



Comparison of visual and refractive outcomes of diffractive bifocal toric and trifocal toric intraocular lenses 12 months after implantation in patients with moderate to high myopia

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Abstract

Purpose To compare the visual and refractive outcomes of bifocal toric and trifocal toric intraocular lenses (IOL) in patients with moderate to high myopia at 12 months after implantation.

Method This is a prospective and comparative study. In 120 eyes with moderate to high myopia and astigmatism, bifocal toric IOLs ($n = 60$ eyes) or trifocal toric IOLs ($n = 60$ eyes) were implanted. Eyes with axial lengths from 24.0 to 26.5 mm were included. Postoperative examinations measured near, intermediate, and distance visual acuity (VA), along with refractive measurements, binocular defocus curves, and patient satisfaction with the National Eye Institute Visual Function Questionnaire.

Results For uncorrected- and corrected distance intermediate VA, the trifocal group showed significantly better VA at 1, 3, 6, and 12 months than the bifocal group. Driving subscale scores from the questionnaire were significantly better in the trifocal than the bifocal group. Concerning the binocular defocus curve, uncorrected distance VA was

significantly higher in the trifocal than bifocal group at test distances of -1.5 D.

Conclusions Both trifocal and bifocal toric IOLs effectively corrected the near, intermediate, and distance vision in patients with moderate to high myopia and astigmatism. However, intermediate vision was significantly better in eyes with trifocal than bifocal toric IOLs.

Keywords Bifocal toric intraocular lens · Trifocal toric intraocular lens · Multifocal intraocular lens · Myopia · Defocus curve

Introduction

In response to the growing demand for the correction of presbyopia at the time of cataract surgery, newly designed intraocular lenses (IOLs) have made it possible to correct presbyopia or concomitant ametropia as well as treat cataract. Among such lenses, by separating incoming light into multiple focal points, multifocal IOLs provide good far, intermediate, and near vision without requiring additional correction with spectacles.

Although multifocal IOLs have become increasingly preferred by patients with cataract, pre-existing corneal astigmatism can complicate the use of multifocal IOLs by adversely affecting visual acuity (VA)

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[1, 2]. The prevalence of preoperative corneal astigmatism exceeding 1.25 diopters (D) in patients with planned cataract surgery has ranged from 15 to 29% [3–5]. In response, toric IOLs or corneal relaxing incisions, if not both, can be used to reduce astigmatism at the time of cataract surgery. However, because corneal relaxing incisions are less effective, stable, and predictable than implanted toric IOLs, multifocal toric IOLs have become more popular in recent years [6, 7].

By dividing incoming light into 2 or more foci, multifocal IOLs provide good vision at different distances, even if they affect the vision quality of out-of-focus images. Traditional bifocal IOLs have also been reported to reduce the quality of images at intermediate distances compared with the quality at far and near distances. Some of those effects are reduced contrast sensitivity, reduced modulation transfer function, and the presence of glare and halos [8, 9]. By contrast, trifocal IOLs are a newly developed type of multifocal IOLs that afford better vision at intermediate distances without impairing near or far vision in the process [10]. Moreover, with the development of trifocal IOLs, differences in visual quality between trifocal and bifocal lenses have been studied to determine the necessity of intermediate focus [11–13]. The answer to that question is pivotal for patients with moderate to high myopia due to their long axial lengths (AL). After all, as studies have shown, biometric changes in myopia exceeding -4 D are the chief factor in the formation of myopia, and such structural changes can reduce visual quality after cataract surgery [14, 15].

Although researchers have compared the visual performance of trifocal and bifocal IOLs, to the best of our knowledge no published studies have involved comparing postoperative visual performance in diffractive trifocal toric versus diffractive bifocal toric IOLs in patients with moderate to high myopia. Thus, the aim of our study was to compare visual quality at 3 working distances (i.e., near, intermediate, and far), along with patient satisfaction outcomes, of trifocal toric and bifocal toric IOLs in patients with moderate to high myopia and pre-existing corneal astigmatism.

Materials and methods

Study design and participants

A prospective randomized trial was performed in the Department of Ophthalmology at the Lazer Eye Hospital in Kayseri, Turkey, after being approved by the Institutional Review Board and Ethics Committee at Erciyes University, Kayseri, Turkey. In compliance with the tenets of the Declaration of Helsinki, all participants received oral and written information about the study and provided their written informed consent to participate before the study commenced.

Randomization was performed using a random number system. Each patient was randomly assigned to one type of implant, bifocal toric or trifocal toric. All patients were informed about which lens to implant before surgery. The 120 eyes of 60 enrolled patients were divided into 2 groups of 60 each according to lens implantation. The trifocal group received diffractive trifocal toric IOLs (PanOptix Toric, Alcon), whereas the bifocal group received diffractive bifocal toric IOLs (AcrySof ReSTOR SND1T, Novartis) (Fig. 1).

