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Original article

Assessment of visual performance and quality of life obtained with two extended depth of focus simultaneous vision lens platforms

Análisis del rendimiento visual y calidad de vida de dos plataformas de lentes de visión simultánea con profundidad de foco extendido

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ABSTRACT

Introduction and objectives: To assess differences in visual performance after implantation of two extended depth-of-focus simultaneous vision intraocular lenses (IOLs) with different optical designs.
Patients and methods: A randomised prospective comparative interventional study in patients requiring cataract surgery for both eyes. Patients were divided into two groups: one given biconvex IOLs (Tecnis Eyhance™, Johnson & Johnson Vision Care, Inc, Jacksonville, FL, USA) and the other inverted meniscus IOLs (ArtIOLs®25, Voptica, Murcia, Spain). One month after the surgical intervention in the second eye, the binocular distance-corrected visual acuity was measured at far, intermediate (66 cm), and near (40 cm) distances. Additionally, binocular distance-corrected defocus curves were obtained. Potential correlations of intermediate visual acuity (VA) with corneal spherical aberration (Z_4°) and pupil size were explored. The Catquest-9SF questionnaire was administered to all patients to assess their vision-related quality of life after IOL implantation.
Results: Overall, 30 patients (60 eyes) were assessed. Binocular distance corrected intermediate visual acuities of 0.20 logMAR (0.10;0.30) ($p = 0.445$), were achieved in both groups. The binocular distance corrected near visual acuity was 0.3 logMAR (0.25; 0,40) in the Tecnis Eyhance™ group and 0.4 logMAR (0.30;0.50) in the ArtIOLs®25 group ($p = 0.050$). Intermediate visual acuity was weakly correlated with corneal spherical aberration and pupil size. The Catquest-9SF score was close to 1 in both groups, but better in the Eyhance group, and the difference was statistically significant ($p = 0.035$).
Conclusions: Both the Tecnis Eyhance™ and ArtIOLs®25 IOLs achieved a binocular distance-corrected intermediate VA of 0.2 logMAR, without compromising distance VA. No differences were observed between the two groups in the outcomes experienced by patients in their daily lives related to their vision problems after cataract surgery.

Palabras clave:
Profundidad de foco
Agudeza visual intermedia
Calidad de vida

RESUMEN

Introducción y objetivos: El propósito del presente estudio es analizar las diferencias en el rendimiento visual al implantar dos lentes intraoculares (LIOs) de visión simutánea con profundidad de foco extendida y diseños ópticos diferentes.
Pacientes y métodos: Estudio intervencional prospectivo comparativo aleatorio. Se incluyeron pacientes que precisan cirugía de catarata en ambos ojos. Los pacientes se dividieron en dos grupos: uno con LIO biconvexa (Tecnis Eyhance™, Johnson & Johnson Vision Care, Inc, Jacksonville, FL, USA) y el otro grupo con LIO de menisco invertido (ArtIOLs®25, Voptica, Murcia, Spain). Al mes tras la cirugía del segundo ojo, se determinó la agudeza visual de lejos, intermedia (66 cm) y cerca con la corrección de lejos. Así mismo, se determinó la curva de desenfoque binocular corregida para visión lejana. Se estableció la existencia o no de correlación entre la aberración esférica corneal (Z_4°) y el diámetro pupilar con la agudeza visual intermedia. El Cuestionario de Calidad de Vida relativa a la visión (Catquest-9SF) fue presentado a todos los pacientes para valorar la calidad de vida tras el implante de las IOLs.

