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Original Article

Refractive results, visual quality and patient satisfaction with a new trifocal intraocular lens design

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Abstract

Aim: To evaluate the outcomes after bilateral implantation of a new trifocal intraocular lens (IOL).

Materials and Methods: The study included patients with visually significant cataract that underwent bilateral implantation of the Acriva Trinova Sinusoidal Trifocal IOL. The preoperative corrected distance visual acuity (CDVA) and postoperative uncorrected distance visual acuity (UDVA), CDVA, uncorrected intermediate (UIVA) and near visual acuities (UNVA) along with manifest refractions were assessed at 1 month and 6 months after cataract surgery. The defocus curve and contrast sensitivity (CS) were evaluated at the 6th month visit. Patient satisfaction and incidence of dysphotopic symptoms were assessed.

Results: The study enrolled a total of 60 eyes of 30 patients, 10 males and 20 females aged 61.78± 8.73 years (range, 45 to 78 years). 90% of the patients (n: 27) achieved a binocular UIVA of 0.1 LogMAR or better at the 6-month visit while, 96.7% (n:29) patients had a binocular UNVA of 0.1 LogMAR or better in the same postoperative visit. The CS results were within the the range of normality at 6 months post-surgery. 6.7% of patients reported marked halo around light sources and 3.3% reported glare that interferes with nighttime driving. 96.6% of the patients reported spectacle independence for all distances and rated their visual function and quality satisfactory at all distances.

Conclusion: Bilateral implantation of the Acriva Trinova Sinusoidal Trifocal IOL seems to provide effective restoration of visual function at all distances after cataract surgery in the majority of patients. Contrast sensitivity results and low incidence of dysphotopic phenomena might be associated with high patient satisfaction.

Keywords: Cataract; diffractive IOLs; dysphotopsia; intra ocular lens; trifocal IOLs

INTRODUCTION

The extraction of the crystalline lens in cataract surgery leads to a loss of patients' accommodative ability (1). For the last three decades, bifocal intraocular lenses (IOL) have been an alternative to provide near and distance visual function in patients seeking for spectacle independence. These bifocal IOLs send light to the retina with a predefined light distribution and generate 2 focal points to provide far and near vision (1). Intermediate vision, on the other hand, which is very important for daily tasks such as desktop and computer work has been unsatisfactory for most patients (2,3).

Recently, IOLs with trifocal optics, which distribute light among three different foci (far, intermediate, and near) have been introduced to enhance intermediate vision (4).

Although visual results for intermediate distance were more satisfactory compared to bifocal lenses, photic phenomena and visual disturbances are still reported with trifocal IOLs (5,6). Some modifications like, asphericity, chromatic aberration control, and diffractive step variations in the optics and design of the lenses have been developed to enhance the visual quality.

A trifocal IOL, the Acriva Trinova IOL (VSY Biotechnology, Amsterdam, The Netherlands) which is equipped with a novel presbyopia correcting design called Sinusoidal Vision Technology (SVT) has been introduced recently. A smooth surface profile with stepless zones was used in this design, instead of diffractive rings with sharp edges (Figure 1), to decrease the amount of light loss caused by the overlapping diffractive pattern of traditional trifocal IOLs.

The primary aim of the present study was to assess the visual and refractive outcomes and contrast sensitivity (CS) of patients with visually significant cataract that receieved bilateral implantation of Acriva Trinova IOL. The secondary objective of the study was to evaluate the patient satisfaction and incidence of dysphotopic phenomena in the postoperative period.

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MATERIALS and METHODS

Study Design

This retrospective chard review included consecutive patients with bilateral visually significant cataract that underwent bilateral cataract extraction and implantation of Acriva Trinova IOL at Okan University Hospital, Ophthalmology Department (Istanbul, Turkey) between February 2019 to July 2020. Inclusion criteria were: age between 40 and 80 years, bilateral visually significant cataract, and patient interest in spectacle independence after cataract surgery. Exclusion criteria included: >1.00 D of corneal astigmatism measured with corneal tomography (Sirius, Costruzione Strumenti Oftalmic, Italy), history of glaucoma, or any retinal, corneal or neuro-ophthalmic pathology, previous corneal or intraocular surgery or history of ocular trauma.