Figure 2 shows the trial profile and the reasons for exclusion. To participate in the study, patients had to be at least 50 years old, undergoing uncomplicated cataract surgery, have myopic astigmatism errors between -4.0 D and -7.50 D of spherical refraction and exceeding 1.0 D of cylindrical refraction, have ALs from 24.0 to 26.5 mm, and be interested in reducing their dependence on glasses in daily life. Other inclusion criteria were a desire for independence from spectacles after surgery, realistic expectations about availability, and a willingness to comply with examination programs. Excluded from the sample was all patients with irregular astigmatism, dense media opacities, any ocular disease other than cataract (e.g., glaucoma, keratitis, amblyopia, uveitis, or retinal disease), pathological myopia, zonular weakness or capsular abnormalities that might cause postoperative decentration or a tilt of the lens (e.g., pupillary synechia, pseudoexfoliation syndrome, Marfan syndrome, or chronic uveitis), or any history of ocular trauma or ocular surgery, including laser procedures.

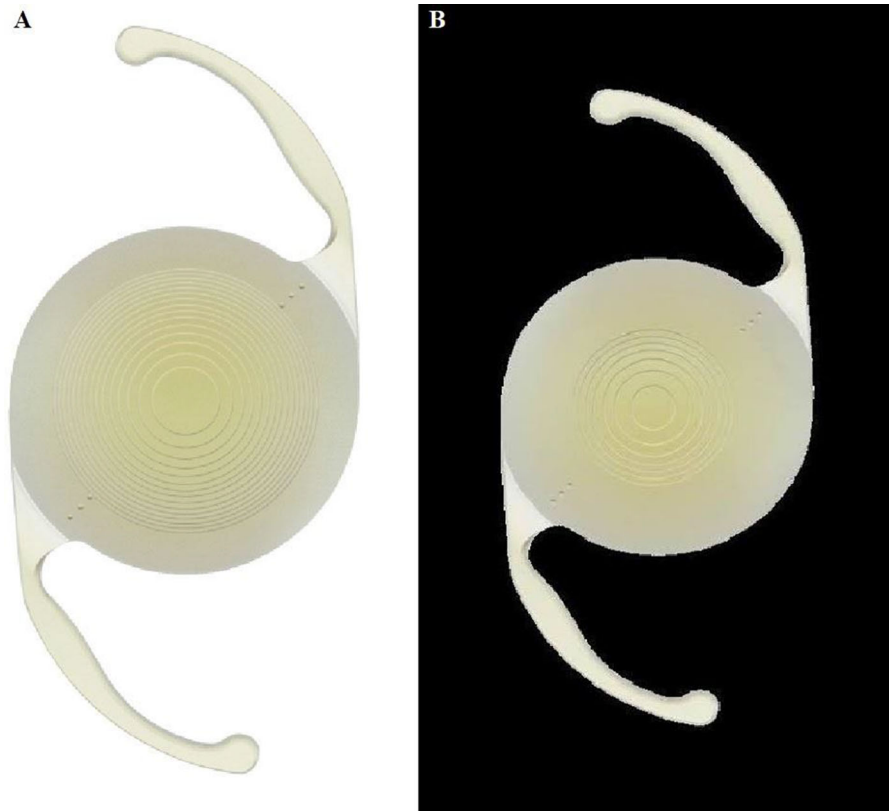


Fig. 1 **a** Diffractive trifocal toric intraocular lens (PanOptix Toric), **b** diffractive bifocal toric intraocular lens (AcrySof ReSTOR SND1T)

Preoperative evaluation

Each participant received a comprehensive ophthalmic evaluation involving a refraction assessment, slit-lamp biomicroscopy, the measurement of intraocular pressure with Goldmann applanation tonometry, dilated fundus examination, corneal topography imaging, and a test for best-corrected and uncorrected VA at far (4 m), intermediate (63 cm), and near distances (40 cm). VA was measured under photopic conditions (85 cd/m^2) at 4.0 m (Early Treatment Diabetic Retinopathy Study charts), 63 cm (Colenbrander, Precision Vision), and 40 cm (Radner Vissum, NeuMed AG, AT, Precision Vision). Corneal topography was performed using a Pentacam rotating Scheimpflug camera (Pentacam HR, Oculus Optikgeräte GmbH), while AL was measured with the IOL Master 500 (Carl Zeiss Meditec Inc).

The power of the IOLs to be implanted was calculated using the manufacturer-provided “A”

constant with a Barrett Toric Calculator (<http://ascrs.org/barrett-toric-calculator>). Measured with the IOL Master 500, keratometric values were used to calculate target refraction considering the surgically induced astigmatism. In all cases, the set target aimed for the minimum residual myopia.

Prior to surgery, patients were seated at a slit-lamp biomicroscope; both eyes were aligned properly to avoid head-tilt errors and then a narrow microscope slit was oriented vertically and horizontally. A sterile ink pen was used to place 2 additional limbal marks denoting the plus axis of astigmatism. Following this, patients were taken directly to the operation room.