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Resultados: Se analizaron 30 pacientes (60 ojos), 15 pacientes en el grupo Tecnis Eyhance™ y a otros 15 pacientes en el grupo ArtIOL®25. En ambos grupos se alcanzó una agudeza visual intermedia binocular corregida para visión lejana de 0,20 logMAR (0,10; 0,30) (p = 0,445). La agudeza visual cercana binocular corregida para visión lejana fue de 0,3 logMAR (0,25; 0,40) en el grupo Tecnis Eyhance™ y de 0,4 logMAR (0,30; 0,50) en el grupo ArtIOLs®25 (p = 0,050). No se encontró correlación entre la aberración esférica corneal, el diámetro pupilar y la AV intermedia. La puntuación Catquest-9SF fue cercana a 1 en ambos grupos, pero mejor en el grupo Tecnis Eyhance™, y la diferencia fue estadísticamente significativa (p = 0,035).
Conclusiones: Tanto la IOL Tecnis Eyhance™ como la ArtIOL®25 proporcionan una AV intermedia binocular corregida para visión lejana de 0.2 logMAR, sin perjuicio de la visión lejana. No se observaron diferencias entre los dos grupos, en los resultados que experimentan los pacientes en su vida diaria relacionados con sus problemas de visión después la cirugía de cataratas.

Introduction

Over the past few years, the number of intraocular lens (IOLs) designs has been growing, providing lenses that improve distance, and/or intermediate and/or near visual acuity (VA). Compared to monofocal lenses, it is known that bifocal lenses achieve good distance and near VA and that diffractive trifocal lenses further improve the outcome for intermediate VA. These lenses improve VA at different distances, but they are often associated with a series of photic phenomena (halos and glare) that may compromise the VA achieved.[1,2]

Various types of IOLs are now available that manage to improve intermediate VA without the quality of distance vision being compromised by photic phenomena. These types of IOLs have been classified in different ways, some classifications describing them as monofocal extended depth-of-focus (EDOF) IOLs [3,4] and others as monofocal plus or enhanced monofocal IOLs.[5] The International Organization for Standardization (ISO) classifies these lenses within the group of simultaneous vision lenses as EDOF IOLs.[6] The basic optical principle of EDOF IOLs is the creation of a single, continuous, elongated focal point, enhancing depth of focus without compromising distant vision.[6,7] Various approaches exist for designing EDOF IOLs, including the creation of concentric optical zones, modification of spherical aberration (SA), and use of small aperture designs and hybrids.[3]

Currently, several classifications for intraocular lenses (IOLs) are available. One is established by the (ISO),[6] another is the functional classification proposed by the European Society of Cataract and Refractive Surgeons (ESCRS),[8] and finally, some authors have developed specific classifications for extended depth of focus (EDOF) IOLs.[3,4]

In our setting, cataract surgery is the most common type of surgical intervention among older adults. With EDOF IOLs, it becomes possible to not only improve distance vision but also improve intermediate vision without photic phenomena.[9,10] This implies improving both quality of vision and quality of life in patients with cataracts.

The purpose of this study was to analyse differences in the visual performance of EDOF IOLs in terms of binocular distance-corrected far, intermediate and near VA. We compared two groups in which IOLs with different geometries were used: patients in one group received Tecnis Eyhance™, Johnson & Johnson Vision Care, Inc, Jacksonville, FL, USA lenses, while those in the other group received ArtIOLs®25, Voptica, Murcia, Spain lenses. One month after surgery, we evaluated differences between groups in terms of VA and quality of life.

Patients and methods

This was a randomised prospective comparative interventional study conducted in accordance with good clinical practice and the principles of the Declaration of Helsinki. The study was approved by the clinical research ethics committee of the Basque Country (CEIm-E, reference: PS2022002).

In our study, we adopted the ISO classification, acknowledging that according to the ESCRS system, the lenses analyzed would be categorized as “simultaneous vision-partial range of field-enhance”.

Due to the spherical aberration they produce, these types of lenses have a greater depth of focus than monofocal IOLs.[11–13] The biconvex Tecnis Eyhance™ IOLs enhance the depth of focus by using a modified aspheric anterior surface that increases lens power within the central 1-mm diameter of the optic, while their peripheral power profile compensates for corneal spherical aberrations, maintaining comparable distance image quality to traditional monofocal IOLs.[14] On the other hand, ArtIOLs® lenses employ a traditional yet effective method of inducing negative spherical aberration to extend the depth of focus through an elongated focal area.[11–13] Traditionally, intraocular lenses are biconvex, focusing primarily on on-axis image quality without addressing peripheral optical quality. In contrast, the ArtIOLs® have an inverted meniscus design to reproduce the natural imaging properties of the crystalline lens that enhances peripheral optical quality, thereby improving peripheral contrast sensitivity detection.[15–17]

Technical specifications of each of the IOLs are summarised in Table 1 , and diagrams illustrating the different designs of the lenses are provided in Fig. 1.

