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Improvement of intermediate vision with new monofocal intraocular lenses: A systematic review and meta-analysis.

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Abstract

Purpose: Monofocal intraocular lenses (IOLs) used in cataract surgery are designed to improve visual acuity (VA). The available evidence of new monofocal IOLs" functional benefits is limited. The aim of this meta-analysis was to analyze the improvement in VA using Tecnis Eyhance monofocal IOLs compared to standard monofocal IOLs Tecnis ZCB00.

Methods: MEDLINE, Web of Science and Scopus were searched for studies assessing improvement in intermediate VA using Tecnis Eyhance IOLs versus Tecnis ZCB00 IOLs. Studies evaluating post-operative VA in patients who underwent cataract surgery were selected. This meta-analysis followed PRISMA guidelines and was registered in PROSPERO. The Cochrane Risk of Bias Tool 2.0. was used to assess the methodological quality of the included studies, risk of selection bias and comparability of cohorts and outcomes.

Results: The search resulted in 1153 articles. Five studies met the inclusion criteria and were included in the meta-analysis. A total of 604 eyes were evaluated, of which 309 received Tecnis Eyhance IOLs and 295 were implanted with Tecnis ZCB00 IOLs. Mean binocular distant-corrected intermediate VA with Tecnis Eyhance IOLs at 2 weeks-1 month showed a significant difference of 0,21 logMAR, $p < 0.001$; and mean binocular distance-corrected intermediate VA with Tecnis Eyhance IOLs at 6 months showed a significant difference of 0,11 logMAR, $p < 0.001$.

Conclusion: Near VA could not be assessed in this meta-analysis as it was measured in very few studies. Preliminary pooled evidence indicates that intermediate VA improved with Tecnis Eyhance IOLs. Further studies evaluating near VA and with longer follow-up are still necessary.

Keywords

Cataract — intraocular lens — ICB00 — tecnis eyhance — intermediate vision — meta-analysis

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Contents

1. Introduction

A wide variety of intraocular lenses (IOLs) are available with different focal characteristics that may improve near, intermediate, far or overall visual acuity (VA). IOLs can be classified into monofocal, bifocal or trifocal, accommodative and toric [1–3]. Eyhance ICB00 IOL has the same support platform as other monofocal IOLs like ZCB00. It is a biconvex refractive lens made of hydrophobic acrylic material, with a 6 mm optical zone and a 360° square edge. In addition, it shows a central deviation of approximately 1 mm, which results in a change in rangeof less than 4μm. This increase in lens power confers higher intermediate VA capability according to Tognetto et al. [2].

Monofocal lenses are designed to improve VA, being one of the most commonly used IOL models. To improve corneal aberrancy, these IOLs are designed with a certain degree of asphericity to enhance the quality of the image obtained [2, 4, 5]. A new monofocal IOL with an extended range of vision has been recently introduced in clinical practice: Tecnis Eyhance (ICB00) IOL (Johnson&Johnson Surgical Vision, Santa Ana). This extended range of vision results from a minimal central variation consisting of an increase in power from the periphery to the center [2]. According to different hypotheses and studies, the use of this type of extended range monofocal IOL results in improved intermediate VA.

Intermediate VA vision is tested in the range 50–100 cm, covering the zone of extended near activities [6]. It is therefore essential in basic daily activities such as writing, using the computer, watching television or playing sports [7, 8]. Therefore, implementation of these monofocal IOLs in public health systems might be crucial for many patients. However, there is still limited evidence on the benefits of Eyhance (ICB00) IOLs in comparison with standard lenses.

The aim of this systematic review and meta-analysis is to compare the improvement of VA with Tecnis Eyhance (ICB00) monofocal IOLs versus the Tecnis ZCB00 standard lenses in patients who underwent cataract surgery.

2. Methods

2.1 Study design and search strategy

A systematic review was conducted on the available scientific literature in accordance with the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines [9]. The study protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) on March 6, 2021 (CRD42021234637).

A search was carried out in the Medline, Web of Science Core Collection (Thomson Reuters) and Scopus (Elsevier) databases until April 1, 2021. Search strategy was conducting by combining the terms “cataract”, “extraction”, “surgery”, “lens”, “intraocular”, “intermediate vision” “tecnis eyhance” and “ICB00”. In addition, the search was completed by examining references from the included articles to increase search sensitivity.

