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ORIGINAL RESEARCH

Enhanced Monofocal IOLs Improve Patient Satisfaction in Phaco-Vitrectomy for ERM

Junya Ota[1,2], Masaaki Matsunaga[3], Fuminori Haga[4], Ayana Suzumura[1], Kazuhisa Yamada[1], Hideyuki Shimizu[1], Shu Kachi[4], Ichiro Ota[4], Goichiro Miyake[4], Kumiko Mokuno[5], Daiki Inooka[2,6], Emi Iwata[2], Tomohiko Akahori[7], Koji M Nishiguchi[1], Hiroki Kaneko[1,8]

[1]Department of Ophthalmology, Nagoya University Graduate School of Medicine, Nagoya, Japan; [2]Department of Ophthalmology, Nishio Municipal Hospital, Nishio, Japan; [3]Department of Public Health, Fujita Health University School of Medicine, Toyoake, Japan; [4]Shohzankai Medical Foundation, Miyake Eye Hospital, Nagoya, Japan; [5]Department of Ophthalmology, Kariya Toyota General Hospital, Kariya, Japan; [6]Department of Ophthalmology, Tosei General Hospital, Seto, Japan; [7]Department of Ophthalmology, Ichinomiya Municipal Hospital, Ichinomiya, Japan; [8]Department of Ophthalmology, Hamamatsu University School of Medicine, Hamamatsu, Japan

Correspondence: Hiroki Kaneko, Department of Ophthalmology, Hamamatsu University School of Medicine, 1-20-1, Handayama, Chuo-ku, Hamamatsu, 431-3192, Japan, Tel +81-53-435-2256, Fax +81-53-435-2372, Email h-kaneko@hama-med.ac.jp

Purpose: Tecnis Eyhance (DIB00V) is a type of monofocal intraocular lens (IOL) categorized as "IOL-plus", a new concept developed to improve not only distance but also intermediate vision. However, its negative effect, eg difficulty in macular surgery that is occasionally seen with the multifocal IOL, has not been ruled out in combined surgery for epiretinal membrane (ERM) and cataracts. This study aimed to compare DIB00V with a conventional monofocal IOL (DCB00V) in terms of visual acuity and patient-reported outcomes of combined surgery for epiretinal membrane (ERM) and cataracts.

Methods: This was a multicenter, prospective, nonrandomized, observational study conducted in Japan. Patients scheduled for combined cataract and pars plana vitrectomy (PPV) for cataract and ERM were enrolled. IOL was selected according to the rules originally applied in each facility. Best-corrected distance visual acuity (BCDVA) and distance-corrected intermediate visual acuity (DCIVA) at 3-month visits postoperatively, surgical parameters, and Japanese-modified Catquest-9SF Questionnaire scores were compared between the two IOL groups.

Results: Sixty-two eyes implanted with DCB00V (Tecnis-1) and 79 eyes implanted with DIB00V (Eyhance) were analyzed. There was no significant difference in BCDVA with Eyhance (0.09 in logMAR) and Tecnis-1 (0.05 in logMAR, $p = 0.174$), and DCIVA with Eyhance (0.35 in logMAR) and Tecnis-1 (0.39 in logMAR, $p = 0.200$). Rasch analysis of the Japanese-modified Catquest-9SF Questionnaire revealed that Eyhance scored higher in patients' general satisfaction ($p = 0.0269$). Subgroup analysis revealed a better postoperative distance-corrected intermediate visual acuity in patients with a certain degree of preoperative myopia (spherical error < -1.5 diopter).

Conclusion: Eyhance provided comparable postoperative visual acuity to the conventional monofocal IOL in combined surgery for cataract and ERM, and surgical parameters are not different in the two types of IOL. Furthermore, Eyhance improved postoperative satisfaction in the overall population and significantly improved intermediate visual acuity in the preoperatively myopic population.