Multifocal toric intraocular lenses

The AcrySof IQ Panoptix trifocal toric IOL used is an aspheric, hydrophobic, non-apodized acrylic IOL with an overall diameter of 13.0 mm, an optic body diameter of 6.00 mm, 0-degree haptic angulation,

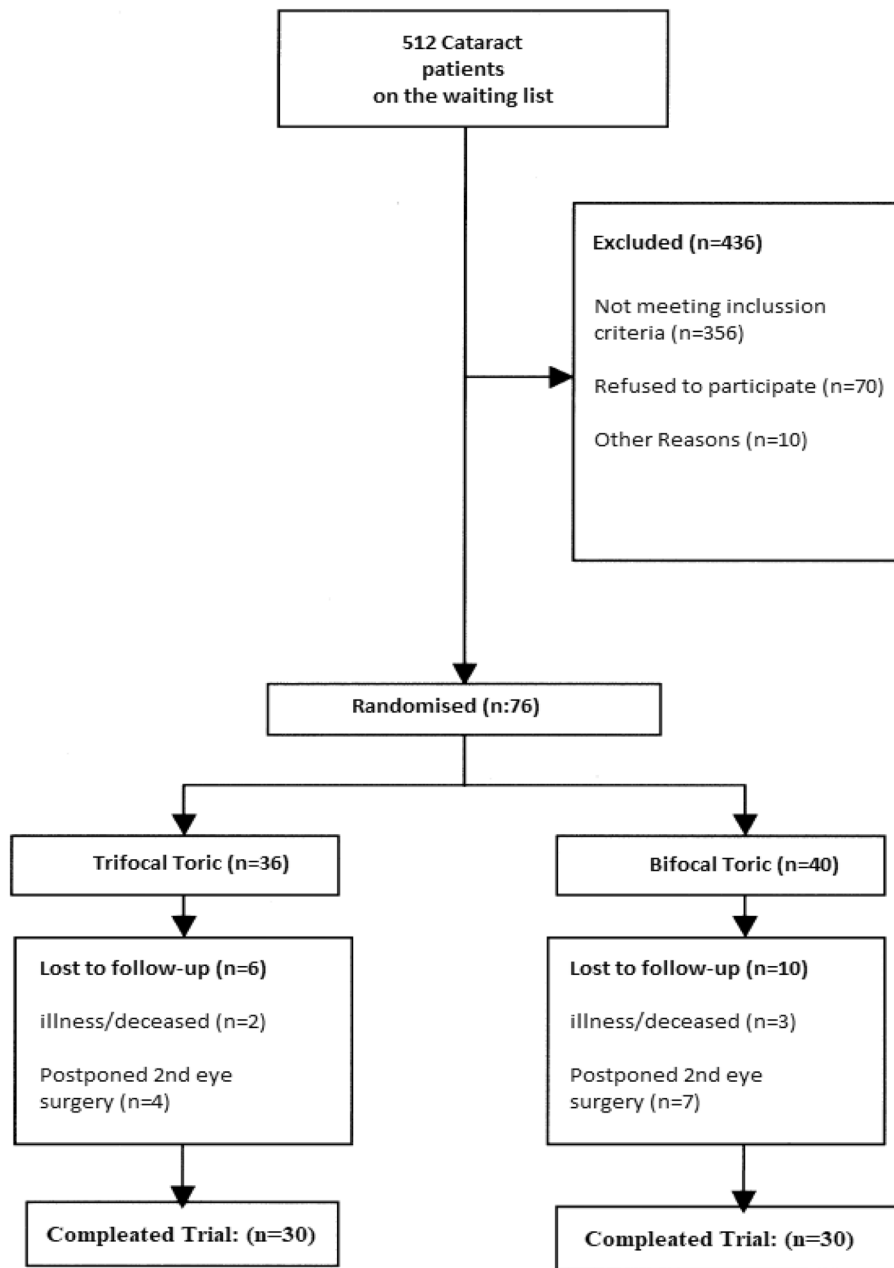


Fig. 2 The trial profile and the reasons for exclusion

and a central trifocal zone of 4.5 mm (15 diffractive zones). For a pupil with a diameter of 3 mm, the IOL transmits 88% of incident light with an asymmetric distribution of 50% to the distance focus and 25% to the near and intermediate foci. The lens also provide an addition of + 3.25 D for near vision and + 2.17 D for intermediate vision at the IOL plane. Optimal close reading distances are provided at 60 and 42 cm.

Although the AcrySof ReSTOR SND1T IOL has a similar design and material as the trifocal toric IOL, they differ in that the bifocal, apodized IOL provides an addition of + 3.00 D for near vision.

Surgical technique

All patients were operated upon by the same experienced surgeon (A.T.). Preoperatively, with each patient in a supine position, three limbal reference marks were made at the positions of 3, 6, and 9 o'clock. After topical anesthesia with proparacaine hydrochloride 0.5% was administered, the eye was prepared and draped, and a lid speculum was placed. With the surgeon positioned superiorly, a femtosecond laser (LenSx, Alcon) was used to create the capsulorhexis and provides phacofragmentation. A 1.5-mm side incision was made at the 2 o'clock position, after which sodium hyaluronate 3.0% and chondroitin sulfate 4.0% (Viscoat, Alcon Surgical) were applied to reform and stabilize the anterior chamber and to protect the corneal endothelium. Corneal incisions were made manually using a 2.2-mm, 45-degree, bevel-up surgical knife at 90 degrees (superior) in both eyes and approximately 1.00 mm anterior to the limbus. Central capsulotomy was performed using forceps. After nuclear cortical hydro-dissection, phacoemulsification was performed in the capsular bag using the Alcon Infiniti System (Alcon). Residual cortical material was cleared with irrigation and aspiration, after which the IOL was inserted into the capsular bag and rotated into the final position by aligning the corneal axis marks with the reference marks on the IOL. Sodium hyaluronate 1% (Provisc, Alcon) was used for intraocular insertion. The ophthalmic viscoelastic device was removed from the anterior chamber and the capsular bag using an irrigation and aspiration unit. The IOL position was checked and balanced salt solution was instilled in the anterior chamber. The corneal incision was closed by hydration. Postoperatively, patients were prescribed moxifloxacin 0.5% ophthalmic solution (Vigamox, Alcon Laboratories) and 0.1% dexamethasone ophthalmic solution (Maxidex, Alcon Laboratories).

