hamid et al. (28) compared the results of AT LISA tri839MP®, FineVision, and Tecnis Symfony® IOLs and reported a lower frequency of photic complaints in the EDOF Tecnis Symfony group compared to trifocal IOLs at 6 months postoperatively. In their study, Ceran et al. (16) reported, at post-operative 6 months, halo in 13.3% of the patients, and glare complaints at a level that would prevent vehicle use at night in 3.33% of the patients. However, there are also studies reporting a higher incidence of photic complaints with multifocal IOLs. Kohnen et al. (29) reported a 93% incidence of halo complaints at 3 months postoperatively with Panoptix.

Contrast sensitivity function is another important aspect that has been investigated with numerous IOLs with different materials and optical designs. Cochener et al. (30) mentioned that EDOF IOLs could theoretically be superior

to trifocal IOLs in terms of contrast sensitivity due to compensation for chromatic and spherical aberrations. Mencucci et al. (31) compared the EDOF Tecnis Symfony with the AT LISA Tri839MP and Acrysof IQ PanOptix trifocal diffractive IOL designs and showed that Tecnis Symfony was associated with improved contrast sensitivity under both photopic and mesopic conditions.

The assessment of improvement in patients' daily activities after cataract surgery is becoming increasingly important. VF-14 has been validated for use in populations with cataract (32). Brydon et al. (33) found higher VF-14 values measured without glasses in the multifocal group compared to the monofocal group in their study. Dyrda et al. (34) compared hybrid multifocal, refractive multifocal, diffractive multifocal, and monofocal IOLs and reported statistically significantly better VF-14 values with hybrid and diffractive optic-designed IOLs compared to monofocal IOLs.

In our study, all patients in the Trinova Pro C group achieved spectacle independence in their daily activities. In the Tecnis Eyhance group, 80% of patients reported using near glasses with varying frequency. Ceran et al. (16) reported a spectacle independence rate of 96.6% at 6 months postoperatively with Trinova. Amigo et al. (17) reported that all patients implanted with Trinova were able to read unaided at near and intermediate distances without difficulty. Ünsal and Sabur reported spectacle independence rates of 97% at distance, 84% at intermediate, and 6% at near with Tecnis Eyhance (21).

Our study has certain limitations. First, it was designed retrospectively. The absence of control groups involving IOL implantations with similar designs is another significant limitation of our study. Objective measurement methods to assess photic phenomena were not used in our study. However, we maintain that any potential bias in our study would equally impact the clinical outcomes of both IOLs.

Conclusion

Trinova Pro C and Tecnis Eyhance IOLs have achieved patient expectations and clinically satisfactory outcomes. Further clinical research is needed to examine visual quality, contrast sensitivity values, and photic phenomena with these IOLs of different designs.

Disclosures

The design of the study and collection, analysis, and interpretation of data and in writing the manuscript were funded by VSY Biotechnology GMBH. The datasets generated and/or analysed during the current study are not publicly available due to the funding polites but are available from the corresponding author on reasonable request.

Ethics Committee Approval: This study was conducted in accordance with the tenets of the Declaration of Helsinki, and written informed consents were obtained from all patients. The study protocol was reviewed and approved by the Institution's local ethics committee of Kartal Dr. Lutfi Kırdar City Hospital before the participants' enrollment with study protocol number of 2022/514/223/3.

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Authorship Contributions: Concept – M.T., A.P., G.A.; Design – M.T., A.P., G.A.; Data Collection and/or Processing – M.T., A.P; Analysis and/or Interpretation – M.T., A.P., G.A.; Writing – M.T., A.P., G.A.; Critical Reviews – M.T., A.P.

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