Keywords: epiretinal membrane, monofocal-plus intraocular lens, Rasch analysis, intermediate visual acuity, Japanese-modified Catquest-9SF Questionnaire

Introduction

Epiretinal membrane (ERM) is a macular disease affecting approximately 4%–11.8% of the population, often leading to reduced visual acuity, metamorphopsia, and macropsia.[1,2] Vitrectomy is frequently required to prevent irreversible vision loss, and in cases where cataracts are present or expected to progress, combined phaco-vitrectomy surgery is performed.[1,3] At the same time, there is a growing demand for vision correction at various distances, which is often difficult to achieve with conventional monofocal intraocular lenses (IOLs). For this reason, multifocal IOLs are gaining popularity.[4,5] However, in eyes with macular diseases, multifocal IOLs may not be recommended due to decreased contrast sensitivity and the reduction of visibility during ERM surgery, which can hinder macular manipulation, whereas monofocal IOLs are typically used in combined surgery.[6,7]

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Tecnis® Eyhance™ Optiblue (DIB00V) is a new type of aspheric monofocal IOL developed by Johnson & Johnson Vision (Santa Ana, CA). It features a continuous change in refractive power from the periphery to the center of the lens while maintaining the same material and size as the company's conventional monofocal IOL, Tecnis® 1-piece Optiblue (DCB00V).[8] This design aims to extend the depth of focus and improve intermediate vision while preserving distance vision. Consequently, Tecnis® Eyhance™ Optiblue partially meets the definition of extended depth of focus lens reported by the American National Standard, and it is currently called one of the monofocal-plus IOLs, mono-EDoF, or enhanced monofocal.[9] Several retrospective studies and randomized controlled trials have shown that Tecnis Eyhance IOLs maintain distance vision and provide significantly better intermediate visual acuity compared to conventional monofocal IOLs in cataract surgery.[10–19] However, there are conflicting reports that show Eyhance does not provide clinically significant improvements in intermediate vision.[20–23]

In addition to visual acuity, there has been a growing emphasis on patient-reported outcomes (PROMs) in therapeutic areas including cataract surgery, with studies analyzing questionnaires assessing the quality of vision.[12,13,19,20,24] Responses to these questionnaires are often assigned ordinal numerical scores, which cannot be analyzed linearly due to the lack of an interval scale. In this case, Rasch analysis is used to convert these scores into a linear interval scale, enabling linear parametric analysis and validation of the results.[25]

A recent clinical study on the use of Eyhance for cataract surgery in eyes with ERM has demonstrated that the lenses provided relatively good distance and intermediate vision with minimal discomfort or complications.[26] However, studies comparing postoperative visual function between conventional monofocal IOLs and Eyhance in combined cataract and ERM surgery are limited to a few single-centered studies.[27–30] Three of these studies include analysis on PROMs although it was merely compared as numerical scale without Rasch calibration.[27–29]

This study aimed to compare the clinical outcomes of combined surgery for ERM and cataract, focusing on best-corrected distance visual acuity (BCDVA), distance-corrected intermediate visual acuity (DCIVA), and PROMs, using the Tecnis® Eyhance Optiblue and Tecnis® 1-piece Optiblue.

Methods

Patients

This was a multicenter, prospective, nonrandomized, observational study. The procedures used in this study adhered to the tenets of the Declaration of Helsinki. The protocol was registered in the UMIN Clinical Trial Registry (registration number: UMIN000047202) and approved by each facility's institutional review board/ethics committee. Table S1 presents approval numbers. All participants provided informed consent. Patients scheduled for combined cataract and pars plana vitrectomy (PPV) surgery for cataract and ERM were recruited from Nagoya University Hospital, Miyake Eye Hospital, Ichinomiya Municipal Hospital, Kariya Toyota General Hospital, and Nishio Municipal Hospital between July 2022 and November 2023. The inclusion criteria were patients aged 20 or older with visual impairment due to cataracts and ERMs. The exclusion criteria comprised corneal disorders affecting visual acuity, corneal astigmatism exceeding 3.0 diopter (D), uncontrolled glaucoma, active uveitis, retinal detachment before or after surgery, sight-threatening macular disorders other than ERM (eg, macular hole, branch retinal vein occlusion, age-related macular degeneration, central serous chorioretinopathy), proliferative diabetic retinopathy, amblyopia, congenital eye abnormalities, vitreous opacity; language barriers, and inability to complete follow-up.

Patients underwent combined surgery with either Tecnis Optiblue (DCB00V) or Eyhance (DIB00V). The IOL was selected according to the rules originally applied in each facility based on patient preference. Informed consent for participation in this observational study was obtained from patients.

