

Extended depth of focus intraocular lens versus a new monofocal intraocular lens: A prospective comparative and interventional study

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Abstract:

PURPOSE: To compare the visual outcome findings between a new monofocal intraocular lens (IOL) (Tecnis Eyhance) and extended depth of focus (EDOF) IOL (Appasamy Supraphob Infocus).

METHODS: This prospective comparative interventional study evaluated 31 patients after implantation of Tecnis Eyhance (15 patients) and Supraphob EDOF IOL (16 patients). The uncorrected and corrected distance and intermediate and near visual acuity were measured at postoperative day 1, 1 week, 4 week, and 3 months. Contrast sensitivity, incidence of halos and glares, and patient satisfaction were assessed at 3 months postoperatively.

RESULTS: The Tecnis Eyhance ($n = 15$) and Supraphob EDOF ($n = 16$) group were comparable with respect to all preoperative parameters including biometry, visual acuity, and cataract status. The average age distribution of participants was 56 ± 6 years. Postoperatively, both groups had similar distance and intermediate vision, but the near vision was significantly better in the EDOF group ($P < 0.01$) as compared to Tecnis Eyhance at 3 months. The contrast sensitivity and patient satisfaction were similar in both the groups. The incidence of halos and glares was present in the EDOF group, but it was statistically insignificant.

CONCLUSION: The Tecnis Eyhance and Supraphob EDOF both were effective in improving distance and intermediate vision, but the near vision was significantly better in the EDOF group. Both the groups retained good contrast sensitivity and the majority of patients were satisfied.

Keywords:

Contrast sensitivity, extended depth of focus intraocular lens, intermediate vision, Tecnis Eyhance

INTRODUCTION

Cataract is the leading cause of preventable blindness in developing countries. Cataract surgery has evolved tremendously during the past decades. Nowadays, cataract surgery has become a refractive procedure for visual rehabilitation because of improvement in the surgical techniques including small incision and introduction of newer intraocular lens (IOL) technologies and they aim toward providing spectacle independence to the patient.

A large number of different types and styles of lenses have been developed during the last 50 years. A patient has the option to choose

between a traditional monofocal IOL with a refractive target of emmetropia, mild myopia, or monovision (e.g. right eye distance, left eye near), a multifocal IOL, an accommodative IOL, or extended depth of focus (EDOF) IOL for greater range of focus.

Monofocal lenses have a fixed refractive power, and the focal length is also fixed. Although monofocal IOLs ensure excellent distance acuity, patients require spectacle for near and intermediate vision. However, nowadays, patients' expectations have highly increased and they want complete spectacle independence after cataract surgery. This demand has driven research into continuous development of newer IOLs.

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An EDOF IOL provides significantly increased range of vision with minimal optical side effects of multifocality. EDOF IOLs work by creating a single elongated focal point to enhance range of vision (near, intermediate, and distance).^[1] They increase depth of focus across a continuous range.^[2] These lenses aim toward decreasing the side effects caused by multifocal IOLs like aberrations, glare, and halos. In this study, we have used Supraphob Infocus EDOF IOL (Appasamy Associates, Chennai, India); it is a proprietary new generation refractive EDOF IOL (bifocal refractive lens with an EDOF profile).^[3] It is a hydrophobic foldable IOL, made up of hydrophobic acrylic material with natural yellow chromophore to protect from ultraviolet (UV) and other harmful radiations. It has overall size of 13 mm and optic size of 6 mm, its central small aperture refractive element increases depth of focus for near vision (3.50 D add) and simulate accommodation, progressive refractive aspheric elements toward the periphery provides clear distance and intermediate vision [Figure 1]. Its 360° square edge design prevents posterior capsule opacification formation.^[4] It reduces the glare by bending the light rays which hits smoothly on the edge of central zone without any reflection, thus eliminating scattering of the light.^[4]

A newer generation of monofocal IOL, TECNIS Eyhance ICB00 (Johnson and Johnson Vision), was launched in October 2019 in India.^[5] This monofocal IOL is designed in such a way that it extends the depth of focus from distance to intermediate vision to meet the patient's expectations [Figure 2]. This is a one-piece, foldable, posterior chamber IOL and made up of UV-blocking hydrophobic acrylic material. It has a total diameter of 13 mm and optic diameter of 6 mm. It has a spherical posterior surface and modified aspheric anterior surface.^[6] There is a continuous change in power from periphery to center of lens; the power increases as we move from periphery to center. It is not based on spherical aberration based or zonal design.^[7] It provides distance vision and dysphotopsia profile comparable to a standard aspheric monofocal IOL. In addition, the lens extends the depth of



Figure 1: EDOF IOL design (Source: Available from: <https://old.appasamy.com/lensview.php?group=HYDROPHOBIC> [Last accessed on 2023 Jun 21])

focus and improves intermediate vision compared to standard aspheric monofocal IOL.