Patients

We included patients who, according to the cataract surgery waiting lists of the Department of Ophthalmology at Cruces University Hospital, required surgery in both eyes. Patients eligible for inclusion were provided information about the study and asked to sign the informed consent form, agreeing to receive either Tecnis Eyhance™ or ArtIOLs®25 IOLs depending on the group to which they had been randomly assigned. To have the same number of subjects in both groups, we used balanced block randomization.

Exclusion criteria were: more than 1 diopter of astigmatism or a history of corneal or retinal disease, any history of corneal or retinal surgery, intraoperative complications or amblyopia. The physical examination before inclusion on the surgical waiting list and postoperative treatment were carried out following the protocol established in the Department of Ophthalmology at Cruces University Hospital.

Preoperative examinations

Before surgery, the corneal spherical aberrations (Z_4°) at a diameter of 6 mm and pupil size were measured by tomography using a Pentacam HR (high-resolution) camera system (Oculus Optikgeräte GmbH, Wetzlar, Germany).

Optical biometric measurements were taken by the same researcher (BLE) in all patients using an IOLMaster 700 ocular biometry system (Carl Zeiss Meditec AG) and the SRK/T formula, with A constants of 119.3 and 120 for the Tecnis Eyhance™ and ArtIOLs®25, respectively. In all cases, the IOL power was selected with the aim of achieving emmetropia.

Table 1
Characteristics of the intraocular lenses.

	Tecnis Eyhance™	ArtIOLs®25
Design	Single-piece Biconvex shape with continuous anterior aspheric surface (Z_4° at 6 mm: −0.27 μm).	Inverted meniscus shape with negative spherical aberration Both surfaces are aspherical (Z_4° at 6 mm: −0.15 μm).
Material	Hydrophobic acrylic, ultraviolet blocker	Hydrophobic acrylic, ultraviolet blocker and blue light filter
n	1.47	1.54

n: refractive index; Z_4°, spherical aberration.

