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ORIGINAL RESEARCH

Biometric Indicators for Maximizing Intermediate Vision with a Monofocal IOL

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Purpose: To determine refractive or biometric variables that might be predictive of increased intermediate vision in patients receiving an Eyhance monofocal intraocular lens (IOL).

Methods: This prospective, single-center, bilateral, non-randomized, open-label, observational study included a total of 110 subjects (220 eyes). Subjects had been previously bilaterally implanted with an Eyhance monofocal IOL (Johnson & Johnson Vision Care, Inc.) and were later divided into 2 groups based on their postoperative visual acuity. Subjects that had binocular distance corrected intermediate visual acuity (DCIVA) of 0.2 logMAR or better were classified into the Enhanced Group, and the remaining subjects were classified into the Non-Enhanced Group. Refractive outcomes and biometric measurements were compared between groups.

Results: The number of subjects in each group was 61 for the Enhanced Group, and 49 for the Non-Enhanced Group. There were significant differences in pupil size between groups, with pupil sizes in the Enhanced Group significantly smaller than in the Non-Enhanced Group ($p < 0.01$). Subjects also reported significantly more dysphotopsias in the Non-Enhanced Group compared to the Enhanced Group ($p = 0.03$). Multiple regression analysis identified pupil size and axial length as significant predictors of increased monocular intermediate vision.

Conclusion: The results of this study suggest that pupil size could be a predictor of increased intermediate vision in a patient receiving an Eyhance monofocal IOL.

Plain Language Summary: Cataract surgery involves removing an opaque natural lens and replacing it with a clear artificial lens. These artificial lenses are called intraocular lenses (IOLs). There are many different types of IOLs, and each type provides varying degrees of clear vision at far, intermediate, and near distances. Clear vision at intermediate distance is especially important for viewing digital devices. One type of monofocal IOL, the Eyhance (Johnson & Johnson Vision Care, Inc.) was designed to improve the depth of focus. However, it is not well understood why some patients experience increased intermediate vision and some patients do not. The purpose of this study was to determine refractive or biometric variables that might be predictive of increased intermediate vision in patients receiving an Eyhance monofocal IOL. The results of this study suggest that pupil size could be a predictor of increased intermediate vision, and patients with smaller pupils may be more likely to experience increased intermediate vision.

Keywords: cataract surgery, Eyhance, aspheric, intermediate visual acuity

Introduction

In cataract surgery, the most frequently implanted intraocular lenses (IOL) are monofocal lenses. Monofocal IOLs generally provide good visual acuity at distance, relatively low visual disturbances, and have a lower cost than advanced technology lenses. However, patients with monofocal IOLs almost universally still require spectacles to see clearly at intermediate or near distances. Functional intermediate vision is increasingly important for patients,[1,2] especially with the widespread use of digital devices. There are two main types of IOLs that attempt to provide functional intermediate visual acuity. The first are trifocal IOLs, which split incoming light into distinct foci to provide good visual acuity at

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distance, intermediate, and near,[3–5] but may also increase dysphotopsias compared to a monofocal IOL.[6] The second are extended depth of focus (EDOF) IOLs, which create a continuous focal point for good visual acuity at distance, intermediate, and near,[7,8] but may also suffer from increased reports of dysphotopsias compared to monofocal IOLs.[6]

The Tecnis Eyhance (Johnson & Johnson Vision Care, Inc.) is a novel monofocal IOL that entered the market as a level A modification of the ZCB00 IOL and was designed to slightly extend the depth of focus. The higher-order aspheric Eyhance IOL utilizes a continuous power change from the periphery to the center of the IOL.[9] On the anterior surface of the IOL, the center optic is approximately 2 mm in diameter and 1.5 µm thick.[10] This center optic has been reported to increase negative spherical aberration to allow for increased intermediate visual acuity.[11–13] Clinical and refractive outcomes with the Eyhance IOL have been reported to deliver patients functional intermediate vision, good distance vision, and low dysphotopsias.[14–18] However, as with any IOL, there is a range for the clinical and refractive outcomes. For binocular intermediate visual acuity, this range has been reported from 0.00 to 0.40 logMAR.[14,15,17] The Eyhance is a relatively new IOL, and there is a lack of understanding of which patients could receive enhanced intermediate vision with this lens. The purpose of this study was to determine any refractive or biometric findings or measurements that could indicate increased intermediate vision in a patient receiving an Eyhance IOL.