This study was approved by the local ethics committee of Okan University School of Medicine and was carried out in accordance with the Declaration of Helsinki. Written and signed informed consent was taken from all participants.

Preoperative Evaluation

All patients had a detailed pre-operative ophthalmologic examination. Ocular surface, tear film and eyelids were examined for any abnormality. The IOL power calculation was performed with the Haigis formula using axial length, corneal power and anterior chamber depth measurements obtained by Aladdin optical biometer (Topcon, Japan) (7). The IOL power was calculated to achieve emmetropia in all cases. Corneal tomography was performed with a rotating Scheimpflug–Placido disk imaging system (Sirius, Costruzione Strumenti Oftalmic, Italy). The macula, fovea, and vitreomacular interface were evaluated using fundoscopy and Optical Coherence Tomography (Topcon Corp., Japan).

Intraocular lens

Acriva UD Trinova is a single piece trifocal IOL with sinusoidal diffractive design. The sinusoidal diffractive pattern (Sinusoidal Vision Technology -SVT) aims to reduce positive dysphotopic phenomena such as halo and glare; and to increase light transmission to the retina. A smoothly varying surface profile has been created in the design of the optics instead of the sharp edges and pointy peaks of the overlapping pattern in traditional trifocal IOLs in order to decrease the unfocused, scattered light and to optimize light distribution to reduce halos and glare (Figure 1). The lens is a biconvex aspheric IOL with hydrophobic acrylic surface and a spherical aberration of -0.165 µm. It has an overall diameter of 11.0 mm and optic diameter of 6.0 mm. The optic has sine wave-like diffractive zones and there are 12 ridges distributed to the 6.0 mm optical surface (Figure 1). The IOL provides an addition of +3.00 D for near and +1.50 D for intermediate vision at the lenticular plane. It has a plate-haptic design with 0^0 angulation and 360^0 all enhanced square edge.

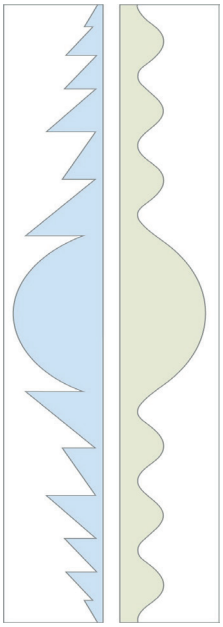

Figure 1. Stepless diffractive rings of the Acriva Trinova IOL with a comparison to traditional diffractive trifocal IOL design

Surgical Technique

All surgeries were performed by the same surgeon (B.B.C.). A 2.2 mm clear corneal incision was performed, followed by intracameral anesthesia with lidocaine hydrochloride. The anterior chamber was filled with ophthalmic viscosurgical device (OVD) (sodium hyaluronate 1.8% [Protectalon, VSY Biotechnology, the Netherlands]) injection, and anterior continuous curvilinear capsulorhexis of approximately 5.0 mm was performed. Following hydrodisection, phacoemulsification, cortical cleanup and posterior capsule polishing, the single-piece trifocal IOL was injected into the capsule bag and OVD was removed from the anterior chamber and behind the IOL. The incisions were hydrated with balanced salt solution, and all surgeries were completed with the injection of intracameral cefuroxime 10 mg/mL. No intra- or postoperative complications sutures were noticed in any of the patients included in the study. The same postoperative topical regimen was used by all patients that included an antibiotic and a steroid drop.

Postoperative Assessment

All patients were evaluated at day 1, week 1, and month 1 and 6. Results from the first month and 6^{th} month were evaluated in the scope of this study. At each visit, uncorrected (UDVA) and corrected (CDVA) distance visual acuities at 6 m were measured with Early Treatment Diabetic Retinopathy Study (ETDRS) chart with 100% contrast under photopic light conditions (165 candelas/m^2), and the results were reported in the logarithm of the minimum angle of resolution (logMAR) notation. Binocular uncorrected near (UNVA-40 cm) and intermediate visual acuity (UIVA-60 cm) were assessed under photopic light conditions.