This study was conducted to compare the visual outcome between a new monofocal IOL (TECNIS Eyhance) and EDOF IOL (Supraphob Infocus EDOF IOL) implantation following cataract extraction. Visual acuity, contrast sensitivity, and photic phenomenon were compared between the lenses.

METHODS

This was a prospective comparative and interventional study. The study was conducted between June 2020 and June 2021 and it was a single-center study. Patients with cataract above the age of 40 years, presenting to the outpatient department of a tertiary care center in northern India during the study period, and who gave consent were offered study enrollment. The sample size was 31 (16 in the EDOF group and 15 in the Tecnis Eyhance group).

Inclusion criteria

- Patients with cataract confirmed by slit-lamp examination preoperatively
- Age of the patient more than or equal to 40 years
- Corneal astigmatism ≤ 1.00 D
- IOL power between + 10.00 and + 32.00 D.

Exclusion criteria

- Patients with irregular corneal astigmatism, corneal dystrophy, and pupillary abnormalities
- Patients with a history of glaucoma or intraocular inflammation, macular disease, or retinopathy
- Intraoperative or postoperative complications (posterior capsular rupture)
- Amblyopia or strabismus
- Capsular or zonular abnormalities affective IOL centration
- History of ocular or refractive surgery prior or during the surgery.

Preoperative evaluation

Patients underwent a comprehensive ophthalmic evaluation before cataract surgery including best-corrected visual acuity (Snellen chart), slit-lamp examination (zeiss), intraocular pressure measurement using Goldmann Applanation Tonometry, after pupillary dilatation fundus was examined with 78/90D lens by slit lamp biomicroscopy following which detail fundus examination was done with indirect ophthalmoscope, specular microscopy, macular optical coherence tomography, biometry (using Bausch and Lomb Keratometer and Immersion A-Scan technique), IOL power calculation was done using SRK-T formula.

Surgical technique

Mydriasis was achieved with 0.8% tropicamide and 5% phenylephrine instilled three times before surgery at 5-min interval. Peribulbar anesthesia, using 2 mL lidocaine 2% mixed with 5–6 mL bupivacaine was given. We used the Oertli

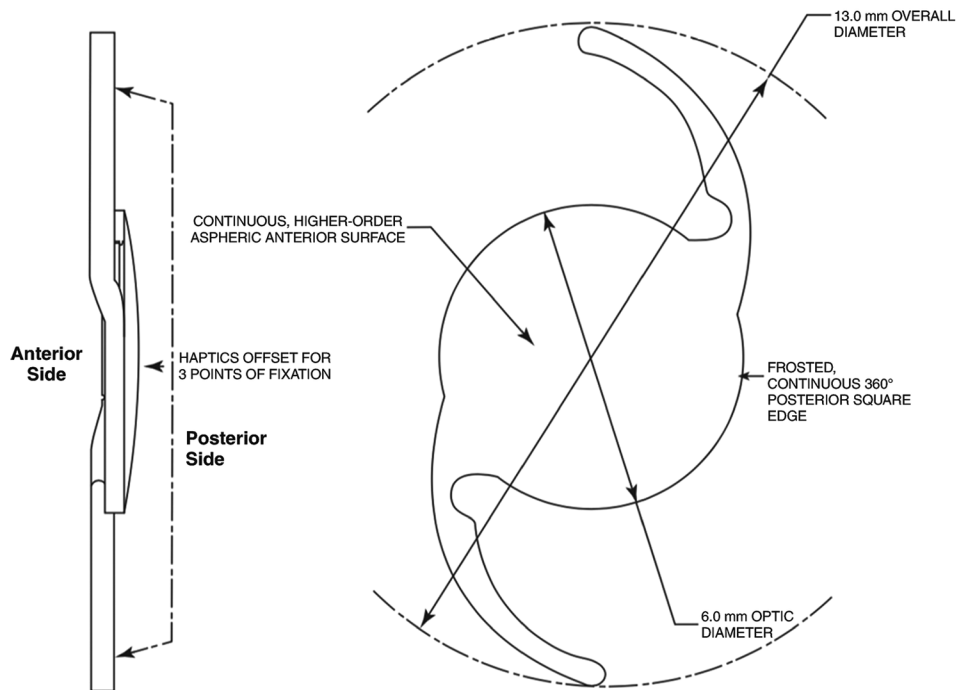


Figure 2: Tecnis Eyhance IOL design (Source: Kanclerz P, Toto F, Grzybowski A, Alio JL. Extended depth-of-field intraocular lenses: An update. *Asia Pac J Ophthalmol* 2020;9:194-202)