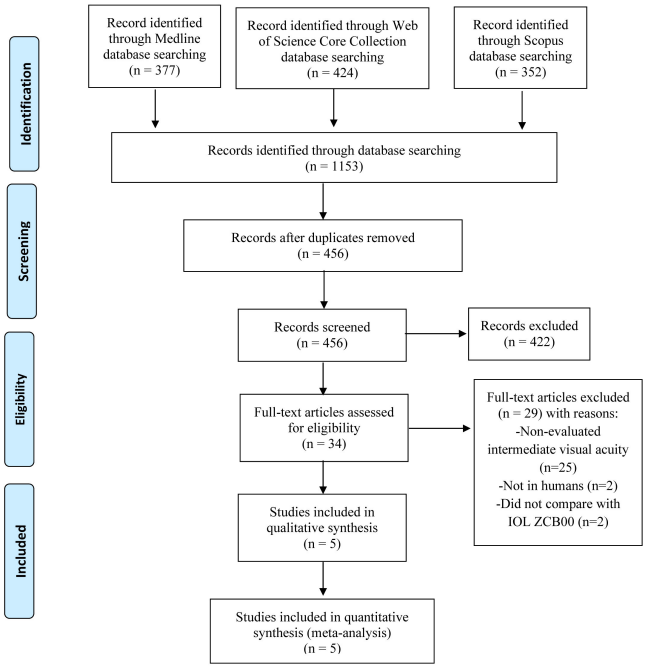

Figure 1. Flow diagram of the selected studies.

2.2 Study selection criteria

The inclusion criteria were cataract patients who underwent cataract surgery and were implanted with a monofocal IOL. The control group was the standard Tecnis IOL ZCB00 (Johnson & Johnson Surgical Vision, Inc., Santa Ana, California). The search was limited to English, Spanish or French languages and to original research, including experimental and observational studies (cohort or case-control design). Other article types, such as case reports, research letters or conference proceedings were excluded. The primary outcome was the assessment of VA. In addition, corneal aberrancy and high-order aberration root-mean-square, binocular defocus curve, pupil size, spherical equivalent and contrast sensitivity were evaluated.

Studies of interest were selected in a two-stage process. First, two researchers (authors 1 and 2) independently screened all the titles and abstracts to identify eligible articles. Then, two other researchers (authors 3 and 4) reviewed the selected studies in full and verified whether they met the inclusion criteria. Any disagreements in these two stages were resolved by a senior ophthalmologist (authors 5 and 6).

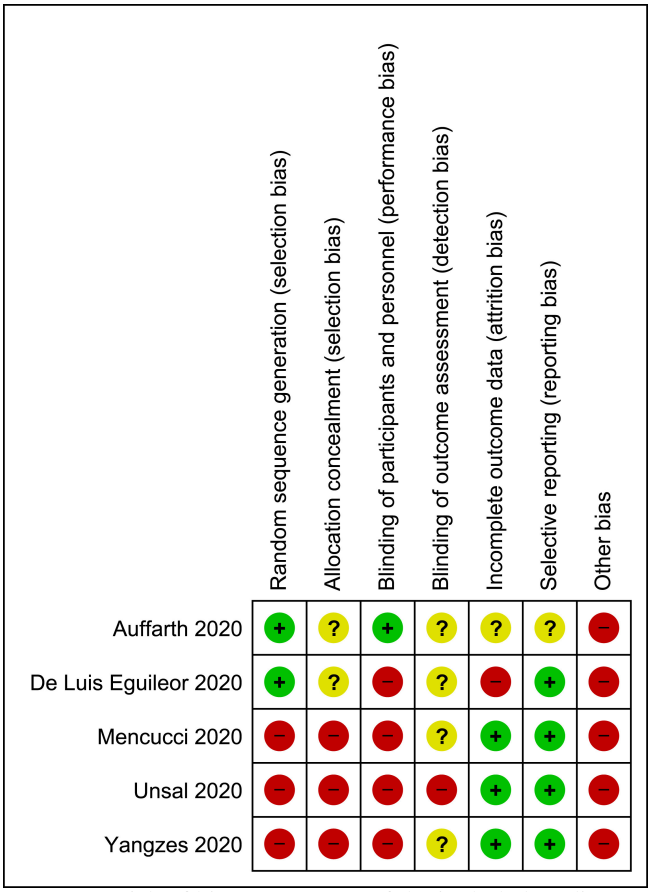

Figure 2. Risk of bias assessment of the included studies according to the cochrane risk of bias tool 2.0.