Preoperative Evaluation

Preoperatively, all patients underwent a comprehensive ophthalmic examination, including measurement of uncorrected and corrected visual acuity, slit-lamp biomicroscopy, non-contact tonometry, fundus examination, manifest refraction, optical biometry, corneal topography, and macular optical coherence tomography. Preoperative monocular uncorrected distance visual acuity (UCDVA) and BCDVA were assessed using the Snellen chart at a 5-m distance. Intraocular pressure (IOP), spherical and cylindrical refractive errors, corneal astigmatism, pupil diameter, and central macular

thickness (CMT) were recorded. The power of the implanted IOL was determined based on biometry data obtained using an IOLMaster 500 or 700 (Carl Zeiss Meditec AG, Jena, Germany). If biometry data could not be obtained using these devices, contact A-scan biometry, OA-2000 (Tomey, Nagoya, Japan), was used. The IOL power was calculated according to the standard protocols of each facility.

Postoperative Evaluation

Spherical and cylindrical refractive errors, BCDVA, UCDVA, uncorrected intermediate visual acuity (UCIVA), DCIVA, IOP, and CMT were recorded during the 3-months follow-up visit. Distance visual acuities were assessed at a 5-m distance, whereas intermediate visual acuity was measured at a 70-cm distance under photopic conditions with 100% contrast. For statistical analyses, decimal visual acuity was converted into logMAR scale.

Surgical Procedure

A 25- or 27-gauge PPV and phacoemulsification were performed using the constellation system (Alcon, Inc, Geneva, Switzerland). Patients underwent phacoemulsification, followed by IOL insertion into the capsule, PPV, and ERM/internal limiting membrane peeling. Surgeons were not masked to IOL type. The total operative and macular manipulation times were recorded. Postoperatively, topical antibiotics, corticosteroids, and nonsteroidal anti-inflammatory drugs were administered.

Japanese-Modified Catquest-9SF Questionnaire

The Japanese-modified Catquest-9SF Questionnaire was used to assess the patients' self-assessed vision quality. Patients who underwent surgery for eyes completed the questionnaire once, and only the first operated eyes were included in the questionnaire score analysis. Each item and response option for the original Catquest-9SF are described in Table S2. The questionnaire was machine-translated into Japanese using DeepL translation (https://www.deepl.com/ja/translator) and subsequently modified by ophthalmologists to enhance comprehension for Japanese speakers. The Japanese-modified Catquest-9SF Questionnaire was previously validated through Rasch analysis elsewhere.[31]

Sample Size Determination

The sample size was determined according to a comparative study of intermediate visual acuity between Eyhance and Tecnis-1 in cataract surgery.[13] In a previous study, it was estimated that 70 patients per group would provide over 98% power to detect a 1-line or greater difference, assuming one-sided testing, an alpha of 0.05, and a standard deviation of 1.5 lines for intermediate visual acuity. For distance visual acuity, a sample size of 70 patients per group would provide over 99% power to detect a 1-line noninferiority margin, assuming a standard deviation of 1.2 lines. Regarding the Rasch analysis of the questionnaire, a sample size of 90 was considered sufficient because the minimum sample size is typically 10 per questionnaire item.[32]

Statistics and Rasch Analysis

Pre- and postoperative quantitative data were compared using the Welch two-sample *t*-test. Fisher's exact test was used to compare categorical data. Rasch analysis of the Japanese-modified Catquest-9SF Questionnaire was performed using WINSTEPS Ver.5.6.0.0. The patient's ability and item difficulty were converted into Rasch calibrated scores with the same "logit" scale, and the scores were treated as parametric statistics.[25] Higher scores for a person's ability indicated lower visual ability, whereas higher scores for the questionnaire items indicated less difficult task completion. The fit of the Rasch model was evaluated using information-weighted mean square fit statistics (Infit MNSQ) and outlier-sensitive weighted mean square fit statistics (Outfit MNSQ). These statistics are used to assess whether the questionnaire items measure a single underlying construct, which is known as unidimensionality. Both statistics are expected to have a value of 1 with an acceptable fit criterion of 0.5–1.5.[33,34] Rasch calibrated scores for ability were compared between the IOL groups using Welch's two-sample *t*-test. Differences in item difficulties between the Tecnis-1 and Eyhance groups were determined using differential item functioning (DIF) analysis. The DIF analysis, which determined the difference in item difficulty scores between the two groups, was performed using the DIF contrast. The significance of the DIF contrast was

identified using the Welch two-sample *t*-test. In this analysis, a larger DIF contrast in the Eyhance group minus the Tecnis-1 group indicates a better performance of the Eyhance group in terms of the performance.