Postoperative evaluation

Each patient was examined at 1, 7, 30, 90, 180, and 360 d postoperatively by the surgeon who performed the surgical procedure. Baseline, 1-, 3-, 6-, and 12-month data were analyzed. Uncorrected distance VAs (UDVA) and corrected distance VAs (CDVA), along with uncorrected and distance-corrected intermediate and near VAs, were measured monocularly

and binocularly at each visit. The defocus test was also performed with each participant, with a -4.0-D spherical correction from the best distance correction. Negative spherical power was decreased in 0.5-D increments, and VA was recorded for each defocus step until only the manifest refraction remained. After that, patients were defocused with + 2.0-D spherical correction from the best distance correction, and positive spherical power was decreased in 0.5-D increments, with logarithm of the minimum angle of resolution (logMAR) acuity recorded at each change in correction until only the manifest refraction remained.

Vision quality was evaluated with the Turkish version of the National Eye Institute Visual Function Questionnaire (NEI-VFQ)-25, which has demonstrated validity and reliability in measuring vision-related quality (Cronbach's alpha = 0.97) at 12-month postoperatively [16]. All questionnaires were filled by same interviewer. The NEI-VFQ-25 considers 11 different aspects of visual function and has been proposed for use to evaluate the efficacy of treatment for different ocular conditions [17]. It consists of 12 subscales, with varying numbers of questions: General Health (1 question), General Vision (1 question), Near Vision (3 questions), Distance Vision (3 questions), Driving (2 questions), Peripheral Vision (1 question), Color Vision (1 question), Ocular Pain (2 questions), Role Limitations (2 questions), Dependency (3 questions), Social Function (2 questions), and Mental Health (4 questions). The answers to each question on the NEI-VFQ-25 were converted to a 100-point scale, in which 100 represents the best possible score and 0 represents the worst. The subscales of General Vision, Near Vision, Distance Vision, Driving, Peripheral Vision, and Color Vision were included in the analysis.

Statistical analyses

All statistical analyses were performed using the Statistical Package for the Social Sciences (version 25.0 for Windows, SPSS). The normality distribution of each continuous variable was calculated with the Kolmogorov–Smirnov *Z* test, and variables were reported as *n* (%) or $M \pm SD$ as appropriate. Categorical parameters between the groups were compared using a chi-squared test, and an independent samples *t*-test was performed to compare variables between

groups for normally distributed data. VA and defocus curve graphs were drawn using Statistica 10.0 (StatSoft). Values of $P < 0.05$ were considered to indicate statistical significance.

Results

Table 1 summarizes the demographic and baseline clinical characteristics of the participants, including the 60 eyes of 30 patients with trifocal toric IOLs (i.e., trifocal group) and the 60 eyes of 30 patients with bifocal toric IOLs (i.e., bifocal group). By mean age, patients in the trifocal group—19 males and 11 females—were 68.21 ± 6.8 years old, whereas patients in the bifocal group—17 males and 13 females—were 70.32 ± 6.5 years old. The mean age and sex distribution between the groups did not differ significantly ($P = 0.635$ and $P = 0.952$, respectively). All patients were examined at all scheduled times. No eyes were excluded from analysis due to intraoperative or postoperative complications. No postoperative IOL rotation was detected in any eyes, and no IOL required repositioning.

Visual acuity and refraction

No significant between-group differences emerged in the preoperative values of UDVA, CDVA, spherical refraction, cylindrical refraction, average keratometry, mean AL, or IOL power (Table 1).

Postoperative VA values are presented in Table 2 and Fig. 3. In terms of mean uncorrected distance intermediate VA (UDIVA) and corrected distance intermediate VA (CDIVA), the trifocal group showed

significantly better VA in postoperative measurements at 1, 3, 6, and 12 months than the bifocal group. The distributions of UDVA, CDVA, uncorrected distance near VA (UDNVA), and corrected distance near VA (CDNVA) were similar between the groups.

As Table 3 shows, no statistically significant difference appeared in postoperative spherical values between the groups at 1, 3, 6, and 12 months postoperatively. Likewise, cylindrical values were similar between the groups at 12-month follow-up (Table 3).