2.3 Quality assessment and data extraction

The quality assessment of the studies was carried out using the Cochrane Risk of Bias Tool 2.0 [10]. Accordingly, randomization of studies, allocation concealment, blinding of participants and assessors, blinding of outcome variables, incomplete outcome data, and selective reporting were labeled as high, low, or unclear risk. Any disagreements were resolved by a senior ophthalmologist (authors 5 and 6).

Data extraction was performed by two authors (authors 1 and 2) with a pre-defined standardized form that collected the information of interest from the selected studies, including: a) name of the first author, b) type of study design, c) year of publication, d) journal impact factor, e) country of publication, f) follow-up time, i.e., short-term (2 weeks and 1 month) and medium-term (6 months), g) number of participants and eyes operated, h) type of IOLs for cases and controls, and i) measures of the primary and secondary outcomes.

2.4 Data synthesis

Quantitative variables were expressed as mean differences (MDs) with 95% confidence intervals (CIs). We applied the inverse-variance weighting method with a random effects model, and heterogeneity was analyzed using the I2 statistic with conventional cut-off values for high ($\geq$ 75%), moderate (50–75%) and low (<50%) heterogeneity, and the Cochran Q test, with significance level set at p <0.20 [11]. Two-tailed tests were performed with significant values set at p <0.05. We did not assess publication bias given the small number of available studies. All statistical analyses were performed using the Cochrane Review Manager 3.0 software.

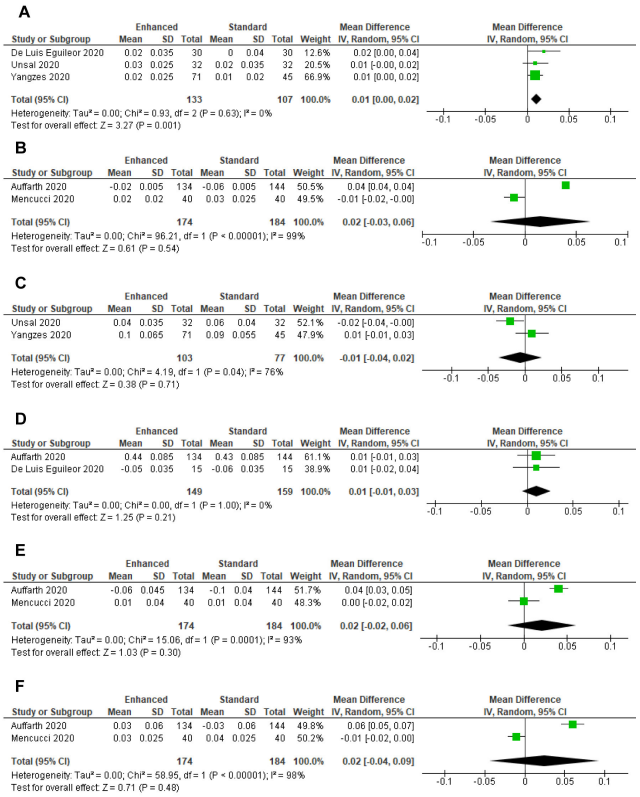

Figure 3. Assessment of far visual acuity. A: Monocular Distance-Corrected Far Visual Acuity (DCVA) at 2 weeks-1 month; B: Monocular DCVA at 6 months; C: Monocular Uncorrected Distance Visual Acuity (UCDVA) at 2 weeks-1 month; D: Binocular DCVA at 2 weeks- 1 month; E: Binocular DCVA at 6 months; F: Binocular UCDVA at 2 weeks-1 month.

