



Evaluation of Vision-Related Quality of Life After Unilateral Implantation of a New Trifocal Intraocular Lens

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Abstract

Objectives: The objective of the study was to evaluate visual performance and subjective quality of life after unilateral implantation of a new trifocal intraocular lens (IOL) in young and middle-aged patients.

Methods: Patients that underwent unilateral cataract surgery with implantation of trifocal TFNT00 IOL with an emmetropic fellow eye were included in the study. Vision related daily activity performance was evaluated in postoperative 6th month. Patients were divided in two groups according to the uncorrected near visual acuity of their fellow eyes: In Group I if worse than the operated eye and in Group II if equal or better than the operated eye. The visual function-14 (VF-14) questionnaire was used with scores of 4 with no difficulty, 3 points with mild difficulty, 2 points with moderate difficulty, 1 point with severe difficulty, and 0 point if unable to perform.

Results: Twenty-one patients were enrolled in this study. Patients had good visual performance, showing VF-14 scores above 3 in all categories. Reading small print (3.67 ± 0.48) and driving at night (3.67 ± 0.48) were found to be the most difficult tasks to perform. No significant difference was found between two groups in any category that was investigated by the VF-14 questionnaire.

Conclusion: Unilateral implantation of TFNT00 trifocal IOL is well tolerated with good patient satisfaction assessed by VF-14 questionnaire in subjects that have cataract in one eye, encouraging single-eye surgical procedure in this particular group of patients.

Keywords: Trifocal intraocular lens, unilateral cataract, vision-related quality of life

Introduction

Cataract is the leading cause of preventable blindness in the world (1). Cataract surgery is becoming a refractive correction procedure with the development of intraocular lens (IOL) technologies (2). Of these, monofocal IOLs are known to provide clear vision over one selected focal point (3). With the advent of multifocal IOLs in late 80's, post-operative achievement of satisfying uncorrected distant and near

visual acuities (UDVA and UNVA) has significantly decreased the dependency to spectacle correction (4). Although diffractive bifocal IOLs provide effective distant and near vision due to the concentric rings that are responsible for diffraction, problems regarding visual performance for intermediate distance (computer screen and front panel of the car while driving) are reported (5). With newly developed trifocal IOLs, good quality for both distant, intermediate, and near vision is reported by several case series (6,7).

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Trifocal TFNT00 IOL (Acrysof IQ PanOptix™, Alcon Laboratories, Fort Worth, TX, USA) is a single bodied, hydrophobic acrylic lens including a blue light filter and a diffractive optical profile. Being the first IOL with a quadrifocal optics, it provides a trifocal IOL performance in practice (8). TFNT00 IOL has three available dioptrical powers for near, intermediate and distant vision. With its inherent ENLIGHTEN (Enhanced Light Energy) technology, it redirects the light usage on the 1st order intermediate focal point in 120 cm for distant vision, while providing efficient intermediate (60 cm) +2,17 D and near (40 cm) +3,25 D powers. With its 4.5 mm diameter diffractive plate, it reduces dependency to pupil size and illuminating conditions (9).

The majority of TFNT00 related studies are consisted of cases with bilateral IOL implantation (10-12). There is no consensus to choose monocular or binocular surgery in cases that suffer from unilateral cataract with fellow non-cataractous eye. The main aim of our study is the evaluation of visual performance and subjective quality of life in monocular TFNT00 implanted young and middle-aged patients.

Methods

This prospective study was performed in Göznuru Eye Clinic in Gaziantep, Türkiye. The study followed the tenets of Declaration of Helsinki and was approved by Institutional Review Board of Gaziantep SANKO University (number: 2020/20-01). Informed consent was obtained from all participants.

Patients that underwent monocular cataract surgery with phacoemulsification and TFNT00 IOL implantation between January 2016 and November 2019 were included in the study. All patients had nuclear and/or posterior subcapsular cataract in their operated eye. Patients with corneal astigmatism higher than or equal to 0.75 D (Sirius 3D, CSO, Italy), congenital and/or traumatic cataract, macular degeneration, diabetic retinopathy, glaucoma, retinal detachment, ocular inflammation, and history of ocular surgery were excluded from the study. Due to inability to acquire adequate refractometry measurements in the majority of cataractous eyes, no pre-operative corrected distant visual acuity was performed in operated eyes.

The post-operative UDVA from 4 m and UNVA from 40 cm were measured with Snellen charts. The uncorrected intermediate visual acuity (UIVA) from 60 cm was measured with Jaeger reading charts. Biomicroscopic and fundoscopic examinations were performed. IOL power calculation was performed with optical biometry (AL-Scan, Nidek, Japan).