Monocular defocus curve testing was performed under photopic conditions starting from -3 D to +1.5 D with 0.5 D increments. This testing was done by varying ETDRS charts to avoid the learning effect.

Contrast sensitivity (CS) was measured at the postoperative 6th month visit with a standardized CS chart (CSV 1000, Vison Sciences Research Corp.)

At the 6-month postoperative visit, all patients were asked to grade their limitations in performing certain vision-dependent daily activities. Reading small print, recognizing people, seeing steps and stairs, doing fine handwork, cooking, driving at night and day were questioned. At the same month visit, patients were asked to evaluate the quality of vision and incidence of halo and glare, in terms of frequency and severity. Spectacle independence was also assessed.

Statistical Analysis

Statistical analyses were performed with the Statistical Package for Social Sciences software (Version 17.0, IBM Corp.). Kolmogorov-Smirnov and Shapiro-Wilk tests were used to assess data normality. Independent t test and One-way ANOVA tests were used when the differences between groups follow normal distribution. When significant differences were found in one-way ANOVA, Tukey HSD was used when variances were homogeneous and Tamhane's Analysis was used when they were not. A level of $p<0.05$ was assumed statistically significant for all tests.

RESULTS

The study enrolled a total of 60 eyes of 30 patients, 10 males and 20 females aged 61.78± 8.73 years (range, 45 to 78 years). Table 1 demonstrates preoperative features of the eyes.

Table 1. Patient Demographics

Characteristic	Value
Preoperative Corneal astigmatism	0.56±0.23 D
Range	0- 0.90 D
Axial length	22.83±0.79 mm
Range	20.9- 24,10 mm
Anterior chamber depth	3.02±0.33 mm
Range	2.20-3.45 mm
IOL power	22.24±1.86 D
Range	19- 27 D
Preoperative CDVA	0.55±0.15
Range	0.20-0.70

Values are presented as means ± SD
D: Diopters, LogMAR: Logarithm of the minimum angle of resolution, CDVA: Corrected distance visual acuity, SD: Standard deviation

At the 1st month visit, the mean UDVA was 0.04±0.12. The mean monocular CDVA significantly increased from preoperative 0.47±0.33 to 0.01±0.109 ($p<0.001$). At the 6th month follow-up, monocular UDVA and CDVA were 0.02 ± 0.102 and -0.04 ± 0.09, respectively.

Cumulative binocular uncorrected intermediate and near visual acuity outcomes are plotted in Figure 2 and 3. At the 1st month period, 86.6% of the patients (n: 26) achieved a binocular UIVA of 0.1 LogMAR or better whereas UIVA of 4 patients (13.3%) was 0.18. Twenty eight (93.3%) patients had binocular UNVA of 0.1 LogMAR or better and 2 patient binocular UNVA of 0.18. At the 6th month period 90% of the patients (n: 27) achieved a binocular UIVA of 0.1 LogMAR or better whereas UIVA of 3 patients (10%) was 0.18. In the same postoperative visit 96.7% (n:29) patients had bilateral UNVA of 0.1 LogMAR or better only 1 patent had a bilateral UNVA of 0.18.