Subgroup Analysis

In previous studies evaluating postoperative intermediate visual acuity using Eyhance, the IOL power was typically calculated to target emmetropia.[10,12–16,20] To facilitate comparison with previous studies focusing on emmetropia, we conducted a subgroup analysis, dividing participants into two groups based on the preoperative spherical error: one subgroup with preoperative myopia stronger than −1.5 D (Sphere < −1.5 D) and another subgroup with preoperative myopia weaker than −1.5 D or with emmetropia or hyperopia (Sphere ≥ −1.5 D). To investigate preoperative patient characteristics associated with a favorable Rasch calibrated patient ability score on the Japanese modified Catquest-9SF Questionnaire in the Eyhance group, the Eyhance group was divided into two groups using a cutoff value, and their preoperative characteristics were compared using the Welch *t*-test. In the subgroup analysis comparing patients with high and low ability scores in the Eyhance group, the cutoff for the Rasch calibrated ability score was set at the third quartile, −4.37 logit, which separated the two peaks of its distribution. These subgroup analyses were exploratory and were not adjusted for multiple comparisons.

Results

Patient Background

A total of 151 eyes from 131 patients were included in this study. Twenty patients underwent combined surgery for ERM and cataracts in both eyes. One patient was excluded due to corneal irregular astigmatism, and another patient was excluded due to branch retinal vein occlusion. Two patients who had surgery on both eyes missed the 3-month follow-up of one eye, and six patients who had surgery on one eye missed the 3-month follow-up. Ultimately, 141 eyes from 123 patients were analyzed. Sixty-two eyes were implanted with Tecnis-1, and 79 eyes were implanted with Eyhance. The mean age of the patients was 71 years, with 48% male and 52% female. The demographic and clinical characteristics of the patients in each IOL group at the preoperative visit are summarized in Table 1. There were no significant differences in these characteristics between two IOL groups.

Table 1 Summary of Preoperative Clinical Data Overall and in the Two Intraocular Lens (IOL) Groups

Mean (SD)	Overall, n = 141	Tecnis-1, n = 62	Eyhance, n = 79	*P*-value
Age (years)	71 (9)	71 (9)	71 (8)	0.715[a]
Gender (male/female)	73/68	34/28	39/40	0.611[b]
UCDVA logMAR	0.78 (0.43)	0.84 (0.45)	0.73 (0.40)	0.166[a]
BCDVA logMAR	0.27 (0.27)	0.27 (0.29)	0.26 (0.27)	0.977[a]
Sphere (D)	−1.4 (3.6)	−1.8 (3.4)	−1.1 (3.7)	0.292[a]
Cylinder (D)	−0.73 (1.17)	−0.78 (1.16)	−0.69 (1.18)	0.675[a]
Corneal astigmatism (D)	−0.81 (0.48)	−0.9 (0.57)	−0.74 (0.38)	0.055[a]
Pupil diameter (mm)	3.14 (0.68)	3.14 (0.66)	3.15 (0.70)	0.934[a]
IOP (mmHg)	14.56 (2.75)	14.73 (2.47)	14.13 (2.95)	0.502[a]
CMT (μm)	402 (85)	411 (83)	395 (87)	0.259[a]

Notes: The corresponding p-values for the comparison between the two IOL groups are shown for each parameter evaluated [a] Welch two-sample t-test[b] Fisher's exact test.

Abbreviations: BCDVA, best-corrected distance visual acuity; CMT, central macular thickness; Cylinder, cylindrical error; D, diopter; IOP, intraocular pressure; logMAR, logarithmic minimum angle of resolution; SD, standard deviation; Sphere, spherical error; UCDVA, uncorrected distance visual acuity.

Outcomes at 3-month Visits

Visual acuity and other measurements at the 3-month postoperative visit are summarized in Table 2. The total operative time and macular manipulation time are presented in Table 2. The mean logarithmic minimum angle of resolution (logMAR) for DCIVA was 0.39 for the Tecnis-1 group and 0.35 for the Eyhance group, with no significant difference ($p = 0.200$, Welch's two-sample *t*-test). The mean logMAR for BCDVA was 0.05 for the Tecnis-1 group and 0.09 for the Eyhance group, with no significant difference ($p = 0.174$). The mean logMAR for UCDVA, with 0.48 in the Tecnis-1 group and 0.37 in the Eyhance group, was not statistically significant ($p = 0.060$). UCIVA was not significantly different in the Eyhance group (0.30 in logMAR) and Tecnis-1 group (0.38 in logMAR), ($p = 0.051$). There were no significant differences in other parameters at the 3-month visit between the two groups. Postoperative central macular thickness (CMT) was significantly reduced compared to preoperative CMT in the Tecnis-1 group, while in the Eyhance group, postoperative CMT did not show a significant reduction. The total operative time and macular manipulation time were 25 and 6.26 minutes overall, 26 and 6.38 minutes in the Tecnis-1 group, and 25 and 6.16 minutes in the Eyhance group, respectively, with no significant differences.