Study			Population			Outcomes	
Author, year	**Region**	**Study design**	**Participants (eyes operated)**	**Inclusion criteria**	**Exclusion criteria**	**Follow-up**	**Outcomes**
Auffarth et al., 2020	Europe	Experimental, multicentric	142 (284)	Adults aged 50 years or older with a preoperative corneal astigmatism of 1.00 D or less in both eyes, had clear intraocular media in both eyes; and had provided signed informed consent.	Pupil abnormalities, any ocular trauma or ocular surgery that was not resolved or could affect visual outcomes. Prior corneal refractive surgery. Corneal abnormalities or degenerative disorders. Conditions associated with increased risk of zonular rupture, or ocular medications that could affect vision, including miotic agents.	6 months	Significant improvement in monocular UIVA of 0.11 ± 0.03 logMAR and DCIVA of 0.11 ± 0.02 logMAR in patients with Tecnis Eyhance (ICB00). Significant improvement in binocular UCIVA of 0,10 ± 0.14 logMAR and DCIVA of 0.11 ± 0.12 logMAR in patients with Tecnis Eyhance (ICB00).
Mencucci et al., 2020	Italy	Experimental, single institution	40 (80)	Patients operated with pre-existing regular corneal astigmatism of less than 0.75 D.	Patients with amblyopia, axial length over 25.0 mm, previous ocular surgery (corneal or refractive surgery), chronic or recurrent uveitis, acute ocular disease or infection, diabetes mellitus, glaucoma or intraocular pressure equal to or higher than 24 mm Hg, patients with pseudoexfoliation syndrome, pathological miosis, treatment with alpha-blockers that may lead to floppy-iris syndrome, choroidal haemorrhage, keratoconus, and corneal endothelial dystrophy. Patients with a level of education lower than secondary school were excluded.	6 months	Monocular and binocular UIVA (P = 0.00 and P = 0.021, respectively) and DCIVA (P = 0.23 and P = 0.004, respectively) were significantly higher in the Eyhance ICB00 group.
de Luis Eguileor et al., 2020	Spain	Observational, prospective	30 (60)	Patients who were on the waiting lists for bilateral cataract surgery of the De Cruces University Hospital and written informed consent was requested.	Patients with corneal astigmatism greater than 1.5D, previous corneal or retinal pathology, previous eye surgery and amblyopia.	1 month	For intermediate vision, the observed VA was better with the extended range monofocal Eyhance IOL, with a statistically significant difference (p <0.001).
Unsal et al., 2020	Turkey	Observational, retrospective	32 (64)	Patients who have undergone cataract surgery at the centre where the study was developed between May 2019 and October 2019.	Patients with corneal astigmatism 1 dioptres or over, who had any eye disease such as chronic or recurrent uveitis, acute ocular disease, any eye infection, diabetic retinopathy, glaucoma, pseudoexfoliation syndrome, keratoconus and corneal dystrophy and underwent any previous eye surgery.	1 month	Monocular and binocular UCIVA and DCIVA values were significantly higher in Tecnis Eyhance group than Tecnis ZCB00 group (p = 0.033, p = 0.038, respectively).
Yangzes et al., 2020	India	Observational prospective	116 (116)	Patients with moderate cataract, in the absence of other ocular pathologies and corneal astigmatism less than 1.00 D.	Not specified	2 weeks	Eyhance group had a significantly better uncorrected intermediate visual acuity (UCIVA) compared to Tecnis ZCB00 group (P <0.01). The visual acuity at intermediate and near were significantly better in Eyhance group compared to Tecnis ZCB00 (p <0.01).

Table 1. Main characteristics of the included studies.

3. Results

3.1 Inclusion of studies and flow diagram

The search strategy yielded a total of 456 articles among the 3 selected databases, after exclusion of duplicates. Following screening of titles and abstract, 34 articles were considered for full text analysis. Finally, 5 articles were included in the meta-analysis: 2 experimental [12, 13] and 3 observational studies; one retrospective [14] and two prospective [15, 16]. Figure 1 summarizes the selection of data based on the available articles.