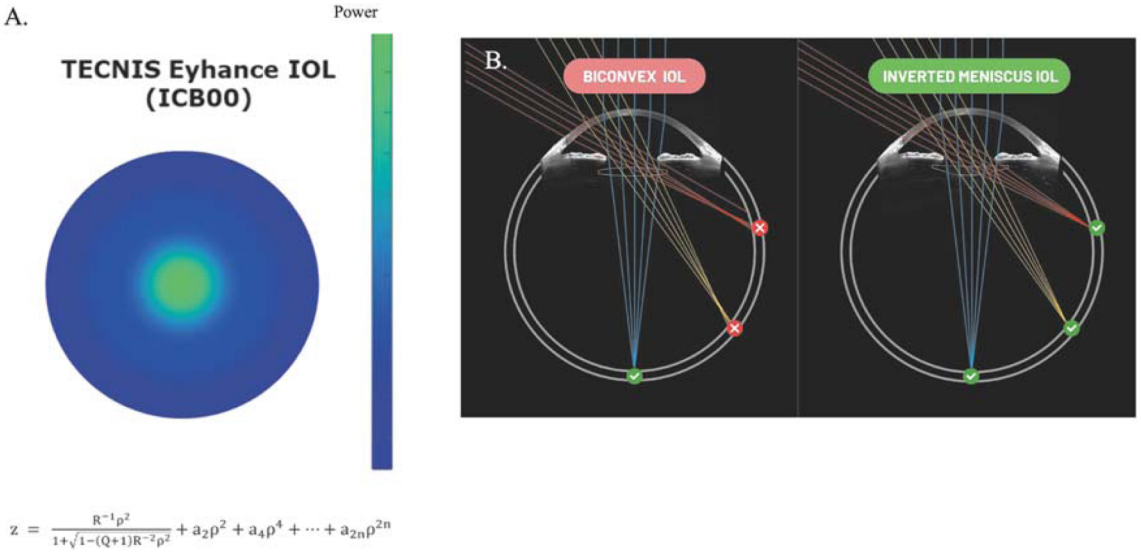

Figure 1. Technical specifications: A. TECNIS Eyhance™; B. ArtIOLs®25.
A. Equation that describes the surface of the TECNIS Eyhance™ intraocular lens.
TECNIS Eyhance™ figure and equation, reprinted with permission from Johnson & Johnson Surgical Vision, Inc.
B. Meniscus shape conceived to mimic the natural crystalline lens that provides optimized field curvature and improved peripheral vision.
ArtIOLs®25 figure, reprinted with permission from Voptica SL.

Surgical technique

All the surgical interventions were carried out by the same surgeon (JEE) under topical anaesthesia and sedation. Tropicamide 1% and phenylephrine 10% were used to achieve mydriasis. Surgery was performed using a temporal approach for both right and left eyes. A clear corneal incision of 2.4 mm was made in all cases. Postoperatively, all the patients received the same treatment, consisting of tobramycin 0.3% and dexamethasone 0.1% tapering over 1 month.

Postoperative examinations

One month after surgery on the second eye, the tests of interest in this study were carried out. Specifically, subjective refraction and binocular uncorrected and corrected VA at different distances were measured. Visual acuities were obtained using Early Treatment Diabetic Retinopathy Study (ETDRS) charts under photopic conditions (85 cd/m^2) adjusted for different test distances: far (4 m), intermediate (66 cm), and near (40 cm). Further, binocular defocus curves were obtained for both eyes from −3.00 D to +1.00 D in steps of 0.5D, using the ETDRS chart with best distance correction and under photopic conditions.

At the 1-month check-up, patients were asked to complete the Catquest-9SF questionnaire. This tool contains questions which assesses the impact of cataract surgery on daily life, visual satisfacyion and performance of specific activities. There are four (summary scoring value) response options for the perceived difficulty levels. The final score was obtained by averaging the scores of all the questions.[17] Scores on this questionnaire were used for analysing the vision-related limitations patients encountered in their activities of daily living.

Statistical analysis

Quantitative variables were described using mean and standard deviation if normally distributed, and otherwise, median and first and third quartiles. The Shapiro-Wilk test was used to assess whether or not data were normally distributed. Qualitative variables were expressed as relative and absolute frequencies for each of the categories.

Student's t or Wilcoxon tests were used for between-group comparisons of normally and non-normally distributed quantitative variables respectively. For qualitative variables, chi-square or Fisher exact tests were used as appropriate. For comparing related samples, appropriate corrections were applied.

Pearson or Spearman rho correlation coefficients were calculated to assess correlations between quantitative variables, depending on the distribution of the variables analysed. Statistical analysis was carried out using R statistical software (version 4.3.1) and differences were considered statistically significant when $p < 0.05$.

Results

A total of 30 patients (60 eyes) were analysed, half of whom received Tecnis Eyhance™ IOLs and the other half, ArtIOLs®25 IOLs.

Table 2
Patient preoperative characteristics.

	Tecnis Eyhance™ group	ArtIOLs®25 group	p
Age (years)	75.33 ± 5.37	71.67 ± 8.09	0.156
Male/Female (%)	26.67/73.33	46.67/53.33	0.449
Axial eye length (mm)	23.58 ± 1.05	23.55 ± 0.70	0.888
Corneal astigmatism (D)[a]	0.47 (0.36; 0.62)	0.58 (0.38; 0.93)	0.239
IOL power (D)[a]	22.50 (21.50; 23.88)	22.25 (21.50; 23.00)	0.401
Pupil size (mm)[a]	2.67 (2.55; 2.88)	2.48 (2.30; 2.61)	0.004[b]
Z_4° (at 6 mm) (μm)	0.35 (0.23; 0.45)	0.29(0.26; 0.35)	0.003[b]

IOL: intraocular lens; Z_4°, spherical aberration.
[a] Non-normal distribution (median).
[b] Statistically significant.

Table 3
Binocular visual acuity [median (25th; 75th)].