Subgroup Analysis

A subgroup analysis was conducted by dividing the participants into two groups based on the preoperative spherical error: one subgroup with preoperative myopia stronger than −1.5 Diopter (D) (Sphere < −1.5 D) and the other subgroup with preoperative myopia weaker than −1.5 D or with emmetropia or hyperopia (Sphere ≥ −1.5 D). The comparison of visual acuity between the two IOL groups in each subgroup is presented in Table 3. UCDVA, UCIVA, and DCIVA tended to be better in the Eyhance group in the subgroup with preoperative spherical error less than −1.5 D.

Rasch Analysis of Japanese Modified Catquest-9SF results

Postoperative PROMs were assessed using the Japanese-modified Catquest-9SF Questionnaire.[31] The original English version of the Catquest-9SF Questionnaire is provided in Table 4. The reverse translated sentence of the Japanese-modified Catquest-9SF can be found in Table S2. A person-item map illustrating the distribution of patient abilities and the difficulty levels of questionnaire items is presented in Figure S1. The fit scores of the Rasch model (Infit MNSQ and Outfit MNSQ) are detailed in Table 4, along with item difficulty levels. In the current analysis, item Q3-2, "Recognizing

Table 2 Summary of Operation Time and 3-month Postoperative Clinical Data Overall and in the Two Intraocular Lens (IOL) Groups

Mean (SD)	Overall, n = 141	Tecnis-1, n = 62	Eyhance, n = 79	*P*-value
UCDVA logMAR	0.42 (0.35)	0.48 (0.38)	0.37 (0.32)	0.060[a]
UCIVA logMAR	0.33 (0.24)	0.38 (0.22)	0.30 (0.25)	0.051[a]
BCDVA logMAR	0.07 (0.18)	0.05 (0.11)	0.09 (0.22)	0.174[a]
DCIVA logMAR	0.37 (0.20)	0.39 (0.15)	0.35 (0.23)	0.200[a]
Sphere (D)	−0.63 (1.06)	−0.83 (1.21)	−0.48 (0.90)	0.068[a]
Cylinder (D)	−0.92 (0.58)	−0.93 (0.62)	−0.91 (0.55)	0.916[a]
Pupil diameter (mm)	3.08 (0.67)	3.15 (0.77)	3.01 (0.57)	0.232[a]
IOP (mmHg)	13.8 (3.6)	13.2 (2.6)	14.3 (4.2)	0.070[a]
CMT	385 (51)	384 (56)	386 (46)	0.819[a]
Total operative time (min)	25 (6)	26 (6)	25 (6)	0.893[a]
Macular manipulation time (min)	6.26 (3.00)	6.38 (3.24)	6.16 (2.81)	0.680[a]

Notes: The corresponding p-values for the comparison between the two IOL groups are shown for each parameter evaluated.a Welch two-sample *t*-test.

Abbreviations: BCDVA, best-corrected distance visual acuity; CMT, central macular thickness; Cylinder, cylindrical error; D, diopter; DCIVA, distance-corrected intermediate visual acuity; IOP, intraocular pressure; logMAR, logarithmic minimum angle of resolution; SD, standard deviation; Sphere, spherical error; UCDVA, uncorrected distance visual acuity; UCIVA, uncorrected intermediate visual acuity.

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Table 3 Subgroup Analysis of Visual Acuity by Intraocular Lens (IOL) Type Dividing Subgroups with Preoperative Spherical Refraction

subgroup	S < −1.5 D			S ≥ −1.5 D		
Mean (SD)	Tecnis-1, n = 27	Eyhance, n = 17	*P*-value	Tecnis-1, n = 32	Eyhance, n = 55	*P*-value
UCDVA	0.75 (0.32)	0.50 (0.35)	0.023	0.27 (0.28)	0.35 (0.30)	0.271
UCIVA	0.38 (0.25)	0.24 (0.17)	0.041	0.39 (0.19)	0.32 (0.27)	0.135
BCDVA	0.05 (0.09)	0.03 (0.10)	0.501	0.06 (0.13)	0.12 (0.25)	0.131
DCIVA	0.39 (0.14)	0.28 (0.18)	0.045	0.42 (0.15)	0.38 (0.25)	0.355

Notes: The corresponding p-values for the comparison between the two IOL groups are shown for each parameter evaluated.Welch two-sample *t*-test.
Abbreviations: BCDVA, best-corrected distant visual acuity; D, diopter; DCIVA, distance-corrected intermediate visual acuity; S, spherical refraction; SD, standard deviation; UCDVA, uncorrected distant visual acuity; UCIVA, uncorrected intermediate visual acuity.