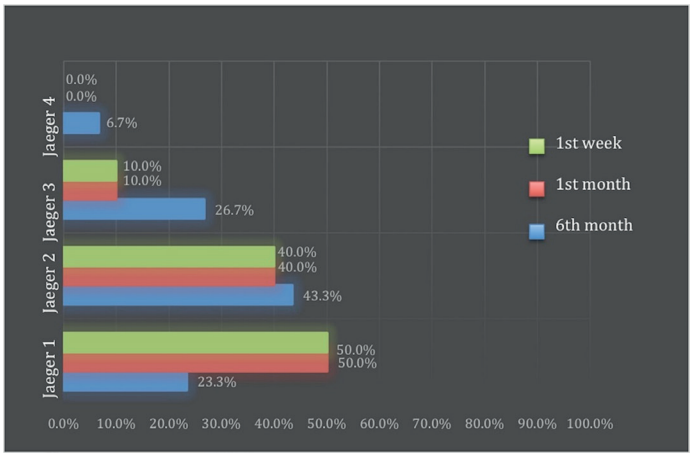

Figure 2. Cumulative binocular uncorrected intermediate visual acuity

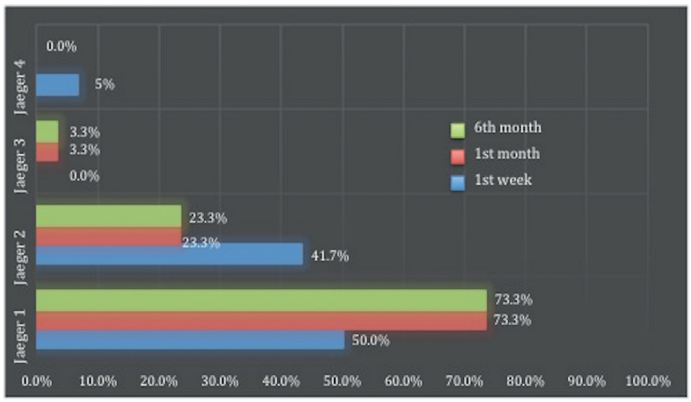

Figure 3. Cumulative binocular uncorrected near visual acuity

Mean spherical equivalent (SE) was 0.37±0.56 at the 1st month visit and 0.25±0.52 at the 6th month visit. Mean cylinder was 0.0.38±0.47. at the 1st month visit and 0.36±0.37 at the 6th month postoperative examination.

Figure 4 shows the defocus curve of the eyes measured at 6-month follow-up. Visual acuity of the eyes shows one peak at the distance focus (0 defocus level) and a second one at near (around -2.5 D defocus level). Between these two peaks, a slight depression is observed at defocus of approximately -1.5 D but the transition had a smooth phase.

Contrast sensitivity function (CSF) graphic of the eyes are demonstrated in Figure 5. In the same graph, in light gray,

the normal CSF levels are also demonstrated for patients of the same age. The mean CS values were within the normal range of age-matched normal values.

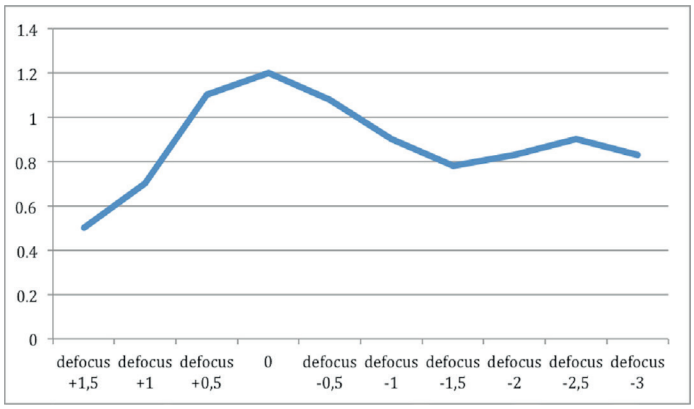

Figure 4. Defocus curve of the eyes

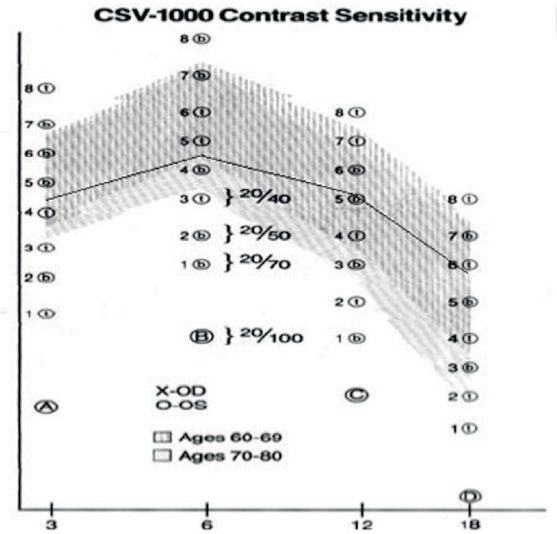

Figure 5. Contrast sensitivity function (CSF) graphic of the eyes

Spectacle Independence and Patient-Reported Outcome Measures

Patient satisfaction was assessed at the 6th month postoperative visit. Patients reported more difficulty reading small print and driving at night and least for recognizing people who are close, or cooking.

