[Original Article]

Improved intermediate visual function with new monofocal intraocular lens in combined cataract and vitrectomy surgery for retinal disease

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Abstract

Purpose: To evaluate the usefulness of a newly generated monofocal intraocular lens (IOL) in patients with various retinal diseases who underwent combined cataract and pars plana vitrectomy (PPV) surgery.

Methods: This prospective observational study included 33 patients with various retinal diseases. Monocular corrected and uncorrected distance visual acuity (BCDVA, UCDVA), uncorrected intermediate visual acuity (UCIVA), uncorrected near visual acuity (UCNVA), and contrast sensitivity were measured and compared with those in 30 age-matched normal controls. Further, UCIVA/UCDVA and UCNVA/UCDVA ratios were calculated.

Results: The mean preoperative BCDVA was 0.94 ± 0.77 logMAR and postoperative BCDVA was 0.14 ± 0.14 logMAR. There was a significant improvement in BCDVA at 3 months follow up. ($p < 0.0001$) At 3 months after surgery, the ratio of UCIVA to UCDVA was 0.82 ± 0.11 in the patient group, which was not significantly different from the control group. ($p = 0.729$) The contrast sensitivities of patients were similar to those of 80% of the normal contrast sensitivity.

Conclusions: Combined cataract and vitrectomy surgery with Eyhance IOL in patients with retinal diseases can benefit from improving intermediate vision without compromising far vision and contrast sensitivity.

Keywords: Intraocular lens, Eyhance IOL, Combined cataract and vitrectomy surgery, Intermediate vision, Contrast sensitivity

INTRODUCTION

Cataract extraction with intraocular lens (IOL) implantation is a surgery that has been commonly performed and tremendously developed in the field of ophthalmology. Techniques for cataract surgery as well as the quality of IOLs are steadily improving along with increasing patients' expectations. These expectations include having a good vision without spectacles at all distances (near, intermediate, and far), which leads to the development of multifocal IOLs. Although various types of multifocal IOLs have been developed and preserved visual acuity of patients for more than two types of aforementioned distances, there is a drawback of multifocal IOLs that potentially compromise contrast sensitivity and induce glare and halo. [1, 2] These disadvantages become more prominent in patients with vitreoretinal disease requiring surgery, so implanting multifocal IOLs is not recommended for patients with vitreoretinal disease. Thus, the majority of IOLs currently being implanted in combined surgery with cataract and pars plana vitrectomy (PPV) are still monofocal IOLs. [3-5]

The Tecnis Eyhance ICB00 IOL (Johnson & Johnson Vision Care, Inc.) is a recently developed monofocal IOL aimed at distinguishing design with continuous change in refractory power from the periphery to the center of the IOL. [6] This feature creates a small central zone in the anterior surface of the IOL, extending the depth of focus and consequently maintaining intermediate vision without lowering the quality of vision at distance. Previous comparative studies between Eyhance IOL and classic monofocal IOL revealed that this new monofocal IOL showed better intermediate vision than the standard IOL with similar performance and dysphotopsia profile at far vision. [7-11] In spite of these encouraging characteristics, none of the studies evaluated the clinical results of using Eyhance IOL in patients with retinal diseases.

We designed this prospective study to investigate whether the new innovative monofocal IOL (Eyhance IOL) can improve vision and contrast sensitivity in patients with retinal diseases. We evaluated early visual outcomes after surgery in terms of uncorrected far, intermediate, and near vision; refraction; and contrast sensitivity.

MATERIALS AND METHODS

This prospective study was conducted in the Department of Ophthalmology at _____ Hospital between August 2021 and March 2022, in accordance with the tenets of the Declaration of Helsinki, and approved by the institutional review board of _____ Hospital (IRB no. _____2021-05-004). Informed consent was obtained from all the patients after receiving full disclosure regarding the study.

Thirty three eyes of 33 patients who underwent uncomplicated cataract and vitreoretinal surgery with implantation of the Eyhance (ICB00, Tecnis) were included in this prospective study. Inclusion criteria for the study were: age > 40 years, impaired visual acuity due to cataract, surgically indicated vitreoretinal disease, and a preoperative corneal astigmatism of 1.5 diopter (D) or less. Exclusion criteria were: history of trauma or ocular surgery, corneal irregularity or abnormality, subluxated and dislocated crystalline lens, presence of uveitis, and intraocular pressure > 21 mmHg. Furthermore, patients with intraoperative complications, such as anterior capsule radial tear, zonular dialysis, and posterior capsule rupture, or with postoperative complications, including IOL dislocation, corneal endothelial decompensation, vitreous hemorrhage, detachment of the retina and/or choroid, cystoid macular edema, and recurrence of epiretinal membrane, were excluded.