Table 4 Item Difficulty and Infit and Outfit MNSQ for Each Item of the Questionnaire

Item (Original sentence of the Catquest-9SF Questionnaire)	Item Difficulty (logit)	Infit MNSQ (logit)	Outfit MNSQ (logit)
Q1. Do you find that your sight at present in some way causes you difficulty in your everyday life?	0.25	0.95	0.83
Q2. Are you satisfied or dissatisfied with your sight at present?	−2.28	0.85	0.85
Q3-1. Reading text in newspapers	−1.09	1.16	1.05
Q3-2. Recognizing the faces of people you meet	2.53	1.65	0.67
Q3-3. Seeing the prices of goods when shopping	−0.82	0.87	0.84
Q3-4. Seeing to walk on uneven surfaces, eg, cobblestones	2.53	1.43	1.44
Q3-5. Seeing to do handicrafts, woodwork etc.	−1.67	0.94	0.91
Q3-6. Reading subtitles on TV.	0.64	1.38	1.18
Q3-7. Seeing to engage in an activity/hobby that you are interested in	−0.1	0.65	0.54

Notes: Infit MNSQ, information-weighted mean square fit statistics; Outfit MNSQ, outlier-sensitive weighted mean square fit statistics Infit MNSQ of 0.5–1.5 is fit. <0.5 is overfit, >1.5 is underfit.

the faces of people you met", showed an underfit Infit value of 1.65, indicating a deviation from the unidimensionality assumption, while the other items fell within the acceptable range of 0.5–1.5.

Patients' abilities were compared based on the mean of Rasch-converted scores and the results are summarized in Table 5. There was no significant difference in overall patients' ability between the Tecnis-1 and Eyhance groups ($p = 0.231$). Figure 1 illustrates the results of DIF, showing differences in item difficulties, referred to as DIF contrast, between the IOL groups. In this analysis, a positive DIF contrast indicates favorability in the Eyhance group. The DIF contrast was significantly positive for Q2, "Are you satisfied or dissatisfied with your sight at present?" The DIF contrast was also significantly positive for Q3-4, "seeing to walk on uneven surfaces, eg cobblestones". DIF contrast for Q3-1 ("Reading text in newspapers") was significantly negative. Likewise, Q3-2 showed negative DIF contrast. However, the Infit MNSQ for Q3-2 did not meet the unidimensionality assumption. To investigate factors associated with the participants achieving better scores in the Eyhance group, preoperative background characteristics were compared by dividing patients into higher and lower ability groups at a specific cutoff value of patient ability, but no clear trend was observed (Table S3).

Table 5 Comparison of Patient Abilities by Intracular Lens (IOL) Group

Mean (Standard Deviation)	Overall, n = 132	Tecnis-1, n = 60	Eyhance, n = 72	*P*-value
Person ability (logit)	−3.03 (1.97)	−3.26 (1.87)	−2.85 (2.03)	0.231

Note: Welch's two-sample *t*-test.