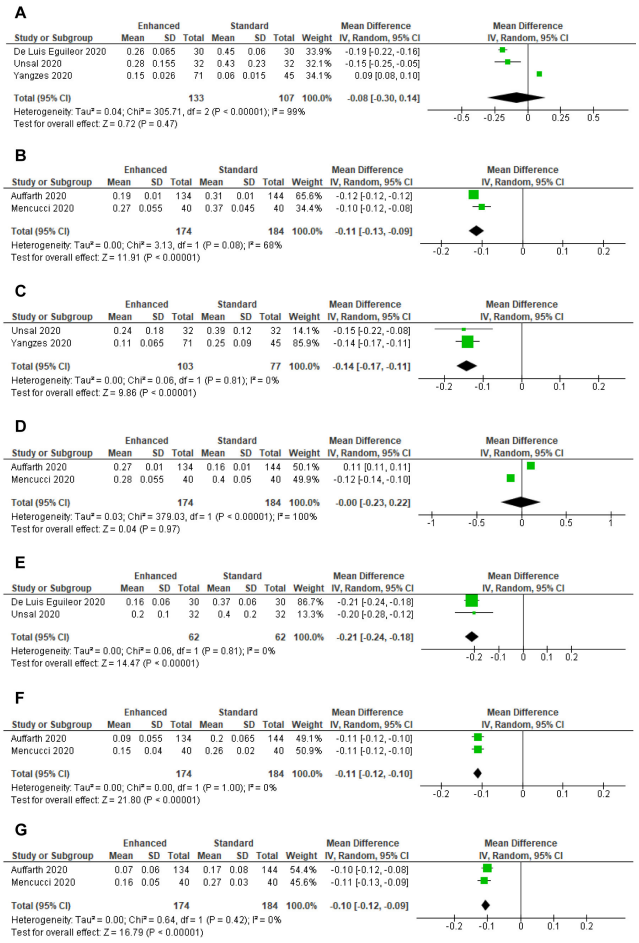

Figure 4. Assessment of intermediate visual acuity. A: Monocular Distance-Corrected Intermediate Visual Acuity (DCIVA) at 2 weeks-1 month; B: Monocular DCIVA at 6 months; C: Monocular Uncorrected Intermediate Visual Acuity (UIVA) at 2 weeks-1 month; D: Monocular UIVA at 6 months; E: Binocular DCIVA at 2 weeks-1 month; F: Binocular DCIVA at 6 months; G: Binocular UIVA at 6 months.

Four of them were performed in a single institution [13–16] and one was multicentric [12]. The studies carried out by Auffarth et al. [12] and Mencucci et al. [13] had an experimental design while the rest of the studies were observational. Three of them were conducted in Europe [12, 13, 16], one in Turkey [14] and one in India [15]. All of them were published between 2020 and 2021. Table 11 summarizes the main characteristics of the included studies.

3.2 Risk of bias assessment

The risk of bias of the selected studies was assessed by the Cochrane Risk of Bias tool v. 2.0., as shown in the supplement (Figure 2). All the identified studies showed risk of bias or difficulties in assessment in some items.

3.3 Main results of the qualitative synthesis

All the reviewed studies reported an overall improvement in intermediate VA with the new Tecnis Eyhance IOL compared to the Tecnis IOL ZCB00 [12–16]. Auffarth et al. were the first to report this finding [12]. On the other hand, Mencucci et al. found that Tecnis Eyhance IOLs allowed greater independence in the use of glasses for intermediate distance, which improved the quality of life of patients [13]. Unsal et al. highlighted that, due to their lower price, Tecnis Eyhance IOLs are a very good option over premium lens implants [14]. Yangzes et al. pointed out that the wider defocus curve obtained with Tecnis Eyhance provides a better VA in a wider range of defocus novices [15].

3.4 Quantitative results: meta-analysis

The selected studies included a total of 604 cataract eyes that were implanted with an IOL, 309 with Tecnis Eyhance and 295 with the Tecnis ZCB00. Figures 3, 4 and 5 show the forest plots of the summarized primary outcomes of the studies (far, intermediate, near VA and refractive parameters), grouped into shortterm (2 weeks and 1 month) and medium-term (6 months). Figure 3 shows the pooled results of the outcomes regarding far VA. Patients implanted with Tecnis Eyhance showed very similar far VA values to the control group.

Only one significant difference favoring Tecnis Eyhance was observed in the best distance-corrected far VA in the short-term (Figure 3D) with 0% heterogeneity in the corresponding forest plot. For monocular and binocular uncorrected far VA at 6 months, only data from Mencucci et al. [13] were available, so they are not included in the meta-analysis. Their results were similar for the two types of lenses evaluated, i.e., no significant differences were found. Accordingly, far VA estimated in various ways (Figure 3) showed no differences between the two lenses, except in the case of distance-corrected monocular VA, which showed favorable results for Tecnis Eyhance. Figure 4 shows the forest plots regarding intermediate VA. Patients who were implanted with Tecnis Eyhance IOLs showed better intermediate VA outcomes in all assessments, both in the short- and medium-term. Heterogeneity of some of the included studies was very high for certain measurements (Figure 4A,4B and 4D) with I2 values of 99%, 68% and 100%, respectively. However, other studies with low heterogeneity (I2=0%) (Figures 4C, 4E, 4F and 4G) also showed significant improvement with Tecnis Eyhance. Only short-term monocular distance-corrected intermediate VA and

monocular uncorrected intermediate VA at 6 months showed no significant differences between lenses. Short-term binocular uncorrected intermediate VA was not evaluated because this measurement was only included in the study by Unsal et al. [14].