Patient satisfaction

Figure 4 presents the distributions of the General Vision, Distance Vision, Near Vision, and Driving subscale scores from the NEI-VFQ-25 in both groups. Driving scores were significantly better in the trifocal group (94.78 ± 6.20) than in the bifocal group (80.25 ± 10.86 , $P < 0.001$). However, no statistically significant differences between the groups surfaced for scores on the General Vision, Distance Vision, and Near Vision subscales ($P = 0.379$, $P = 0.669$, and $P = 0.407$, respectively).

Binocular defocus curve

Figure 5 presents the uncorrected binocular defocus curves in the two groups. As expected, UDVA peaked at the 0.0-D level in both groups but was significantly higher in the trifocal group than in the bifocal group at test distances of -1.5 D, that is, corresponding to a reading distance of approximately 67 cm. Other results concerning defocus curve were not significantly different at other test distances.

Table 1 Demographic and clinical characteristics of participants

	Trifocal group ($n = 60$)	Bifocal group ($n = 60$)	p values
Age, years	68.21 ± 6.8	70.32 ± 6.5	0.635 [†]
Male/female	19/11	17/13	0.951 [*]
Spherical refraction, D	$- 6.50 \pm 2.55$	$- 6.25 \pm 2.80$	0.725 [†]
Cylindrical refraction, D	2.21 ± 1.24	1.87 ± 0.82	0.612 [†]
Average keratometry, D	43.45 ± 1.42	43.39 ± 1.51	0.824 [†]
Preoperative, logMAR	0.88 ± 0.35	0.90 ± 0.40	0.756 [†]
UDVA	0.49 ± 0.18	0.53 ± 0.21	0.625 [†]
CDVA			
Axial length, mm	25.82 ± 1.45	25.68 ± 1.56	0.732 [†]
IOL power	$+ 12.75 \pm 1.50$	$+ 13.50 \pm 1.75$	0.518 [†]

Values are expressed as n or mean \pm standard deviation.

^{*}Chi-Square test, [†]

Independent sample t-test

Table 2 Mean visual acuity outcomes in the follow-up period

Visual acuity, logMAR	1st month	3rd month	6th month	12th month
UDVA				
Trifocal group	0.15 ± 0.04	0.11 ± 0.03	0.09 ± 0.04	0.08 ± 0.02
Bifocal group	0.17 ± 0.05	0.12 ± 0.04	0.10 ± 0.03	0.07 ± 0.04
p values*	0.481	0.526	0.572	0.637
CDVA				
Trifocal group	0.06 ± 0.17	0.04 ± 0.15	0.02 ± 0.13	0.01 ± 0.16
Bifocal group	0.08 ± 0.14	0.06 ± 0.13	0.04 ± 0.11	0.02 ± 0.15
p values*	0.541	0.426	0.373	0.612
UDIVA				
Trifocal group	0.16 ± 0.09	0.13 ± 0.08	0.11 ± 0.05	0.07 ± 0.03
Bifocal group	0.25 ± 0.12	0.22 ± 0.10	0.21 ± 0.08	0.19 ± 0.08
p values*	0.005	0.003	0.001	< 0.001
CDIVA				
Trifocal group	0.15 ± 0.08	0.12 ± 0.09	0.10 ± 0.07	0.07 ± 0.02
Bifocal group	0.23 ± 0.13	0.21 ± 0.09	0.20 ± 0.10	0.18 ± 0.07
p values*	0.006	0.004	0.002	0.001
UDNVA				
Trifocal group	0.17 ± 0.08	0.14 ± 0.06	0.12 ± 0.06	0.09 ± 0.04
Bifocal group	0.18 ± 0.06	0.16 ± 0.07	0.15 ± 0.06	0.13 ± 0.05
p values*	0.652	0.315	0.232	0.068
CDNVA				
Trifocal group	0.14 ± 0.07	0.13 ± 0.05	0.11 ± 0.08	0.08 ± 0.05
Bifocal group	0.14 ± 0.08	0.12 ± 0.06	0.12 ± 0.07	0.09 ± 0.08
p values*	0.788	0.674	0.643	0.436

UDVA; uncorrected distance visual acuity, CDVA; corrected distance visual acuity. UDIVA; uncorrected distance intermediate visual acuity, CDIVA; corrected distance intermediate visual acuity, UDNVA; uncorrected distance near visual acuity, CDNVA; corrected distance near visual acuity. Values are expressed as mean ± standard deviation. * Independent sample test

Discussion

In our study, statistically significant differences in postoperative UDIVA and CDIVA at 1, 3, 6, and 12 months were detected between eyes implanted with trifocal toric IOLs and bifocal toric IOLs, whereas values for UDVA, CDVA, UDNVA, and CDNVA were similar between the groups.

Allowing wearers to focus on multiple object distances with various parts of the lens, multifocal toric IOLs are a good option for correcting distance and near vision as well as corneal astigmatism during cataract surgery. Recently, as bifocal and trifocal IOLs have been increasingly used multifocal IOLs in clinic practice, studies evaluating their visual performance and patients' satisfaction with bifocal and trifocal IOLs have become available [18–21]. However, in patients with moderate to high myopia, outcomes of implanting trifocal and bifocal toric IOLs have not been compared. Our study, with results from a

12-month period, thus marks the first of its kind in the literature.