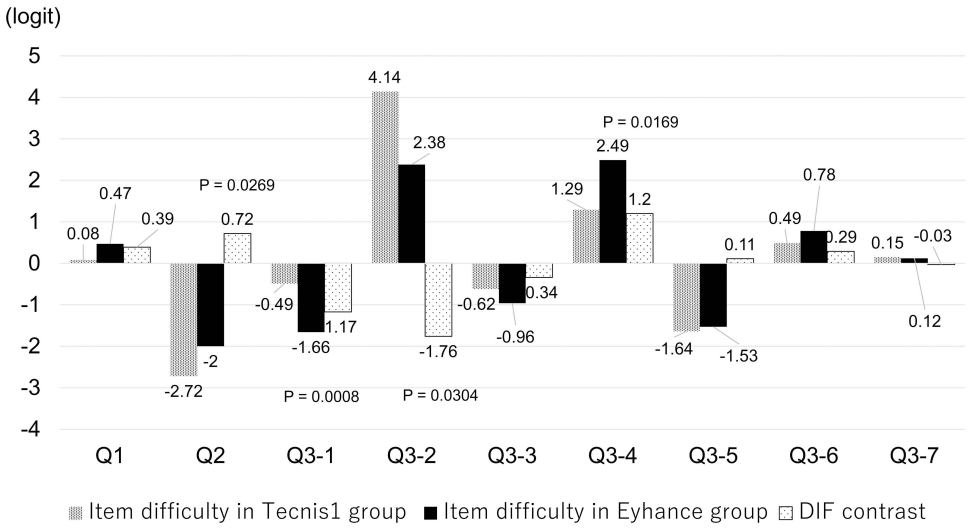

Figure 1 The Differential Item Functioning (DIF) of each item in the Japanese modified Catquest-9SF Questionnaire for the two intraocular lens (IOL) groups The corresponding *p*-values for group comparisons are provided when the absolute value of DIF contrast exceeds 0.5 logits. A higher score for questionnaire items indicates lower difficulty. In this figure, the DIF contrasts are presented as the value of the Tecnis-1 group subtracted from the Eyhance group. A positive difference suggests that the Eyhance group finds the items less difficult, or patients are more satisfied in the Eyhance group than in the Tecnis-1 group.

Discussion

This study prospectively compared the outcomes of Eyhance and Tecnis-1 IOL in combined vitrectomy and cataract surgery for ERM from both clinical and patient-reported perspectives. Overall, the Eyhance group showed comparable clinical outcomes in terms of postoperative BCDVA, DCIVA, UCDVA, and UCIVA. Because multifocal IOLs have raised concerns about reduced visibility during ERM surgery and its potential impact on macular manipulation,[7] we compared total operative times and macular manipulation time to investigate whether similar concerns apply to enhanced monofocal IOLs, which are designed to extend depth of focus using a different optical concept from multifocal IOLs.[8] The results showed no significant differences in total operative time or macular manipulation time compared to conventional monofocal IOLs. These findings are consistent with the previous clinical study and experimental results using model eyes under a non-contact wide-angle viewing system.[30,35] In particular, a subgroup analysis of patients with some degree of myopia demonstrated better DCIVA in the Eyhance group, while BCDVA remained consistent between groups. In addition to these clinical outcomes, PROMs were assessed using Rasch analysis of the Japanese-modified Catquest-9SF Questionnaire. This analysis revealed that general patient satisfaction was significantly higher in the Eyhance group compared to the Tecnis-1 group.

Our results reflect the mixed findings in previous literature: while some RCTs reported meaningful improvements in intermediate visual acuity with Eyhance,[10–16,18] others found only minimal differences.[20–22] Also, a study in Japan comparing functional visual acuity, which reflects changes in visual function in various conditions, found no significant differences at intermediate distances.[23] On the other hand, regarding combined surgery for ERM and cataracts, three previous single-centered, non-randomized studies have shown a significant improvement in intermediate visual acuity with Eyhance compared to Tecnis-1 even after combined surgery for ERM.[28–30] However, there were no significant differences in DCIVA in the Eyhance group in the current and another similar study.[27] To explain this discrepancy, it is important to consider differences in study design and patient characteristics. Regarding this study, this discrepancy is possibly due to the baseline characteristics of the patient group. Specifically, although not statistically significant, the Eyhance group had a trend toward lower preoperative corneal astigmatism compared to the Tecnis-1 group. Another possible factor is the difference in refractive targets between studies. Previous studies generally aimed at achieving the predicted post-operative refraction closest to emmetropia,[28–30] whereas the IOL target was not disclosed in the other study, and our study could include cases in which the target at mild myopia because the selection of IOL types and power was based on the original rules of each facility.[27] The refraction of preoperatively myopic patients could be targeted toward myopia rather than emmetropia, since a certain percentage of myopic patients prefer to see near distances without spectacles.[36,37] Such imbalances in preoperative

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characteristics and IOL target settings could have contributed to the absence of a significant difference in DCIVA, representing a major limitation of the study.

In addition to the above considerations, when comparing postoperative visual acuity among different IOLs within subgroups based on preoperative spherical error of −1.5 D, both UCIVA and DCIVA tended to be better in the more myopic subgroup. Since this study used 70 cm of intermediate visual acuity as the endpoint, we set −1.5 D with a focal length of about 70 cm as the cutoff for the two subgroups. These findings suggest the potential benefit of using Eyhance for improving intermediate vision, despite postoperative refraction being more emmetropic. However, the possibility of selection effects from non-standardized IOL targeting remains, so follow-up studies are needed.