Halos were observed by 26.6% (n:8) of the patients at the one-month evaluation; this percentage decreased to 13.3% after 6 months. Three cases (10%) reported severe halo in the first month visit, which dropped to 2 cases (6.66%) after 6 months. Bothersome glare that would interfere with nighttime driving was evident in 3 people (10%) at 1 month, which decreased to 1 person (3.33%) at 6 months.

Twenty nine of 30 patients (96.6%) reported spectacle independence at the one-month and 6-month visits. One patient, whose postoperative SE was +0.50 D, necessitated glasses for reading small print.

At 6 months post-surgery 96.6% of the patients rated their visual quality as good or very good at all distances.

DISCUSSION

The internet and the availability of smartphones and tablets have greatly influenced the reading habits of people. The requirements for near or intermediate-distance reading are increasing among the elderly and the demand for spectacle independence is equally getting high. To accomplish clear distant and near vision without glasses after cataract surgery is the challenge for today's cataract surgeons.

Various designs of bifocal IOLs have been developed in the last two decades to accomplish spectacle independency after cataract surgery. The optics of those lenses were designed to provide functional vision at near and distance by creating two images on the retina from near and distant objects, namely, by simultaneous vision (8). But the inefficient intermediate vision, in addition to low CS results and undesired photic phenomena with bifocal lenses, led manufacturers develop newer lens designs (9,10).

Lately, trifocal lens technology has become popular since it provides better intermediate vision resulting with higher levels of patient satisfaction and spectacle independency (11-13). Although undesired optical phenomena are less prominent with trifocal IOLs compared to bifocal lenses, a significant percentage of the patients still suffer from CS loss and dysphotopsia (5).

For this reason, novel trifocal IOLs with different design principles are being developed. The present study investigates the visual, refractive outcomes and visual quality of patients after bilateral implantation of a novel trifocal IOL with sinusoidal optic design.

Trifocality of Acriva Trinova IOL is achieved by the help of "Sinusoidal Vision Technology" that displays a sine wave like surface profile (Figure 1). This design of the IOL is suggested to increase the amount of light reaching the retina according to the manufacturer. Light distribution plays an important role in obtaining continuous seamless vision and conventional trifocal IOL designs may fail to distribute the light to all focal points evenly. As a result, zones of discontinuity may be noticeable to some of the patients. The sinusoidal surface profile of the Acriva Trinova IOL was suggested to provide a more continuous light energy distribution since it does not exhibit sharp edges on the optic, which may allow the patients to have better light utilization and thus have a satisfactory near and intermediate vision especially under mesopic conditions.

In the present study, the mean UDVA was 0.04±0.12 and 0.02±0.102 at 1 and 6 months respectively, which were comparable to the findings of past case series with other trifocal IOLs in the literature with a similar length of postoperative follow up (14-16). In their study, Mojzis et al followed 60 eyes with AT LISA tri 839 MP for 6 months, and reported the mean postoperative UDVA to be -0.03±0.09 logMAR whereas Jonker et al reported UDVA as 0.01±0.11 logMAR with FineVision IOL (11,17).

Binocular near and intermediate visual acuities were satisfactory according to our study. By the end of 6 months, 90% of the cases achieved binocular UNVA and UIVA of 0.1 LogMAR or better. Only 3.33% of the cases (n:1) had an increase in visual acuity at near and intermediate distances between 1 month to 6 months. This finding is in contrast to Nagy et al's study, where there was a significant improvement between 1 month to 3 months and between 1 month to 6 months (16). They explained this improvement with the neuroadaptation process which may take longer for near and intermediate distances compared to far distance. We strongly believe in the importance of neural adaptation, the slight difference we found in our study may be relevant to the limited sample size of the study.