All operations were performed by a single surgeon (___) under retrobulbar or general anesthesia. A 23-gauge 3-port PPV and clear corneal incision phacoemulsification with the Eva vitrectomy system (DORC Inc., Zuidland, the Netherlands) was performed in all patients. After anesthesia, 23-gauge valved trocars were inserted in the inferotemporal (infusion line), superonasal, and superotemporal quadrant 3.5 mm posterior to the limbus. Following routine phacoemulsification surgery with a 2.8 mm clear corneal incision in the superior quadrant, the Eyhance IOL was implanted in the bag. Corneal incisions were sealed by hydration without sutures. This was followed by sequential vitreoretinal surgery. Various techniques depending on vitreoretinal pathology were used at the surgeon's discretion, including core and peripheral vitrectomy, vitreous shaving, epiretinal and/or internal limiting membrane (ILM) peeling, photocoagulation, endodiathermy, using perfluorocarbon liquids, fluid/air exchange, and silicone oil or gas insertion. The trocars were removed by the end of

procedures and the sclerotomies were sutured with 8-0 vicryl if necessary. The tightness of all incision sites was checked. A subconjunctival injection of dexamethasone was administered. In the postoperative period, topical antibiotics, corticosteroids and nonsteroidal anti-inflammatory drugs were administered to all patients four times a day for one month [12], and ointment containing neomycin sulfate, polymyxin B sulfate, and dexamethasone (Forus ophthalmic ointment®; Samil, Seoul, Korea) was administered at bedtime for 7 days.

Preoperatively, all patients underwent a comprehensive ophthalmic examination, including measurement of uncorrected and corrected visual acuity at 4 m distance, slit lamp biomicroscopy, Goldmann applanation tonometry, fundus examination, manifest refraction, optical biometry, corneal topography, and macular optical coherence tomography (OCT) (Spectralis; Heidelberg Engineering, Heidelberg, Germany). The power of the IOL to be implanted was based on biometry data measured by IOL Master 500 (Carl Zeiss Meditec AG, Jena, Germany). If the biometry data were not measured by the IOL Master (ex. Vitreous hemorrhage), contact A-scan biometry were used. Patients for whom biometry data were not obtained, were excluded from the study. IOL power was calculated to target emmetropia for all eyes in the study using the Barret Universal II formula.

Routine postoperative examinations were performed at 1 day; 1 week; and 1, 3, and 6 months after surgery. The results at the 6-month follow up visit were reported in which manifest refraction, monocular corrected and uncorrected distance visual acuity (BCDVA, UCDVA), uncorrected intermediate visual acuity (UCIVA), and uncorrected near visual acuity (UCNVA) were noted. Distance visual acuity was measured at 4 m using early treatment diabetic retinopathy study (ETDRS) charts (Precision Vision, La Salle, Illinois, USA). Intermediate and near visual acuity were measured using the Sloan ETDRS Format Near Vision Chart (Precision Vision, La Salle, Illinois, USA) at 66 cm and 40 cm, respectively. All visual acuities were measured under photopic conditions with 100% contrast. The measured values of visual acuity were converted to the logarithm of the minimum angle of resolution (logMAR) for statistical analyses.

The contrast sensitivity was recorded using a Metrovision MonPack vision monitoring system (Pérenchies, France). Monocular, corrected distance contrast sensitivity test was performed at

postoperative 6 months under both photopic and mesopic conditions. The contrast sensitivity was measured using vertical sinusoidal bars at various spatial frequencies. Each bar was first presented at a low contrast, and then the contrast was progressively increased by the instrument. The point at which the patient first recognized the grating bars was recorded. The Metrovision contrast sensitivity test was carried out at 0.6, 1.1, 2.2, 3.4, 7.1, and 14.2 cycles/degree (cpd) spatial frequencies and at lumination levels of 0-30 decibels (dB).