In previous studies, researchers have shown that implanted trifocal IOLs afford good distance, intermediate, and near VA [22–25]. Among them, Mojzis et al. demonstrated that patients with trifocal IOLs have better intermediate VAs than patients with bifocal IOLs [26]. Added to that, Vilar et al. compared visual outcomes of patients who were bilaterally implanted with diffractive trifocal IOLs or who received a blended implantation of two different near added-power bifocal IOLs in each eye and reported that the trifocal group experienced significantly better performance at intermediate distances [12]. Moreover, Gundersen et al., who investigated the refractive and visual outcomes in patients with bilaterally implanted diffractive trifocal toric IOLs or apodized diffractive bifocal toric IOLs 3 months after implantation, found that the trifocal toric IOLs improved their intermediate vision without negatively affecting visual function or

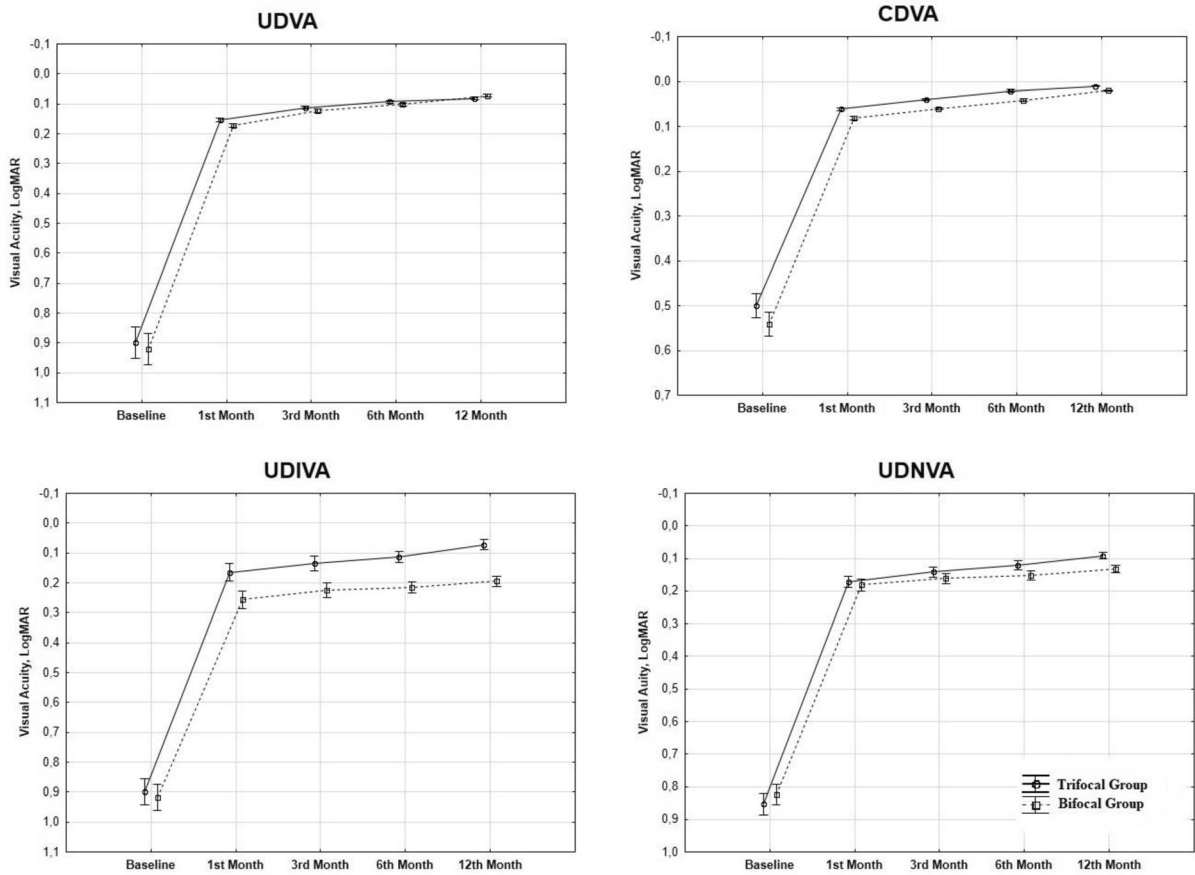


Fig. 3 Mean visual acuity measurements in the preoperative and postoperative periods UDVA; uncorrected distance visual acuity, CDVA; corrected distance visual acuity. UDIVA;

uncorrected distance intermediate visual acuity, UDNVA; uncorrected distance near visual acuity

Table 3 Refractive outcomes in the follow-up period

Refraction, D	Baseline	1st month	3rd month	6th month	12th month
Spherical refraction					
Trifocal group	- 6.50 ± 2.55	- 0.18 ± 0.41	- 0.10 ± 0.45	- 0.07 ± 0.30	- 0.05 ± 0.25
Bifocal group	- 6.25 ± 2.80	- 0.16 ± 0.32	- 0.11 ± 0.40	- 0.08 ± 0.38	- 0.07 ± 0.34
p values*	0.576	0.833	0.880	0.932	0.795
Cylindrical refraction					
Trifocal group	2.21 ± 1.24	0.56 ± 0.26	0.45 ± 0.32	0.40 ± 0.30	0.38 ± 0.24
Bifocal group	1.87 ± 0.82	0.54 ± 0.30	0.43 ± 0.24	0.39 ± 0.43	0.35 ± 0.32
p values*	0.081	0.719	0.675	0.809	0.599