	Tecnis Eyhance™ group	ArtIOLs®25 group	p
UDVA (4 m)	0.00 (−0.09; 0.07)	0.00 (0.00; 0.00)	0.657
CDVA (4 m)	−0.02 (−0.10; 0.00)	0.00 (0.00; 0.00)	0.001[a]
UIVA (66 cm)	0.20 (0.10; 0.25)	0.20 (0.10; 0.25)	0.949
DCIVA (66 cm)	0.20 (0.10; 0.30)	0.20 (0.10; 0.30)	0.445
UNVA (40 cm)	0.30 (0.20; 0.35)	0.40 (0.30; 0.50)	0.049
DCNVA (40 cm)	0.30 (0.25; 0.40)	0.40 (0.30; 0.50)	0.050

UDVA: uncorrected distance visual acuity; CDVA: corrected distance visual acuity; UIVA: uncorrected intermediate visual acuity; DCIVA: distance-corrected intermediate visual acuity; UNVA: uncorrected near visual acuity; DCNVA distance-corrected near visual acuity.
[a] statistically significant.

Table 2 summarises the preoperative characteristics of study patients. It was observed a statistically significant between-group differences in preoperative pupil size and corneal spherical aberration.

All the surgical interventions were carried out without incident. There was no need to exclude any patients due to intra- or postoperative adverse events. No patients were lost to follow-up and none withdrew their consent to participate in the study. The median [25th;75th] postoperative subjective spherical equivalent was −0.12 D [−0.50;0.00] in the Tecnis Eyhance™ group and 0.00 D [−0.19;0.09] in the ArtIOLs®25 group ($p < 0.01$). The results in terms of binocular uncorrected and corrected VA at the distances analysed are shown in Table 3 . Both groups achieved binocular uncorrected and corrected distance VAs of at least 0.00 logMAR. Further, with both IOLs, Tecnis Eyhance™ and ArtIOLs®25, uncorrected intermediate visual acuity (UIVA) and the distance-corrected intermediate visual acuity (DCIVA) reached values of 0.20 logMAR.

Binocular distance-corrected defocus curves are presented in Fig. 2.

We compared binocular DCIVA and DCNVA values obtained with the specific approved test for each distance and from defocus curves for −1.5 D and −2.5 D. For the Tecnis Eyhance™ group, the binocular DCIVA was 0.20 logMAR using the chart at 66 cm and 0.17 logMAR from the defocus curve for −1.50D ($p = 0.5$); and the binocular DCNVA was 0.31 logMAR with the chart at 40 cm and 0.48 logMAR from the curve for −2.5D ($p = 0.003$). In the ArtIOLs®25 group, the binocular DCIVA values were 0.20 logMAR and 0.29 logMAR with the chart and defocus curve respectively ($p = 0.04$); and binocular DCNVA values were 0.40 logMAR and 0.70 logMAR with the chart and defocus curve, respectively ($p = 0.0008$).

Regarding potential associations between binocular DCIVA and parameters that might influence image quality, namely, pupil size or corneal spherical aberrations: the correlation (Spearman Rho) binocular DCIVA and pupil size were 0.383 ($p = 0.036$) in the Tecnis Eyhance™ group and −0.253 in ArtIOLs®25 group and the correlation (Spearman Rho) binocular DCIVA and corneal spherical aberrations were 0.304 in the Tecnis Eyhance™ group and −0.001 in ArtIOLs®25 group. For both parameters analyzed, each eye was correlated with the binocular DCIVA. We only found a moderate correlation with pupil size in the Tecnis Eyhance™ group. The Catquest-9SF scores were 1.11 and 1.25 in the Tecnis Eyhance™ and ArtIOLs®25 groups, respectively, the difference being statistically significant ($p = 0.035$).

Discussion

After cataract surgery, image quality in pseudophakic eyes is influenced by various parameters: corneal aberration, IOL design and pupil size, among others.[18,19] The greater depth of focus of the IOLs analysed in this study comes from their design providing negative spherical aberration in the case of ArtIOLs®25 and an increase in lens power within the central 1-mm diameter in the case of Tecnis Eyhance™.[3,15,17]

Our results in terms of binocular uncorrected and corrected distance VA are similar to those of previous studies based on these IOL platforms.[14,19–25] This indicates that the distance VA remains excellent and unchanged with the EDOF IOLs, Tecnis Eyhance™ and ArtIOLs®25, compared to results obtained with traditional monofocal IOLs.