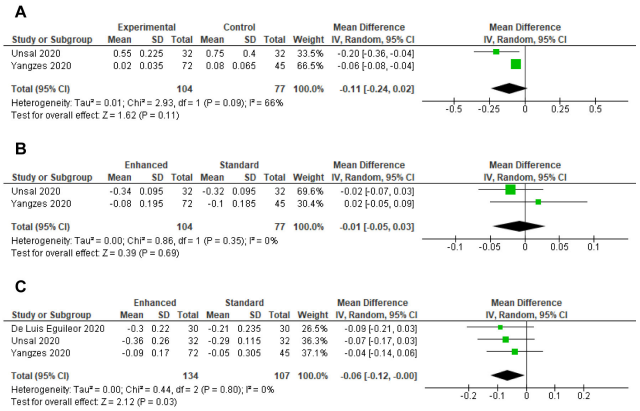

Figure 5. Assessment of near visual acuity and refractive parameters.A: Monocular Distance-Corrected Near Visual Acuity (DCNVA) at 2 weeks-1 month; B: Cylinder equivalent at 2 weeks-1 month; C: Sphere equivalent (SE) at 2 weeks-1 month.

Figure 5 shows the assessment of near VA and different refractive parameters. Near VA (Figure 5A) was similar in both lenses. However, this outcome was measured only in two studies [14, 15], thus quantitative synthesis was not possible and no significant differences were found. Only the study conducted by Yangzes et al. [15] showed significant improvement in near VA with Tecnis Eyhance versus Tecnis ZCB00.

Concerning refractive outcomes, such as cylinder or spherical equivalent, there seems to be no significant differences between the two IOLs in the short-term. At 6 months, these data were only collected by Auffarth et al. [12], thus no comparison could be made.

4. Discussion

This systematic review and meta-analysis summarize the state-of-the-art evidence on the benefits of Tecnis Eyhance IOL (ICB00) in patients who underwent cataract surgery. Preliminary studies comparing Tecnis Eyhance IOLs versus Tecnis ZCB00 IOLs are comparable in all measurements, particularly in intermediate VA. However, there are still very few published studies and certain limitations preclude robust conclusions.

Regarding the inclusion criteria on the participants in the studies included in the meta-analysis, the IOLs implanted in the patients participating in the different studies [12–15] were Tecnis Eyhance (ICB00) models (Johnson&Johnson Surgical Vision, Santa Ana) and Tecnis ZCB00 models (Johnson&Johnson Surgical Vision, Inc., Santa Ana, California). All patients had astigmatism of 1.00 D or less [12, 14, 15], except in the study by Eguileor et al., which included patients with astigmatism equal to or greater than 1.50 D [16]. The exclusion criteria were similar among the studies: participants should not have pupillary or corneal abnormalities such as keratoconus [12–14, 16], previous ocular surgery [12–14, 16], or previous ocular disease such as uveitis [12–15]. Additional exclusion criteria included amblyopia [13, 16], receiving ocular medication such as miotic agents, history of ocular trauma, or intraocular pressure (IOP) greater than or equal to 24 mmHg [12, 13]. Moreover, Mencucci et al. excluded patients with an educational level lower than high school.

Preoperative tests consisted of complete ocular examination including corrected and uncorrected VA, corneal aberrancy or keratometry, among others [12–16]. As for the surgical technique, phacoemulsification was performed in all studies. Different incision approaches were used, ranging from 5.5 mm [13], 2.8 mm [14] or 2.4 mm [16]. Auffart et al. corrected the degree of astigmatism of the included patients intraoperatively [16].

Follow-up was variable among the studies, from 2 weeks [15], 1 month [16], 3 months [14] to 6 months [12, 13]. The immediate postoperative period management consisted of topical antibiotics [13, 14, 16] such as cefuroxime [13] or tobramycin [16]; non-steroidal anti-inflammatory drugs for 15 days [14] or 1 month [13]; and administration of topical dexamethasone for 1 month [16].