phacoemulsification machine. Rise of infusion bottle was 90–100 cm depending on the program. Aspiration/flow rate was 40–50 ml/min and the levels of vacuum 350–400 mmHg. The surgery was performed by the same experienced surgeon performing phacoemulsification through a 2.75 mm clear corneal incision (CCI). All conjunctiva sacs were rinsed with povidone iodine. Two-side ports were created for aspiration and irrigation tips. A 2.75 mm self-sealing limbal incision was made at the 12 o' clock position to prepare the corneal tunnel (CCI). Phacoemulsification was performed using longitudinal continual mode. The nuclear fracturing was done with the divide-and-conquer technique. A foldable acrylic hydrophobic IOL (16 patients with EDOF and 15 with Tecnis Eyhance) had been placed into the capsular bag. After surgery, eye drops containing moxifloxacin and dexamethasone were used hourly, and oral antibiotics and analgesics were given and all patients were examined by an ophthalmologist the day after surgery.

Follow-up was done at Day 1, 1 week, 4 week and 3 months postoperatively, at every follow-up visit patients were examined with: Uncorrected distance visual acuity (UDVA) and best corrected distance visual acuity using Snellen's distant visual acuity chart, uncorrected near visual acuity (UNVA) and best corrected near visual acuity near visual acuity using Jaeger's near visual acuity chart mono ocularly, uncorrected intermediate visual acuity (UIVA) and best corrected intermediate visual acuity intermediate visual acuity using Jaeger's chart at 66 cm, contrast sensitivity using Pelli-Robson contrast sensitivity chart and slit lamp examination (Zeiss) [Figures 3 and 4]. The above visual acuity values were then converted into logMAR values.

Statistical analysis

All the data were recorded in Microsoft Excel and were analyzed using IBM SPSS Statistics for Windows, Version 23.0. (Armonk, NY: IBM Corp). To describe about the data descriptive statistics frequency analysis were used for categorical variables and the mean and standard deviation were used for continuous variables. To find the significant difference between the bivariate samples in independent groups, the Mann–Whitney *U*-test was used. To find the significance in categorical data, Chi-square test was used; similarly, if the expected cell frequency was <5 in 2×2 tables, the Fisher's exact was used. In both the above statistical tools, the probability value <0.05 was considered statistically significant. The final sample size was 31 and were divided into two groups based on the type of IOL implanted. Both the groups were comparable with respect to all parameters including demographics, biometric, visual acuity, and cataract status.

RESULTS

We included 16 patients in the Supraphob EDof Infocus group and 15 patients in the Tecnis Eyhance group during the study period. The mean age of the participants was 56 ± 6 years, 17 (54.8%) were male, and 14 (45.2%) were female. Eyes were comparable with respect to all parameters including demographics, biometric, visual acuity, and cataract status.

Table 1 shows the comparison between the postoperative parameters at 3 months. The mean UNVA was significantly better in the Supraphob EDof Infocus group as compared to the Tecnis Eyhance group without loss of contrast sensitivity.

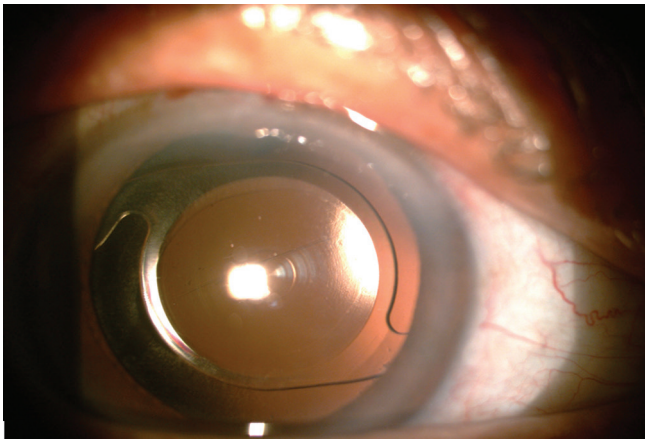


Figure 3: The slit-lamp retroillumination photo showing extended depth of focus intraocular lens in capsular bag (postoperative day 1)