Values are expressed as mean ± standard deviation. *Independent sample test

distance, near, or low-contrast VA compared to bifocal toric IOLs [27]. Unlike other studies, however,

our study involved comparing visual and refractive outcomes after the implantation of trifocal or bifocal

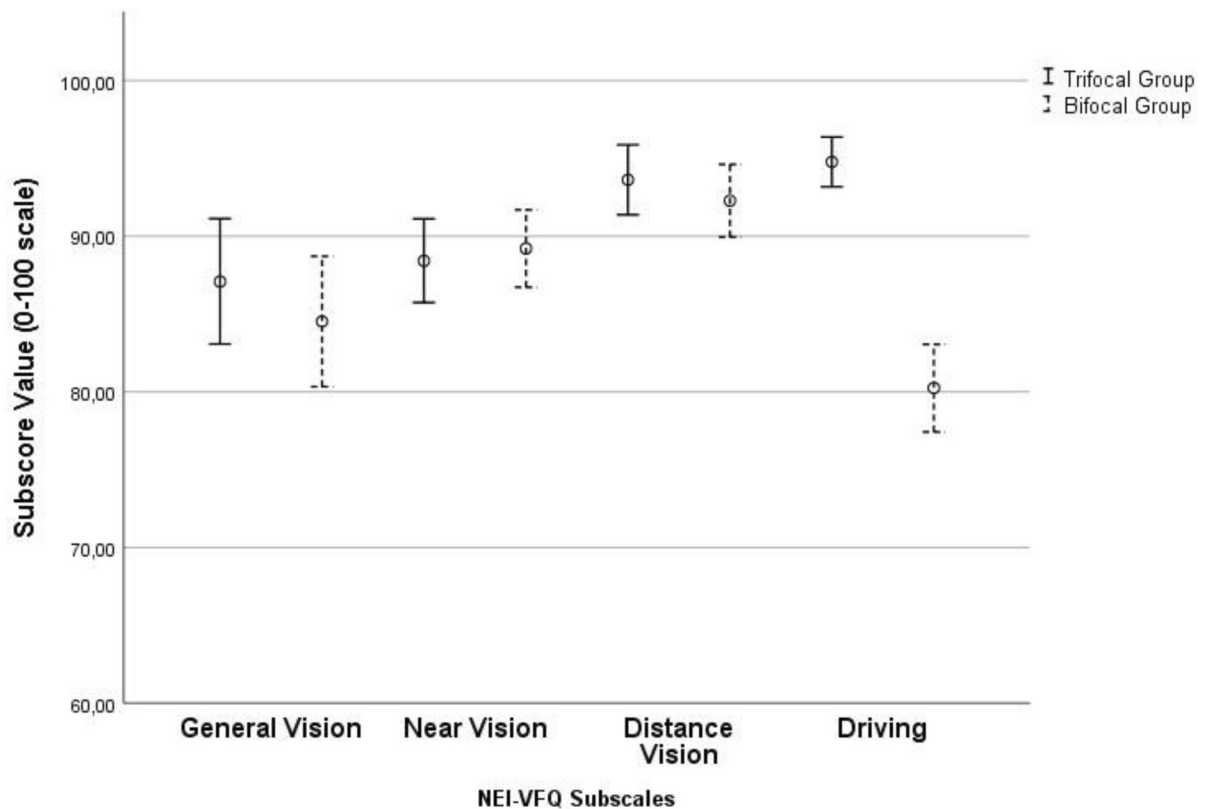


Fig. 4 National Eye Institute Visual Function Questionnaire (NEI-VFQ)-25 subscale scores

toric IOLs in patients with moderate to high myopia and ALs exceeding 25 mm. The additional intermediate focal point in the trifocal toric IOLs was not observed to adversely affect distance or near vision. Moreover, intermediate VA was significantly better in eyes with trifocal toric IOLs than in ones with bifocal toric IOLs at 1, 3, 6, and 12 months after surgery.

The defocus curves obtained for the trifocal and bifocal toric IOLs evaluated indicate that VA was significantly higher at -1.5 D in moderate to high myopic eyes with trifocal than with bifocal toric IOLs. To be clear, the level of -1.5 D corresponds to intermediate vision, that is, vision of a target 67 cm away. Gatinel et al., who compared bifocal and trifocal IOLs, observed that trifocal IOLs showed a true third intermediate focal point that was not observed with bifocal IOLs [28]. In previous studies, defocus curves have shown similar patterns in both bifocal and trifocal toric IOLs, and clinical research evaluating bifocal toric IOLs and the multifocal component of trifocal toric IOLs has reported similar defocus curves to the ones observed in our study [29, 30]. However,

even though both IOLs have similar patterns, defocus curves in our study support the conclusion that trifocal toric IOLs provide better intermediate VA than bifocal toric IOLs.