All surgeries were performed by the same experienced ophthalmic surgeon (CO). Main corneal incision was made with a 2.75 mm blade through the steep meridian. A 5.5 mm anterior capsular opening was created with continuous curvilinear capsulorrhexis. Following phacoemulsification

procedure (Whitestar Signature phocoemulsification system, Abbott Medical Optics, Inc.), the PanOptix® diffractive multifocal IOL (Alcon Laboratories, Fort Worth, TX) was implanted into the capsular bag. Moxifloxacin 0.5% and dexamethasone 0.1% eye drops were used 5 times per day following the surgery with tapering the doses for 3 weeks postoperatively. Pre-operative ocular examination and ancillary test procedures were repeated in post-operative follow-up visits in first, 3rd and 6th months. Patients were divided in two groups based on their near visual acuity: Group I included patients whose fellow eye had worse near visual acuity than the operated eye, and Group II included patients whose fellow eye had equal or better near visual acuity than the operated eye, therefore Group I is consisted of presbyopic patients with UNVA and UIVA scores higher than 0.10 logMAR and Group II is consisted of pre-presbyopic patients with UNVA and UIVA scores equal to 0.00 logMAR in their fellow eyes. Any presence of IOL decentralization and formation of posterior capsule opacity was noted during the post-operative follow-up.

A Turkish language version of visual function-I4 (VF-I4) questionnaire was administered to all subjects for assessment of post-operative visual performance. Subjects were instructed to 14 questions that the responses were graded between 0 and 4 points. Total maximum score available was 56. The responses were evaluated with 4 points if daily activities were performed with no difficulty, 3 points with mild difficulty, 2 points with moderate difficulty, 1 point with severe difficulty, and 0 point if unable to perform. No response was given for the activities which the subject was unable to perform due to any impairment that was unrelated to VF (i.e., orthopedic disability to climb stairs, and driving). The need for spectacle correction and the recommendation of surgery by the subjects to their entourage in 6th month were noted.

Statistical analysis was performed with SPSS 22.0 (SPSS Inc., Chicago, IL, USA). Normal distribution of values was tested with Shapiro-Wilk's test. Mean and standard deviations, min-max values were given as descriptive statistics. Mann-Whitney U test was performed for independent groups, Wilcoxon Signed-Rank test was used for dependent groups comparison. Fisher's exact test was performed for categorical variables. $P < 0.05$ was considered statistically significant.

Results

A total of 21 patients (7 females) were enrolled in the study (Group I/II = 12/9). Mean age was 45.1 ± 12.4 years (range: 24-67), with Group I patients (52.9 ± 8.0 ; range: 42-67) significantly older than Group II patients (34.8 ± 9.2 , range: 24-50) ($p < 0.001$). Follow-up time was 6 months

for all subjects. Clinical characteristics of the patients for each group are given in Table 1. Anterior chamber depth was found smaller in Group I ($p=0.036$). The post-operative UDVA of operated and fellow eyes was statistically similar (0.04 ± 0.05 and 0.08 ± 0.08 logMAR, respectively, $p=0.118$). The operated eyes had significantly better 40 cm UNVA and 60 cm UIVA when compared with the fellow eyes ($p=0.025$ and $p=0.017$, respectively). Visual acuity outcomes of Groups I and II are given in Table 2. The UDVA, UNVA, and UIVA differences between post-operative and fellow eyes in Group I were found significant ($p=0.026$, 0.003 , and 0.003 respectively), while Group II patients have shown significant difference for their UNVA and UIVA results ($p=0.008$ and 0.014 , respectively).

The results of VF-14 questionnaire are given in Table 3. All cases had high visual performance scores for reading small print (3.67 ± 0.48), reading a newspaper or a book (3.81 ± 0.40), reading a large-print book or numbers on a tele-

phone (3.95 ± 0.22), recognizing nearby people (3.95 ± 0.22), seeing steps, stairs or curbs (3.95 ± 0.22), reading traffic signs, Street signs or store signs (3.95 ± 0.22), doing fine handwork (3.95 ± 0.22), writing checks or filling out forms (3.90 ± 0.30), playing games (3.95 ± 0.22), taking part in sports (3.95 ± 0.22), cooking (3.95 ± 0.22), watching television (3.81 ± 0.40), driving during the day (3.90 ± 0.30), and at night (3.67 ± 0.48). Patients in Group I who had worse near and intermediate vision in their fellow eye had no significantly worse visual performance score when compared with patients in Group II (all $p>0.05$).