Postoperative tests included the Early Treatment Diabetic Retinopathy Study (ETDRS) score, performed under photopic light conditions in all studies except in Mencucci et al. [13]. Far VA was evaluated at 4 meters distance [12–16], at 66 cm [12–14, 16] and at 80 cm [15]; while near VA was assessed at 40 cm [13–15]. The binocular defocus curve measured [13, 14, 16] ranged from +1.00 D to +2.50 D [13] or from 2.50 D to +0.50 D [16] (progressive increase by 0.50 D in all cases). One of the studies also measured IOP and fundus [14]. Different methods were used to evaluate the subjective perception of the intervention and the implant, including the Patient-Reported Visual Symptoms Questionnaire or the validated Catquest-SF9 questionnaire [12], the National Eye Institute Refractive Error Correction Quality of Life Questionnaire (NEI-RQL-42) [13], or specific questions on how often the patients needed to wear glasses for far, intermediate or near distances [14].

Regarding the outcomes evaluated in the studies, Auffarth et al. found a significant improvement of intermediate vision of at least one line (20/25), independent of pupil size (in pupil diameters greater than 2.5mm) with the use of the Ehance IOL (ICB00), and found no significant differences in refractive outcomes between both lenses [12]. These results differ from other studies which found no correlation between pupil size and the lens used [16]. With regard to the binocular defocus curve, better results were observed with Eyhance (ICB00) [12, 13, 15, 16], from 1D and 1.5D (22), 1.5D to 0.5D (25), 0.5D to 4.0D, and 0.5D to 2.0D [11]. However, Unsal et al. found no significant differences between the defocus

curves of both IOLs [14]. Similarly, no significant differences were found between the two lenses [12–16], although the spherical equivalent obtained was lower compared to the control group. This is a the rather interesting finding as this might be a confounding factor regarding the better results of intermediate vision. No significant between-group differences in contrast sensitivity were observed [12–14]. Of note, de Luis et al. [16] reported significant correlations ($p < 0.001$) between intermediate binocular VA corrected with root mean square higherorder aberration and intermediate binocular VA corrected with corneal aberrancy. Future randomized experimental studies on visual acuity after cataract surgery, as the one designed by Lambert et al. [17] are still required. Given the association of cataract surgery with decreased mortality and prevention of negative outcomes [18, 19], optimization of this technique and its materials are of great interest. Finally, we believe that other outcomes, different from VA improvement, should be further explored in future research to enrich our results.

4.1 Limitations

The most relevant limitations of the included studies concern their high heterogeneity, the paucity of articles published so far, and the limited sample sizes of the reviewed studies, which are still insufficient to draw definite conclusions. However, given the short time that the lenses evaluated have been clinically used and the novelty of our study, we believe that the preliminary pooled results of their first clinical results are relevant and useful to continue with their applications and with further evaluation of their properties. In addition, the follow-up of individual studies was variable, thus results corresponding to 2 weeks and 1 month after the procedure were combined in order to obtain reliable estimators. The secondary outcomes were not homogeneous, making comparisons difficult. Finally, it should be noted that results from several trials have not yet been published due to the few time that these lenses have been on the market. In sum, although preliminary results are promising, future studies will be needed to corroborate the data currently available. We present several keys for future studies to homogenize follow-up and measurements.

4.2 Future perspectives

Given the limitations of the studies evaluated, it is advisable to carry out new studies with a randomized experimental design and longer follow-up periods, which would allow an objective monitoring on the benefits of the lenses and whether they are maintained, diminished, or enhanced. In addition, it is necessary to homogenize all the evaluation measurements and follow-up times to facilitate comparisons between different studies and future meta-analyses. All this would allow for greater homogeneity in the future between studies from different institutions that could reflect more conclusive results.

5. Conclusions

This systematic review and meta-analysis summarize the current scientific evidence on VA assessment in patients implanted with the new Tecnis Eyhance (ICB00) IOL. Preliminary results suggest that these lenses are comparable to standard-of-care lenses in terms of the main visual parameters, offering significant improvement in intermediate VA. However, several limitations (e.g., limited number of studies and sample sizes or heterogeneity) preclude drawing robust conclusions with the information currently available. Therefore, further studies which homogenize outcome measurements and include longer follow-up times are still necessary.

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Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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