Evaluating subjective perceptions of visual ability has been recognized as an important part of studies on multifocal IOLs. In our study, the NEI-VFQ-25 was used to assess the satisfaction of participants with bifocal or trifocal toric IOLs. Although all participants reported similar subscale scores for General Vision, Near Vision, and Distance Vision, driving values were significantly better in the trifocal than in the bifocal group. This result indicates that patients with trifocal toric IOLs have better overall subjective comfort than ones with bifocal toric IOLs. Clinically, trifocal toric IOLs are associated with less photic phenomena because more light is focused and less light is lost, and glare and blare are less common. Therefore, the driving score may have been found better in patients with trifocal lenses.

Although potential sources of error were minimized in the study, one limitation merits attention: contrast

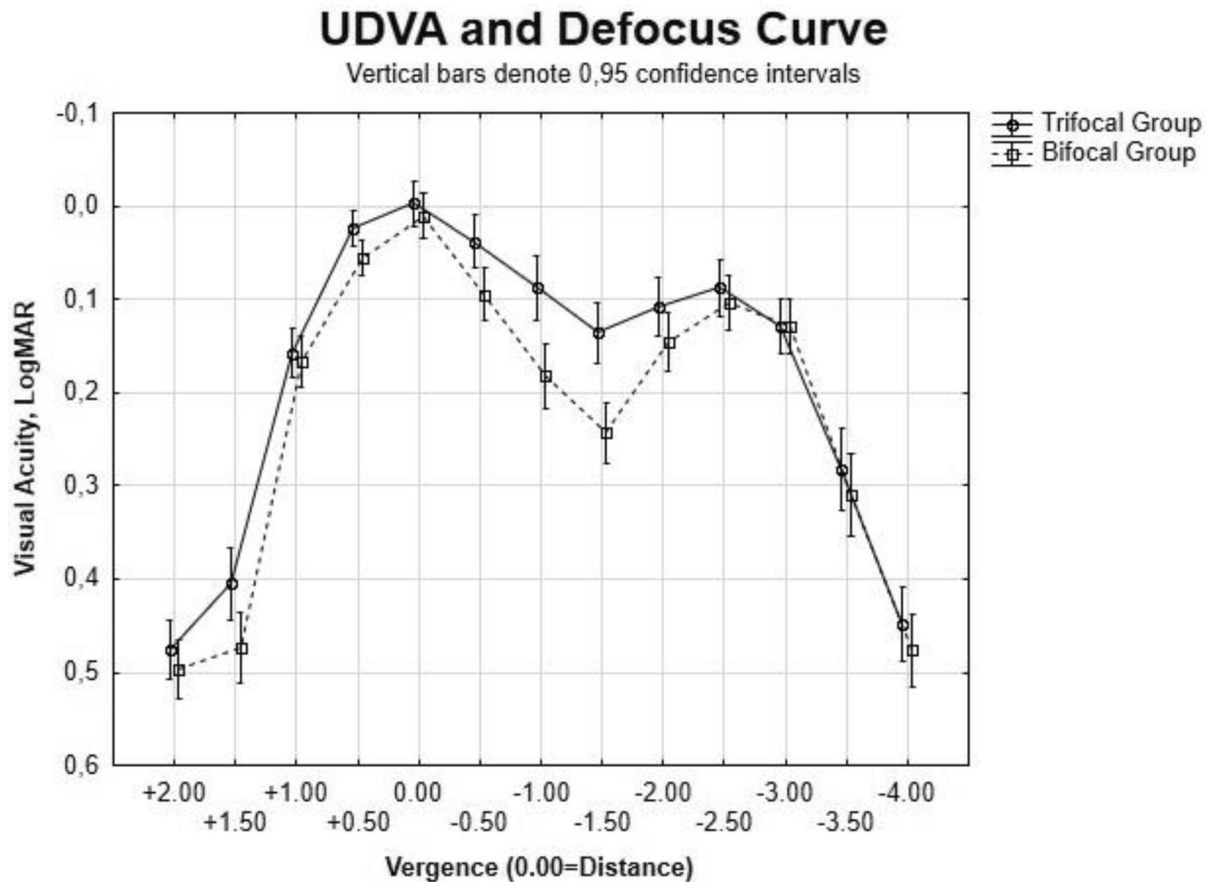


Fig. 5 Defocus curve of uncorrected distance visual acuity (UDVA)

sensitivity could not be assessed in patients during the postoperative period. Therefore, visual quality between the groups could not be objectively compared.

In sum, both trifocal and bifocal toric IOLs effectively corrected the near, intermediate, and distance vision in patients with moderate to high myopia and astigmatism. However, intermediate vision was significantly better in eyes with trifocal than bifocal IOLs. Further comparative studies with longer follow-up periods are thus needed to evaluate visual outcomes and objective visual quality in patients with moderate to high myopia.

Author's contribution A.T. and M.G. contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript.

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Code availability Non-digital data supporting this study are stored by the corresponding author at the Lazer Eye Hospital.

Declarations

Conflicts of interests The authors have no relevant financial or non-financial interests to disclose.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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