Methods

This was a non-interventional, prospective, single center, bilateral, non-randomized, open-label, observational clinical study of the factors influencing good distance vision with enhanced visual acuity at intermediate and near with a new monofocal IOL. This study was reviewed and approved by an institutional review board (WCG IRB, approval number 1326375) and all subjects gave written informed consent. The study was conducted in accordance with the tenets of the Declaration of Helsinki, Good Clinical Practice (GCP), and International Harmonization (ICH) guidelines. The study was also registered on clinicaltrials.gov (NCT05611073). Data are not available for sharing.

Inclusion criteria for the study were adults (≥40 years of age) who had previously undergone uncomplicated cataract removal by phacoemulsification with a clear corneal incision in both eyes, received implantation of bilateral Eyhance IOLs (DIB00/DIUxxx; Johnson & Johnson Vision Care, Inc.), corrected distance visual acuity of 0.1 logMAR or better, with clear intraocular media, and, if there was visually significant posterior capsular opacification (PCO), a minimum of two-weeks post Nd:YAG capsulotomy. Exclusion criteria were any corneal abnormality (other than regular corneal astigmatism) that could confound the outcomes of the study, presence of or a predisposition to vision-reducing retinal conditions, amblyopia or strabismus, history of or current anterior or posterior segment inflammation, neovascularization on or within the eye, uncontrolled or controlled glaucoma, any degenerative eye disorder, or an acute or chronic disease or illness that would confound the results of this investigation (eg immunocompromised, connective tissue disease, clinically significant atopic disease).

Subjects had one assessment visit, at least 3 months after uncomplicated cataract surgery. At this visit demographic information was collected as well as a manifest refraction, monocular and binocular distance-corrected visual acuity at distance (CDVA), intermediate (DCIVA, 66 cm), and near (DCNVA, 40 cm), automatic (iTrace 7.0, Tracey Technologies) and manual pupil (VIP-300, NeurOptics) measurements under photopic and mesopic conditions, biometry using the IOLMaster 700 (Carl Zeiss Meditec AG), Atlas 9000 topography, imaging with the iTrace, and a questionnaire was administered. Subjects were split into 2 groups based on postoperative binocular DCIVA. Subjects that had DCIVA of 0.2 logMAR or better were classified as “distance with enhanced intermediate” (Enhanced Group), and the remaining subjects were classified as “distance with minimal intermediate” (Non-Enhanced Group). All biometric measurements were done under the same light setting as visual acuity measurements for consistency.

The primary endpoint was to compare demographic, biometric, refractive, and visual acuity data between the 2 groups. The secondary endpoint was to compare responses on a questionnaire between groups. The exploratory endpoint was to determine if there are preoperative factors that could predict if patients could have enhanced intermediate vision with the Eyhance IOL.

The statistical software R (version 4.2.2; The R Foundation for Statistical Computing, Vienna, Austria) was used for statistical analysis. Normality was assessed using the Shapiro Wilk test. Comparisons of parametric data were performed using a Welch two sample *t*-test, comparisons of non-parametric data were performed using the Wilcoxon rank sum test, and comparisons of categorical data were performed using Pearson's chi-squared test. A p-value ≤0.05 was considered significant for all statistical tests; however, p-values were adjusted using the Holm–Bonferroni correction to control the family-wise error rate. We estimated that the study would require a sample size of 110 subjects (220 eyes) for the multiple regression analysis, using the formula N = 50 + 8(m),[19] where m is the number of variables.

Results

A total of 110 subjects (220 eyes) completed the study. The demographic data are shown in Table 1. More participants were classified into the Enhanced Group (61) compared to the Non-Enhanced Group (49). Approximately, equal numbers of female (58) and male (52) participants were included in the study overall; however, there was a higher percentage of male subjects that were classified into the Enhanced Group (60.7% compared to 30.6%). This difference was significant (p = 0.003). The ages of subjects in the two groups were similar (p > 0.05).

Table 2 summarizes the refractive outcomes. The manifest refractions were similar between groups, with the Non-Enhanced Group having an average MRSE −0.36 ± 0.79 D compared to −0.17 ± 0.73 D in the Enhanced Group, though the difference was not significant (p > 0.05). Keratometry and total keratometry readings were also similar and not significantly different between groups (p > 0.05).