The values of BCDVA and OCT before and 6 months after surgery were compared using a paired t-test. We recruited 30 eyes of 30 age-matched individuals whose UCDVA was more than 0 logMAR as controls. Uncorrected distance, intermediate, and near visual acuities of the patients after surgery were compared with those of the control group using the Mann-Whitney U test. Considering the low vision due to the patient's retinal disease, the ratios of intermediate vision to distance vision and near vision to distance vision were calculated and compared. The value of the contrast sensitivity test was also compared between the patients and controls. All statistical analyses were performed using SPSS version 19.0 (IBM Corp., Armonk, NY, USA). Statistical significance was set at $p < 0.05$.

RESULTS

The 33 patients in the study group had a mean age of 59.42 ± 8.54 (range, 47-71) years and twenty-one patients were women and twelve patients were men. Thirty subjects (20 women, 10 men) were recruited for control group and had a mean age of 60.39 ± 6.15 (range, 48-69) years. There was no difference in age ($p = 0.623$) and sex distribution ($p = 0.501$) between the patients and controls.

The preoperative and postoperative clinical data of the patients are presented in Table 1. The major concomitant vitreoretinal diseases requiring vitrectomy were vitreous hemorrhage (VH, 12 patients), epiretinal membrane (ERM, 9 patients), rhegmatogenous retinal detachment (RRD, 4 patients), vitreomacular traction (VMT, 2 patients), macular hole (MH, 3 patient), vitreous opacity (2 patient), and uveitis (1 patient). The reasons for VH were diabetic retinopathy (DR, 7 patients), retinal vein occlusion (RVO, 2 patients), retinal tear (1 patient), and wet age-related macular degeneration (AMD). In seven

eyes, including RRD and MH, 18% sulfur hexafluoride (SF_6) was used as a tamponade. There was no patient using silicone oil as a tamponade. The average surgery time was 49.39 ± 9.13 minutes. Complications associated with IOL were not observed.

The average of preoperative BCDVA was 0.94 ± 0.77 logMAR and postoperative BCDVA was 0.14 ± 0.14 logMAR. There was a significant improvement in BCDVA at 6 months follow up. ($p < 0.0001$) The mean preoperative central macular thickness (CMT) was 402.13 ± 237.02 μm. Macular OCT was not detected in twelve patients, because of nine patients with VH and three patients with macula-off RRD. The mean CMT after 6 months of operation was 301.33 ± 80.56 μm and changes were statistically significant. ($p = 0.0004$) The average of axial length was 23.96 ± 1.31 mm and the average of postoperative spherical equivalent (SE) was -0.35 ± 0.49.

The mean UCDVA, UCIVA, and UCNVA of patients after surgery were 0.2 ± 0.15 logMAR, 0.28 ± 0.12 logMAR and 0.53 ± 0.16 logMAR, respectively, and the mean UCIVA and UCNVA of normal subjects were 0.08 ± 0.07 logMAR and 0.17 ± 0.08 logMAR, respectively. (Table 1 and Figure 1) The UCIVA and UCNVA of patients were significantly lower than those of normal subjects. ($p < 0.0001$) The ratio of UCIVA to UCDVA was 0.82 ± 0.11 in patient group and 0.86 ± 0.13 in control group, which was not significantly different. ($p = 0.729$) The ratio of UCNVA to UCDVA was 0.47 ± 0.13 in patient group and 0.69 ± 0.13 in control group, which was significantly different. ($p = 0.004$) The contrast sensitivities of patients were significantly lower than those of normal subjects in almost all spatial frequencies, which were similar to those of 80% of normal contrast sensitivity. (Table 2 and Figure 2)

DISCUSSION

While the Eyhance IOL is designed as a monofocal IOL, due to the unique continuous refectory change by higher-order spheres, it can enhance intermediate vision after cataract surgery. [6, 13] Previous studies comparing Eyhance IOL with standard monofocal IOL demonstrated the superior performance of Eyhance IOL, providing significant improvement of intermediate vision without compromising distance/near visual acuity and photic phenomena. [7-11] Eyhance IOL has been

considered as an advanced monofocal IOL that provides additional advantages of enhanced intermediate vision while maintaining the benefits of monofocal IOL. However, no study has used the Eyhance IOL not only in combined cataract and vitreoretinal surgery but also in patients with retinal disorders. Our study showed that combined cataract surgery and vitrectomy with Eyhance IOL in patients with retinal disorders effectively improved far vision without compromising contrast sensitivity and also promised intermediate vision.