Regarding binocular DCIVA and DCNVA, only results using the Tecnis Eyhance™ IOL can be compared with previous studies. Huh et al.[21] reported binocular DCIVA and DCNVA values close to 0.00 logMAR, while Corbelli et al.[23] obtained results close to 0.00 logMAR for binocular DCIVA, but binocular DCNVA values similar to those found in our study. Other authors have not reported near VA, but their intermediate VA results have been similar to those in our patients.[19,24]

Menucci et al.[26] compared three enhanced monofocal IOLs: ISOPure 123 (BVI-Physiol), Tecnis Eyhance™ (Johnson & Johnson) and Vivinex (Hoya Surgical Optics). Reported binocular intermediate VA were: 0.03, 0.04 and 0.02 logMAR respectively but they used corrected intermediate VA. However, their outcomes were based on corrected intermediate VA measurements rather than DCIVA.

Goslings et al.[27] found comparable DCIVA results when comparing two enhanced monofocal IOLs, Tecnis Eyhance™ and Vivinex, with mean values of 0.16 and 0.28 logMAR respectively.

To date, there are no publications that analyse VA at different distances with the ArtIOLs®25 IOL, beyond the study cited above by Villegas et al.[15] who measured the corrected distance VA and peripheral optical quality in patients with ArtIOLs®25, but results have been reported for other ArtIOLs® lenses. Marín et al.[25] assessed the performance of ArtIOLs®40 and ArtIOLs®70, which are designed for a full range of vision with more negative spherical aberration. They found better intermediate and near VA (0.01 and 0.09 logMAR respectively) compared to the results obtained in our sample. This difference is to be expected, however, due to the enhanced design features of the ArtIOLs®40 and ArtIOLs®70 lenses.

In the present study, binocular distance-corrected visual performance using an intermediate VA chart in patients with Tecnis Eyhance™ and ArtIOLs®25 was comparable and equivalent at an in-

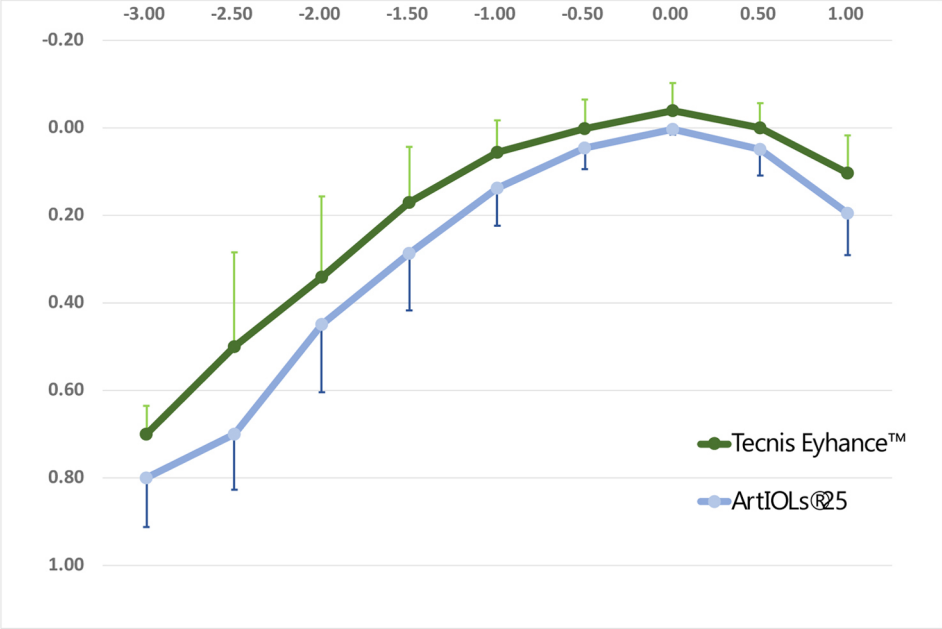

Figure 2. Binocular defocus curves.