Discussion

The use of trifocal IOLs that provide intermediate vision next to distant and near correction has an increasing trend with satisfactory results approved by numerous studies in terms of both refractive outcomes and daily visual performance of the patients (7,13-15). Of these multifocal lenses, TFNT00 IOL has a good distance (infinity) and 80 cm, 60 cm, and 40

Table 1. Clinical characteristics of the patients

Parameters	Group I (n=12)		Fellow eye (n=9)		p
	Mean±SD	Range	Mean±SD	Range	
Age	52.9±8.0	(42, 67)	34.8±9.2	(24, 50)	<0.001
Gender (female:male)	3:9	–	4:5	–	0.397
Axial length	23.53±0.85	(22.57, 25.24)	23.81±0.90	(22.27, 25.01)	0.477
Anterior chamber depth	3.33±0.38	(2.67, 3.82)	3.76±0.26	(3.38, 4.10)	0.036
Flattest keratometry (D)	43.12±1.28	(40.96, 45.42)	42.71±1.84	(39.00, 45.86)	0.499
Steepest keratometry (D)	43.65±1.26	(41.46, 45.92)	43.45±1.80	(39.75, 46.42)	0.776

D: Diopter, logMAR: Logarithm of minimal angle.

Table 2. Comparison of visual acuity outcomes between Group I and Group II patients

Parameters	Group I (n=12)		Group II (n=9)		p
	Mean±SD	Range	Mean±SD	Range	
Preoperative UDVA (logMAR)	0.73±0.31	(0.30, 1.20)	0.67±0.35	(0.20, 1.00)	0.660
Preoperative BCDVA (logMAR)	0.68±0.28	(0.30, 1.00)	0.57±0.31	(0.20, 1.00)	0.386
Postoperative UDVA (logMAR)	0.04±0.05	(0.00, 0.10)	0.04±0.05	(0.00, 0.10)	0.901
Postoperative UNVA (logMAR)	0.00±0.00	(0.00, 0.00)	0.08±0.04	(0.00, 0.10)	<0.001
Postoperative UIVA (logMAR)	0.01±0.03	(0.00, 0.10)	0.07±0.05	(0.00, 0.10)	0.006
Fellow BCDVA (logMAR)	0.13±0.08	(0.00, 0.20)	0.01±0.03	(0.00, 0.10)	0.001
Fellow UNVA (logMAR)	0.20±0.10	(0.00, 0.30)	0.00±0.00	0.00	<0.001
Fellow UIVA (logMAR)	0.19±0.07	(0.10, 0.30)	0.00±0.00	0.00	<0.001
Postoperative spherical equivalent (D)	-0.10±0.29	(-0.50, 0.38)	-0.28±0.16	(-0.50, 0.00)	0.134

logMAR: Logarithm of minimal angle of resolution, UDVA: Uncorrected distant visual acuity, UNVA: Best corrected near visual acuity, UIVA: Best corrected intermediate visual acuity, BCDVA: Best corrected distant visual acuity, D: Diopter.

Table 3. Mean values of VF-14 questionnaire categories in patients with unilateral cataract surgery. Group I subjects had fellow eye UNVA worse than the operated eye and Group II subjects had fellow eye UNVA equal or better than the operated eye

VF-14 categories	All cases	Group I (n=13)	Group II (n=8)	p ^a
Reading small print, such as medicine bottle labels, a telephone book, or food labels	3.67±0.48	3.67±0.49	3.67±0.50	1.000
Reading a newspaper or a book	3.81±0.40	3.83±0.44	3.78±0.44	0.754
Reading a large-print book or large-print newspaper or numbers on a telephone	3.95±0.22	4.00±0.00	3.89±0.33	0.248
Recognizing people when they are close to you	3.95±0.22	4.00±0.00	3.89±0.33	0.248
Seeing steps, stairs or curbs	3.95±0.22	4.00±0.00	3.89±0.33	0.248
Reading traffic signs, street signs or store signs	3.95±0.22	4.00±0.00	3.89±0.33	0.248
Doing fine handwork like sewing, knitting, crocheting, carpentry	3.95±0.22	4.00±0.00	3.89±0.33	0.248
Writing checks or filling out forms	3.90±0.30	4.00±0.00	3.78±0.44	0.094
Playing games such as bingo, dominos, card games, or mahjongb	3.95±0.22	4.00±0.00	3.89±0.33	0.248
Taking part in sports like bowling, handball, tennis, golfb	3.95±0.22	4.00±0.00	3.89±0.33	0.248
Cooking	3.95±0.22	4.00±0.00	3.89±0.33	0.248
Watching television	3.81±0.40	3.92±0.29	3.67±0.50	0.159
Driving during the day	3.90±0.30	4.00±0.00	3.78±0.44	0.094
Driving at night	3.67±0.48	3.75±0.46	3.56±0.53	0.361
Total score	54.38±3.04	55.17±1.03	53.33±4.42	0.232