The biometric measurements are summarized in Table 3. Of the biometric data compared, only the 3 measurements of pupil size were significant after the Holm-Bonferroni adjustment. This includes the pupil size measurements obtained manually, automatically, and using the IOLMaster 700 under mesopic conditions. These differences also appeared clinically relevant and ranged from 0.40 to 0.52 mm. There were no significant differences in Q values between groups.

Table 1 Subject Demographics

Demographic Factor	Enhanced	Non-Enhanced
Eyes (Participants)	122 (61)	98 (49)
Sex		
Female N (Percentage)	24 (39.3)	34 (69.4)
Male N (Percentage)	37 (60.7)	15 (30.6)
Age Mean ± SD (Range)	69.8 ± 7.3 (54 to 90)	69.6 ± 6.5 (51 to 83)

Abbreviation: SD, standard deviation.

Table 2 Refractive Outcomes

Refractive Outcomes	Enhanced Mean ± SD (Range)	Non-Enhanced Mean ± SD (Range)	P value	P Adjusted
Sphere (D)	0.00 ± 0.75 (−2.50 to 2.25)	−0.16 ± 0.82 (−2.50 to 1.25)	0.148	1.000
Cylinder (D)	−0.34 ± 0.37 (−1.50 to 0.00)	−0.40 ± 0.42 (−2.00 to 0.00)	0.318	1.000
MRSE (D)	−0.17 ± 0.73 (−2.50 to 1.75)	−0.36 ± 0.79 (−2.75 to 1.25)	0.099	1.000
K Astigmatism (D)	1.11 ± 0.69 (0.00 to 3.47)	1.28 ± 0.83 (0.11 to 4.08)	0.156	1.000
K Average (D)	43.79 ± 1.66 (40.60 to 47.52)	44.01 ± 1.49 (40.17 to 47.54)	0.227	1.000
TK Astigmatism (D)	1.14 ± 0.75 (0.14 to 2.98)	1.34 ± 0.88 (0.00 to 3.64)	0.097	1.000
TK Average (D)	43.64 ± 1.64 (40.22 to 47.37)	43.91 ± 1.43 (40.33 to 47.11)	0.091	1.000

Note: P values were determined with the Wilcoxon rank sum test and were adjusted using the Holm–Bonferroni correction.
Abbreviations: D, diopters; K, keratometry; TK, total keratometry; MRSE, manifest refraction spherical equivalent; SD, standard deviation.

Table 3 Biometric Measurements

Biometric Outcomes	Enhanced Mean ± SD (Range)	Non-Enhanced Mean ± SD (Range)	P value	P Adjusted
Anterior Chamber Depth (mm)	3.19 ± 0.41 (2.23 to 4.8)	3.25 ± 0.32 (2.52 to 3.90)	0.135	1.000
Axial Length (mm)	24.34 ± 1.52 (21.27 to 28.61)	24.33 ± 1.36 (22.06 to 28.97)	0.841	1.000
Central Corneal Thickness (μm)	549.89 ± 33.00 (469 to 630)	547.95 ± 37.39 (439 to 654)	0.601	1.000
Pupil Size IOLMaster 700 (mm)	3.60 ± 0.77 (2.10 to 5.70)	4.00 ± 0.88 (2.00 to 6.60)	0.001	0.014
Pupil Size Automated (mm)	3.64 ± 0.77 (2.14 to 5.78)	4.16 ± 0.77 (2.53 to 5.93)	0.000	0.000
Pupil Size Manual (mm)	4.29 ± 0.75 (2.60 to 6.19)	4.75 ± 0.76 (2.76 to 6.70)	0.000	0.001
Q Value	−0.31 ± 0.18 (−0.70 to 0.33)	−0.34 ± 0.23 (−0.80 to 0.59)	0.032	0.576
Higher Order Aberrations (RMS)	0.67 ± 0.30 (0.30 to 2.7)	0.65 ± 0.25 (0.40 to 1.80)	0.594	1.000
Lower Order Aberrations (RMS)	1.13 ± 0.72 (0.00 to 3.6)	1.31 ± 0.88 (0.10 to 4.10)	0.194	1.000
Total Aberrations (RMS)	1.36 ± 0.70 (0.50 to 3.7)	1.52 ± 0.81 (0.50 to 4.50)	0.101	1.000
Spherical Aberration (RMS)	0.31 ± 0.15 (−0.13 to 0.91)	0.29 ± 0.16 (−0.02 to 1.14)	0.094	1.000

Notes: P values were determined with the Wilcoxon rank sum test and were adjusted using the Holm–Bonferroni correction. Pupil sizes were obtained under mesopic conditions.
Abbreviation: RMS, root mean square; SD, standard deviation.