termediate distance, both groups achieving around 0.20 logMAR. We found a statistically significant difference in binocular UNVA between the two lenses (0.30 logMAR for Tecnis Eyhance™ and 0.40 logMAR for ArtIOLs®25); however, several factors may influence these results. First, subjective refraction shows a statistically significant difference between the two groups, with the Tecnis Eyhance™ group being more myopic. This difference could slightly impact the binocular uncorrected intermediate and near VA outcomes. Additionally, the CDVA was better in the Tecnis Eyhance™ group, with the difference being statistically significant. It is unclear whether this difference is due to the lenses themselves or the characteristics of individual patients. In this case, the differences between the groups are smaller. Nonetheless, a larger sample size is needed to determine whether this difference is inherent to the lenses.

Analysing the binocular defocus curve data, we observed marked differences in both groups in the intermediate and near VA between values as measured using charts for specific distances and using the defocus curve for levels of defocus considered optically equivalent to the same distances. Notably, chart-based VA was better than that from the defocus curves for all of the distances considered. We should take into account that the vergence generated at different distances is negative, that is, when a defocus curve is evaluated with the test distance at 4 m, a −2D lens placed in front of the eye does not actually generate a total divergence of −2D but rather of −2.25D.[28] This would not explain our results, however, since the VA is better with the charts than with the defocus curve. Other authors such Pieh at al.[29] have suggested that due to the decrease in image size produced by negative lenses and the miosis produced when approaching a test, the defocus curve underestimates the true VA.

On the other hand, although no studies have been published on this topic, the process of obtaining the defocus curve is tiring, especially for older patients, and this may also help explain the differences in VA obtained with this method and chart-based measurements.

After cataract surgery, the visual outcomes in a pseudophakic eye are influenced by various parameters, including corneal aberrations, IOL design, and pupil diameter. We analysed the correlation between binocular DCIVA and corneal spherical aberration or pupil diameter. Considering preoperative characteristics, we detected significant differences in both variables, corneal spherical aberration and pupil diameter. Although there seemed to be a trend towards a correlation between binocular DCIVA and pupil size for the Tecnis Eyhance™ group, for example, we cannot conclude that intermediate VA is associated with either pupil size or Z_4°. Further studies with larger samples and better-matched groups are needed to draw conclusions about such potential correlations.[19] Establishing associations with preoperative characteristics would allow us to choose patients likely to achieve the best outcomes as a function of the characteristics of each IOL platform used.

Finally, the quality of life achieved, as indicated by the results of the Catquest-9SF questionnaire, demonstrates positive outcomes across all patients. Moreover, they subjectively reported a significant improvement in their quality of life. Nonetheless, results in the Tecnis Eyhance™ group were somewhat better than ArtIOLs®25.

This study has several limitations that should be considered, including a small sample size and a short follow-up period. Additionally, the correlations between pupil size and spherical aberration were assessed using binocular DCIVA. Future studies should evaluate these correlations over longer follow-up periods.

To conclude, both Eyhance and ArtIOLs25 IOL platforms improve intermediate VA, without compromising distance VA. This helps our patients achieve a better quality of life, by facilitating activities of daily living. Larger studies with different EDOF IOLs are necessary to confirm the improvement observed in intermediate VA, establish which eye characteristics are associated with better visual outcomes with EDOF IOLs, and determine whether there are differences in VA as measured using the defocus curve and charts for each distance.

Informed consent

Participants were provided with information regarding the study and asked to give written informed consent.

Ethical approval

This study was approved by the Clinical Research Ethics Committee of Euskadi (CEIm-E, reference: PS2022002). In accordance with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Declaration of Generative AI and AI-assisted technologies in the writing process

The authors have no use artificial intelligence for manuscript preparation.

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Declaration of competing interest

Beatriz de Luis Eguileor declares that she has not conflict of interest. Borja Santos Zorrozúa declares that she has not conflict of interest. Jaime Etxebarria Ecenarro declares that she has not conflict of interest.

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