^aMann-Whitney U test. ^bActivities were modified on the translated questionnaire according to the cultural differences. VF-14: National eye institute visual function-14 questionnaire. Grading scores: 4 points: No difficulty, 3 points: Mild difficulty, 2 points: Moderate difficulty, 1 point: Severe difficulty, 0 point: Unable to perform.

cm near performances in both 3.0 mm and 4.5 mm pupil sizes (16). The visual performance of multifocal IOLs had been usually investigated in cases with bilateral cataract surgery; (13,15,17-19) however, there are fewer studies which investigate visual outcomes in patients which underwent unilateral implantation of a multifocal IOL with either phakic or monofocal pseudophakic fellow eye (14,20-22) To the best of our knowledge, this is the first study that investigates the visual performance of TFNT00 multifocal IOL with monocular implantation to patients that have unilateral cataract.

In our study, patients with unilaterally implanted TFNT00 IOL have shown good visual performance which was quantified with VF-14 questionnaire. Patients had virtually no difficulty while performing any daily activity that was questioned. Even the most challenging two activities, reading small print and driving at night, had mean visual performance scores above 3 points, indicating little or no difficulty while performed by patients. It appears that the inter-eye differences in UIVA and UNVA scores did not have a clinical significance over the visual performance of the subjects. Another outcome of our study was that there was no difference in terms of near and distant vision related activities between Group I patients that present presbyopia in their fellow eye and Group II patients that still have their accommodative

ability intact, showing that unilateral implantation of multifocal TFNT00 IOL was well tolerated for each subject group. Therefore, our study presents encouraging results in terms of considering monocular multifocal IOL implantation for patients with unilateral cataract, regardless of the presbyopic status of their fellow eye.

The results of our study have shown similarities with the study held by Levinger et al.(14) which reported results of unilateral refractive lens exchange procedure with a multifocal IOL (FineVision Micro F IOL, PhysIOL SA, Liège, Belgium) in 26 emmetropic presbyopic patients with mean logMAR values of 0.18±0.32 for UDVA, 0.17±0.21 for UIVA, and 0.02±0.10 of UNVA and a high visual satisfaction rate among all participants. Similar studies held by Cionni et al.(23) and Mesci et al.(22) with different IOL types have shown that unilateral implantation of multifocal IOLs was well tolerated with good visual satisfaction that were comparable to bilateral IOL implantation. Cionni reported good vision-related daily activity performance in unilateral multifocal IOL (AcrySof ReSTOR SN60D3, Alcon Laboratories, Fort Worth, TX) implanted patients with a spectacle independence rate and contrast sensitivity that was statistically similar to those with bilateral implantation. However, they detected significant differences in favor of bilateral implantation while performing several in-

termediate/near tasks: “Performing fine handwork,” “writing checks or paying bills,” “reading small print,” and “reading a restaurant menu in dim light.” Another study held by Akman et al. compared the visual performance of subjects with bilateral cataract who underwent cataract surgery with TFNT00 IOL implantation that had an interval of at least 3 months between each surgery (10). Similarly evaluated with a VF-14 questionnaire, they have reported that patients had well tolerated the period with monocular IOL, while significant improvements were observed following the fellow eye surgery in “doing fine handwork like sewing” and “using a personal computer” only. The present study differs from the mentioned study held by Akman et al. on the point that the subjects had emmetropic fellow eyes without any presence of cataract, which could imply that patients that have cataract in one eye only could still maintain a better adaptation process to a unilateral multifocal IOL implantation without any need for a mandatory lens exchange procedure to the fellow emmetropic eye.

The main limitations of our study are its small sample size and the lack of a control group that includes either healthy subjects or patients that were underwent unilateral or bilateral monofocal IOL implantation. Future studies with larger number of subjects and control groups might allow more reliable results in assessment of the visual performance for trifocal IOLs that are unilaterally implanted in this particular group of patients.

Conclusion

Unilateral implantation of the TFNT00 multifocal IOL in patients with unilateral cataract could provide good distant, intermediate and near vision with good patient satisfaction and vision-related daily activity performance, regardless of the presbyopic status of the fellow eye. With the introduction of future studies, the approach for unilateral multifocal IOL implantation in patients that suffer from unilateral cataract could be further encouraged in clinical practice.

Disclosures

Ethics Committee Approval: Gaziantep SANKO University Institutional Review Board, 2020. Number: 2020/20-01.

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Conflict of Interest: None declared.

Authorship Contributions: Concept – C.O., A.S.; Design – C.O., C.K., A.S.; Supervision – C.O., A.S.; Resource – C.O.; Data collection and/or processing – C.O., C.K.; Analysis and/or interpretation – C.O., C.K., A.S.; Literature search – C.O., C.K.; Writing – C.K.; Critical review – C.O., A.S.

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