The difference in Q Value between groups also appears to be clinically insignificant. Approximately, 250 variables exported from the iTrace were also compared between groups but were not significant ($p > 0.05$).

Table 4 summaries the monocular and binocular visual outcomes between groups. Monocular and binocular visual acuities at distance (uncorrected and corrected) were similar between groups ($p > 0.05$). Monocular and binocular visual

Table 4 Postoperative Visual Outcomes

	Enhanced Mean ± SD (Range)	Non-Enhanced Mean ± SD (Range)	P value	P Adjusted
Monocular (logMAR)				
CDVA	0.03 ± 0.05 (0.00 to 0.14)	0.05 ± 0.05 (0.00 to 0.14)	0.033	0.065
DCIVA	0.21 ± 0.11 (0.00 to 0.60)	0.37 ± 0.12 (0.16 to 0.70)	0.000	0.000
DCNVA	0.38 ± 0.19 (0.00 to 0.86)	0.51 ± 0.21 (0.06 to 1.00)	0.000	0.000
UDVA	0.16 ± 0.17 (0.00 to 0.88)	0.20 ± 0.19 (0.00 to 0.96)	0.062	0.065
UIVA	0.22 ± 0.16 (0.00 to 0.98)	0.29 ± 0.16 (0.00 to 0.90)	0.000	0.001
Binocular (logMAR)				
CDVA	0.01 ± 0.02 (0.00 to 0.10)	0.03 ± 0.04 (0.00 to 0.14)	0.061	0.121
DCIVA	0.12 ± 0.07 (0.00 to 0.20)	0.30 ± 0.07 (0.22 to 0.46)	0.000	0.000
DCNVA	0.29 ± 0.15 (0.00 to 0.72)	0.41 ± 0.20 (0.06 to 0.80)	0.004	0.017
UDVA	0.08 ± 0.10 (0.00 to 0.54)	0.09 ± 0.09 (0.00 to 0.44)	0.264	0.264
UIVA	0.12 ± 0.12 (0.00 to 0.46)	0.18 ± 0.12 (0.00 to 0.48)	0.007	0.020

Note: P values were determined with the Wilcoxon rank sum test and were adjusted using the Holm–Bonferroni correction.
Abbreviations: CDVA, corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity; DCNVA, distance-corrected near visual acuity; logMAR, log of minimum angle of resolution; SD, standard deviation; UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity.

Table 5 Questionnaire Responses

Question	Group	Percentage of Responses				
		Never	Rarely	Occasionally	Frequently	Always
Over the last week, how often did you experience glare, halos, or starbursts?	Enhanced	66	2	11	21	0
	Non-Enhanced	45	16	12	24	2
Over the last week, how often did you use glasses for distance vision (6 feet or more away)?	Enhanced	84	3	5	2	7
	Non-Enhanced	69	6	2	12	10
Over the last week, how often did you use glasses for intermediate vision (2 to 6 feet away)?	Enhanced	59	7	3	10	11
	Non-Enhanced	55	6	10	14	14
Over the last week, how often did you use glasses for near vision (within 2 feet away)?	Enhanced	30	23	3	11	33
	Non-Enhanced	24	16	12	10	37

acuities at intermediate were significantly better in the Enhanced Group, though this is expected since DCIVA was used as the criteria to classify subjects into either of the two groups. Mean monocular and binocular DCNVA were 0.13 and 0.12 logMAR better in the Enhanced Group compared to the Non-Enhanced Group, respectively ($p < 0.02$).

The distribution of responses on the administered questionnaire is shown in Table 5. In the Enhanced Group, 68% of respondents indicated Never or Rarely experiencing glare, halos, or starbursts, compared to 61% in the Non-Enhanced Group. The differences in the distribution of responses were significant ($p = 0.03$). Generally, subject-reported spectacle independence at distance, intermediate, and near were higher in the Enhanced Group, though the differences were not significant ($p > 0.05$).