In this study, Rasch analysis enabled more accurate assessment of patient satisfaction and functional vision, accounting for item difficulty and patient ability on a unified scale.[32] In addition to the previously established validity of the Rasch analysis of the Japanese modified Catquest-9SF in cataract surgery,[31] the current analysis adhered to the assumptions of the Rasch analysis in terms of the Infit MNSQ and Outfit MNSQ, except for one question item (Q3-2).

Although no significant differences were observed between the two IOL groups in total patient ability scores, comparisons using DIF analysis revealed significant differences in several items. Despite the expected extended depth of focus with Eyhance, two items that were believed to assess near (Q3-1) or intermediate (Q3-2) distance vision were more difficult (higher logit of items) in the Eyhance group than in the Tecnis-1 group. Some previous studies comparing the results of the Catquest-9SF Questionnaire between Tecnis-1 and Eyhance in cataract surgery have reported better outcomes in the Eyhance group.[12,13] However, our present results showed an opposite trend. This may be attributed to the more myopic postoperative spherical power in the Tecnis-1 group compared to the Eyhance group, as residual myopia can improve near or intermediate vision. Although the item Q3-4 "Seeing to walk on uneven surfaces, eg cobblestones" was significantly less challenging in the Eyhance group, it may not accurately reflect overall visual function. This is because previous studies of the Japanese modified Catquest-9SF Questionnaire,[31] and the Catquest-9SF in other countries have shown a poor fit to the Rasch model.[38,39] Remarkably, Q2, which asks about general patient satisfaction, showed significant improvement in the Eyhance group. Even if there is no significant difference in visual acuity, and even if there is a possibility of experiencing difficulty seeing in specific situations related to items Q3-1 and Q3-2, this suggests Eyhance improved overall visual quality.

In the person-item map of the Eyhance group (Figure S1), we observed two peaks around −3 and −5 logits in the distribution of patients' abilities. Therefore, we divided the participants at the third quartile (−4.730 logits) to investigate the characteristics within this distribution, but no differential trend was identified. Although it remains uncertain whether such a distribution is limited to participants in this study, patients with ERM characteristics suitable for Eyhance are expected to be elucidated.

In this study, several limitations remained. Because this was a non-randomized prospective study, the possibility of selection bias cannot be ruled out. Randomized controlled trials are needed to enable more balanced comparisons. This study recruited only Japanese patients from Japanese hospitals, so the results may not apply in the same way to people from other countries or ethnic backgrounds. The number of patients finally included in the analysis as Tecnis-1 group did not meet the predetermined sample size, 70. Case enrollment was completed with a total of 151 cases, with more than 70 cases enrolled in each group; however, the final number was insufficient due to exclusion criteria and missing values. This might have affected the final statistical analysis. The lack of preoperative data in the questionnaire prevents pre- and postoperative comparisons. There were multiple surgeons, and the detailed procedures were not standardized. CMT was measured using different devices at each institution, and ERM stages were not classified to allow matching between the two IOL groups in this study.[40,41] These points were limitations of the multi-centered study. The standardization of ERM grading and OCT devices could improve reproducibility of study. The Japanese-modified Catquest-9SF Questionnaire was translated by Japanese ophthalmologists, without undergoing back-translation. Thus, it cannot be directly compared with other language versions. In addition, the Catquest-9SF Questionnaire is designed for cataract surgery, and further examination is needed to determine if it can be appropriately used for ERM.

Conclusions

In a real-world clinical setting in Japan, Eyhance demonstrated postoperative visual acuity and surgical parameters comparable to those of the conventional monofocal IOL in patients undergoing combined ERM and cataract surgery. Notably, in patients with preoperative myopia, Eyhance may offer an additional benefit in enhancing intermediate vision. Moreover, patient-reported outcomes indicated significantly higher general satisfaction in the Eyhance group.

Data Sharing Statement

The datasets generated during the current study are available from the corresponding author on reasonable request.

Ethics Approval and Informed Consent

The procedures of this study conformed to the tenets of the Declaration of Helsinki and were approved by each facility's institutional review board/ethics committee: Nagoya University Graduate School of Medicine (approval number 2022-0092), Fujita Health University School of Medicine (approval number HM22-405), Miyake Eye Clinic (approval number 2022-003), Kariya Toyota General Hospital (approval number 790), Nishio Municipal Hospital (approval number 102), Ichinomiya Municipal Hospital (approval number 1329). All participants provided informed consent.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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