Visual acuity at intermediate distances is vital for common daily life, such as walking upstairs and downstairs, which has become more important because of the increased use of electronic devices, including tablets, and computers. The growing importance of intermediate vision has led to a desire for an IOL that improves visual acuity at far as well as intermediate distance. But to date, there has been a lack of clinical evidence demonstrating preservation of visual acuity at intermediate distances with standard monofocal IOL. [14] Previous studies using the Eyhance IOL demonstrated that the Eyhance IOL is the first monofocal IOL with the ability to improve intermediate vision. [7, 9-11] However, in our study, the patients showed significantly impaired visual acuity and contrast sensitivity despite successful cataract surgery, because of their own retinal disorders. However, when calculating the ratio of uncorrected distance vision to uncorrected intermediate vision, our patients had a similar ratio that was not significantly different from age-matched normal controls. In addition, the contrast sensitivity of the study group showed a value similar to 80% of the normal contrast sensitivity. Because of the importance of intermediate visual acuity in daily tasks, these results give us confidence that advanced visual performance of enhanced monofocal IOL will contribute to improved quality of life in retinal patients who undergo combined cataract and vitreoretinal surgery.

One of the major reasons of hesitation for the use of multifocal IOL in cataract surgery performed together with vitrectomy is that difficult situations can be encountered during surgery through multifocal IOL. The multiple concentric optical zones with different refractive powers of these IOLs interfere with the surgeon's view during surgery. Since these optical limitations make surgeons hesitate during macular surgery, a previous study comparing the operation time between monofocal IOL and multifocal IOL showed that eyes with multifocal IOLs spend more time in macular surgery for ERM and/or ILM peeling

than eyes with monofocal IOL. [15] Patel et al. reported that combined PPV with multifocal IOL can increase the risk of retinal break, and Altun also reported an increased risk of iatrogenic retinal break in eyes with multifocal IOL. [15,16] However, according to our experience with Eyhance IOL, there was no distortion of the surgical field via IOL, not only in membrane peeling but also in shaving the peripheral vitreous. (Supplementary Video) Our study proved that the Eyhance IOL has the advantage of monofocal lens in retinal surgery by attempting Eyhance IOL for the first time in retinal patients.

An important factor that determines the success of cataract surgery is the prediction of the refractive power. The clinical importance of refractory power after cataract surgery is most prominent in the implantation of multifocal IOLs. If postoperative refractory power does not achieve emmetropia, it results in patient dissatisfaction with blurred vision and halos. [17,18] The axial length cannot be detected precisely in several retinal disorders, such as vitreous hemorrhage and macula-off retinal detachment. [19] Moreover, there can be myopic shift after phacovitrectomy. [20] For these reasons, multifocal IOL implantation has been hesitated in patients who require combined cataract and vitreoretinal surgery. The target refraction was emmetropia, but the SE of the two patients with macula-off RRD (cases 1 and 28) was -1.75. (Table 1) This may be caused by incorrect measurement of axial length due to the subretinal fluid in macular area. If this situation occurred in patients with multifocal IOL, the patients would experience discomfort, such as blurred vision and compromised contrast sensitivity. Although the postoperative refractory power of these patients did not achieve emmetropia, the Eyhance IOL satisfied the patients with their ability to preserve intermediate vision and contrast sensitivity. Unsal et al. also founded that Eyhance IOL was more forgiving to residual refractive errors than standard monofocal IOL. [8]

A major limitation of our study is that it is not a complete comparative study of specific retinal disease entities. Therefore, it is difficult to tell whether the worse vision and worse contrast sensitivity of the study group compared to those of the normal control group are due to IOL or underlying retinal pathology and determine whether this new monofocal IOL is superior to conventional monofocal and/or premium multifocal IOLs in patients with retinal disorders. If a patient satisfaction questionnaire was implemented, it would have been possible to show a comparison with multifocal IOL in terms of photic

phenomena. However, it is meaningful that we applied this novel IOL in combined cataract and vitreoretinal surgery for various retinal diseases and first demonstrated the usefulness of Eyhance IOL in patients with retinal diseases. A comparative study with monofocal and/or multifocal IOLs is required to definitively address the advantage of this new monofocal IOL. Furthermore, because of the recent release of the new IOL, the study period was too short and the number of patients included in our study was small. Therefore, the differences in visual acuity and contrast sensitivity according to the types of tamponade, causes of VH, or underlying macular pathology could not be compared statistically.