This study was powered for a regression analysis for 6 variables. The independent variables investigated were pupil size (automated), Q value, spherical aberration, anterior chamber depth, axial length, and average K power. For increased predictability, monocular DCIVA was used as the dependent variable. A stepwise multiple regression selected pupil size (automated) and axial length as the variables in the final model. Table 6 summarizes the coefficients in the final regression model. Using these coefficients, predicted monocular logMAR DCIVA for a patient eye is calculated as DCIVA = 0.223 + 0.062*Pupil.size.automated + −0.011*Axial.Length. The coefficient for pupil size was positive, while the coefficient for axial length was negative, indicating that eyes with smaller pupil sizes and longer axial lengths are more likely to get enhanced intermediate visual acuity. The final model had a R Squared of 0.17.

Discussion

This study compared refractive, visual, and biometric variables between subjects that experienced versus those who did not experience enhanced intermediate vision with the Eyhance IOL. To the best of our knowledge, this is the first such report. We did not observe any significant differences in refractive outcomes between the two groups. Auffarth et al[20] reported on the refractive outcomes between the Eyhance and the Tecnis monofocal IOL (Johnson & Johnson Vision Care, Inc.). The authors observed no differences in postoperative refraction between the two IOL groups, concluding that

Table 6 Final Model Coefficients

	Estimate	Standard Error	t value	P value
Intercept	0.223	0.117	1.906	0.058
Pupil Size Automated (mm)	0.062	0.009	6.938	< 0.001
Axial Length (mm)	−0.011	0.005	−2.187	0.030

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refraction does not play a role in the enhancement of intermediate visual acuity with the Eyhance. Other studies have reported improved intermediate visual acuity with the Eyhance compared to a monofocal, but with similar postoperative refractive outcomes between the lenses,[17,21,22] also suggesting that refraction does not play a role in the enhancement of intermediate visual acuity with the Eyhance. The results of our study and other studies support the conclusion that postoperative refraction is not a significant factor for enhanced intermediate visual acuity.

Of the postoperative biometric outcomes compared between the Enhanced and Non-Enhanced Groups, only pupil size was significantly different between groups. For each measurement of pupil size (automated, manual, and IOLMaster 700) the Enhanced Group had a smaller mean pupil size than the Non-Enhanced Group, suggesting that a smaller pupil size could lead to better visual outcomes at intermediate. A likely explanation is that there is an increase in the depth of focus with a small pupil size.[23] Pupil size may also explain the higher proportion of male subjects in the enhanced group, as male patients after cataract surgery have been reported to have smaller pupil sizes than female subjects after cataract surgery.[24] Vega et al[25] investigated the in vitro optical performance of the Eyhance and reported that small pupil sizes (<3.5 mm) had a large impact on the optical performance of the Eyhance compared to a monofocal, but larger pupil sizes did not. In addition, the authors observed a −0.40 D myopic shift with the Eyhance lens at a 2 mm pupil compared to a 3 mm or 4.5 mm pupil. Pieh et al[26] also observed a myopic shift with the Eyhance with a 3 mm pupil compared to a 4.5 mm pupil in vitro. The results of our study and other studies suggest that a smaller pupil size could lead to enhanced intermediate visual acuity with the Eyhance.

To the best of our knowledge, this is the first report of a model predicting monocular intermediate visual acuity with the Eyhance. Our model included pupil size and axial length as predictors of monocular intermediate visual acuity, though the coefficient was larger for pupil size. This is supported by the results of our study and other studies that have looked at the effect of pupil size on the performance of the Eyhance.[25,26] For example, our model predicts that a patient eye with an axial length of 24.2 mm would have a monocular intermediate visual acuity of 0.20 logMAR with a 4.0 mm pupil and 0.08 logMAR with a 2.0 mm pupil. The effect is much lower for axial length. The model predicts a 1 letter improvement in intermediate visual acuity for an eye with axial length 24.5 mm compared to 22.5 mm. We acknowledge the limitation that this model was built with data from a single center and remains untested with data from other centers. However, it may serve as a useful tool for surgeons to roughly predict the intermediate vision with Eyhance for a particular patient eye.

Another limitation of this study was that subjects were grouped based on binocular visual acuity, though they were compared based on monocular refractive and biometric outcomes. This was done because biometric measurements can only be monocular, but binocular DCIVA is what is functionally most important. It is worth noting that we performed a separate analysis using monocular visual acuity to group subjects (not reported for the sake of brevity). This analysis also revealed that pupil size was the only variable that was significantly different between groups.

In conclusion, the results of this study suggest that pupil size could be used as a predictor of enhanced intermediate vision in a patient receiving an Eyhance IOL.

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