The defocus curve of the eyes in our study showed one peak at the distance focus (0 defocus level) and the second one at near (around -2.5 D defocus level). Between these two peaks, although a slight depression was observed at defocus of approximately -1.5 D, the transition has a smooth phase which indicates that the trifocal IOL implanted in this cohort provides a satisfactory level of functional vision between +0.5 D and -3 D. Our results are in accordance with previous studies of Nagy and Sezgin et al with other trifocal IOLs (16-18).

Contrast sensitivity measurement is important to assess the possible loss of light transmission after multifocal IOL implantation. In order to provide high CS under low lightening conditions, natural chromophore at 0.02% concentration is used in Acriva lens. CS function following implantation of the Acriva IOL was within the range of normality, which was consistent with Piovella et al and Gyory et al's findings (19,20).

Spectacle independence was high in our study group, which was comparable to previous studies of bilateral trifocal IOL implantation (21-23). The majority of the patients did not need to use spectacles for any distance, whereas 1 patient required glasses for reading small print.

In addition we aimed to assess the visual quality of the patients. Although patients stated that they had more difficulty reading small print and driving at night, there was an overall high level of satisfaction concerning the patients' visual function and our findings were comparable to other published studies, which evaluate visual quality and patient satisfaction after trifocal IOL implantation (19, 20). Akman et al evaluated quality of life after implantation of another trifocal IOL, Panoptix (Alcon Laboratories, Fort Worth, TX), and found that the most difficult tasks to perform were reading small print, driving at night and doing fine handwork (24). The patient satisfaction and vision-related quality of life was high in their study, which was similar with our results.

Correcting spherical and longitudinal chromatic aberrations (CA) is crucial for satisfactory visual quality as reported in previous studies (25). Although many of the bench studies were performed under monochromatic light, the real world is polychromatic (26,27). A study of Vinas et al demonstrated differences between the objective and subjective longitudinal CAs with different trifocal IOLs (28). The authors reported that the objective longitudinal CA was lower than subjective longitudinal CA, which was in agreement with previous studies on phakic patients and pseudophakic patients with monofocal IOL. Incidence of photic phenomena is reported to be relatively high with bifocal and trifocal IOLs, but decrease with the neuro-adaptation process in most cases (29,30). When these phenomena resist, the visual disturbance the induce can be bothersome for the patient, resulting in IOL explanation and exchange. The Acriva Trinova IOL has a very low CA (Abbe number: 58). Moreover, the smooth ring transition zones providing achromatic optics are suggested to contribute to preventing halo and glare. When dysphotopic problems of the patients were questioned separately, 2 patients reported bothersome halo around light sources and 1 marked glare that will interfere with nighttime driving. This relatively low incidence of severe dysphotopsic problems might have been related to the design and optimum CA of the IOL.

No safety related issue was observed in our study in the 6-month postoperative period. No tilt or decentration was observed at the 6 month postoperative period. Although posterior capsular opacification formation should be followed up for a longer period of time, none of the eyes necessitated nd:YAG laser capsulotomy in the first 6 months.

The retrospective nature of the study and relatively small sample size are the main limitations of the current study. In addition, results may differ over a longer follow up period. Therefore, further studies with larger sample sizes are warranted to confirm the findings of our study. Nonetheless, our findings may contribute to the literature since our study is the first to report the outcomes of a new design trifocal IOL.

CONCLUSION

In conclusion, the Acriva Trinova IOL provided favorable visual and refractive outcomes, as well as high patient satisfaction and good level of spectacle independence up to 6 months after bilateral implantation.

Conflict of interest : The authors declare that they have no competing interest.

Financial disclosure: There are no financial supports.

Ethical approval: 56665618-204.01.07; Institutional Review Board of Okan University Medical Faculty Ethics Committee.

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