In conclusion, to the best of our knowledge, our study is the first to demonstrate that combined cataract and vitreoretinal surgery with Eyhance IOL can improve intermediate vision without compromising far vision and contrast sensitivity. Despite not being as expensive as the premium multifocal IOLs, Eyhance IOL is able to provide an effective option in combined cataract and vitrectomy surgery for both patients and surgeons regarding improvement of intermediate and distance visual acuity preserving contrast sensitivity and better visualization of the fundus during surgery. Even though our study only included patients undergoing combined surgery, it can be inferred from our study that Eyhance IOL can be a good option for single cataract surgery in patients with retinal or optic nerve disease. Eyhance IOL will provide retinal patients who undergo combined cataract and vitreoretinal surgery with an alternative to monofocal IOL, which might offer improved quality of vision for daily performance.

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Figure legends

Figure 1. Graphs presenting the contrast sensitivities of patients and controls under photopic and mesopic conditions.

Figure 2. Comparative chart showing the mean UCIVA, UCNVA, UCIVA/UCDVA and UCNVA/UCDVA values between patient and control group. Mann-Whitney U test was used for statistical analysis.

Video legends

Video 1. Internal limiting membrane peeling via Eyhance intraocular lens (case 22) and Peripheral vitreous shaving around the retinal break via Eyhance intraocular lens (case 4)

Table 1. Preoperative characteristics of patients in the two intraocular lens groups. (Mean ± SD)

	Eyhance ICB00 (n=33)	Tecnis ZCB00 (n=40)	P value*
Age (year)	59.42±8.55	62.40±13.39	0.953
Sex (male/female)	12/21	14/26	0.904
SE (D)	1.04±4.61	1.22±5.30	0.862
Cylinder (D)	-0.66±0.36	-0.63±0.32	0.841
Axial length	23.91±1.28	24.12±1.83	0.694
Pre-operative CDVA (logMAR)	0.94±0.93	0.93±0.83	0.020
Pre-operative CMT (um)	402.10±167.79	354.92±139.48	0.711
Main reason for vitrectomy			0.511
VH	12	12	
RRD	4	9	
Opacity	3	9	
ERM	9	8	
MH	3	2	
VMT	2	0	

SE, spherical equivalent; D, diopter; CDVA, corrected distant visual acuity; CMT, central macular thickness. *Mann-Whitney U test

Table 2. Postoperative characteristics of patients in the two intraocular lens groups. (Mean ± SD)

	Eyhance ICBZ00 (n=33)	Tecnis ZCB00 (n=40)	P value*
Operation time (min)	49.39±9.13	48.53±20.66	0.141
Post-operative CMT (um)	301.33±80.56	325.60±83.32	0.017
Post-operative SE (D)	-0.35±0.49	-0.47±0.52	0.963
Post-operative CDVA (logMAR)	0.13 ± 0.14	0.20 ± 0.25	0.295
Post-operative UCDVA (logMAR)	0.19 ± 0.14	0.25 ± 0.27	0.832
Post-operative UCIVA (logMAR)	0.29 ± 0.14	0.49 ± 0.28	0.001
Post-operative UCNVA (logMAR)	0.54 ± 0.20	0.62 ± 0.28	0.267
Post-operative UCIVA/UCDVA	0.81 ± 0.11	0.66 ± 0.20	<0.001
Post-operative UCNVA/UCDVA	0.47 ± 0.12	0.45 ± 0.19	0.239

CMT, central macular thickness; SE, spherical equivalent; D, diopter; CDVA, corrected distant visual acuity; UCDVA, uncorrected distant visual acuity; UCIVA, uncorrected intermediate visual acuity; UCNVA, uncorrected near visual acuity. *Mann-Whitney U test

Table 3. Univariate and multivariate analysis of post-operative UCIVA in Eyhance IOL patients.

Post-operative UCIVA in Eyhance IOL(ICB00) patients (n=33)

	Univariate analysis			Multivariate analysis		
	β	95% CI	P value	β	95% CI	P value
Age	0.283	(-0.809, 1.375)	0.186			
Sex	-0.032	(-0.153, 0.089)	0.880			
SE	0.044	(-0.122, 0.210)	0.836			
Cylinder	-0.016	(-0.076, 0.044)	0.940			
Axial length	-0.167	(-0.773, 0.439)	0.450			
Pre-operative CDVA	0.126	(-0.228, -0.024)	0.020	0.205	(0.036, 0373)	0.028
Pre-operative CMT (um)	-0.002	(-0.008, 0.004)	0.994			

CDVA, corrected distant visual acuity; UCIVA, uncorrected intermediate visual acuity; SE, spherical equivalent; CMT, central macular thickness