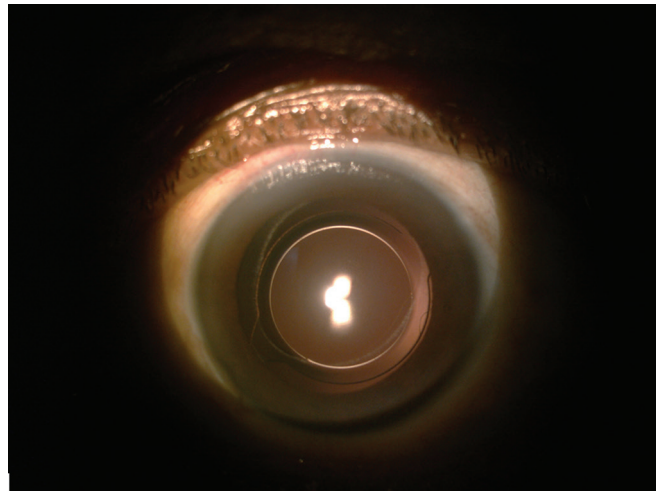


Figure 4: The slit-lamp retroillumination photo showing Tecnis Eyhance intraocular lens in capsular bag (postoperative day 1)

Table 1: Comparison between the postoperative parameters at 3 months

Variable	Suprathob EDOF Infocus	Tecnis Eyhance	P
UDVA logMAR	0.0625±0.05	0.0667±0.0488	0.812
CDVA logMAR	0.0625±0.05	0.0667±0.0488	0.812
UIVA logMAR	0.1050±0.02	0.1053±0.02	0.963
CIVA logMAR	0.1050±0.02	0.1053±0.02	0.963
UNVA logMAR	0.1050±0.02	0.1533±0.03	<0.01
CNVA logMAR	0.1050±0.02	0.1160±0.0331	0.262
Contrast sensitivity	2.047±0.072	2.060±0.076	0.617
Halos and glares	2	0	0.484

logMAR: Logarithm of the minimum angle of resolution, UDVA: Uncorrected distance visual acuity, CDVA: Corrected distance visual acuity, UIVA: Uncorrected distance visual acuity, CIVA: Corrected distance visual acuity, UNVA: Uncorrected near visual acuity, CNVA: Corrected near visual acuity, EDof: Extended depth of focus

Both the groups reported high levels of satisfaction with the visual recovery for distance and intermediate vision, but patients with the Suprathob EDof Infocus group had much greater satisfaction for near vision.

DISCUSSION

The aim of cataract surgery is nowadays becoming a refractive surgery rather than just the removal of cataract. Surgical devices and lens technologies continue to evolve along with increased expectations of patients from the cataract surgery. Newer IOL technologies are emerging rapidly. Several methods have been used in the recently introduced EDof IOLs to increase the depth of focus across a continuous range, without restricting it to 2–3 focal points as seen with bi-trifocal IOLs. Suprathob EDof IOL is based on refractive optics, which is used in our study. In the novel Tecnis Eyhance IOL, there is a difference of 1.5 microns with a diameter of approximately 2 mm in the optical center. This difference provides a power increase of approximately 0.5 D. In addition, by increasing the power from periphery to center, it increases the depth of focus and improves the intermediate vision improving the quality of life of the patients.

Various studies have been conducted in the past with both the IOLs to prove their safety and efficacy in providing good visual outcomes, but there are only few studies that compare the visual outcome between both the lenses. This study aims to compare the visual outcome of these two lenses.

In our study out of 31 patients, 16 patients (51.6%) were implanted with EDof IOL and 15 patients (48.4%) were implanted with Tecnis Eyhance IOL.

In our study, demographic age distribution between the two groups and comparison between gender with groups was analyzed using Pearson’s Chi-squared test and it shows no statistical significant association between age and groups and between gender and groups ($P = 0.431$ and 0.870).

Comparison of logMAR UDVA by Mann–Whitney *U*-test at postoperative day 1, 1st week, 4th week, and 3rd month was analyzed. The mean logMAR UDVA at 1st day, 1st week, 4th week, and 3rd month in the EDof and Tecnis Eyhance groups was 0.16 ± 0.04 and 0.18 ± 0.09 ($P = 0.900$), 0.1263 ± 0.05 and 0.1267 ± 0.05 ($P = 0.982$), 0.08 ± 0.05 and 0.07 ± 0.04 ($P = 0.436$), and 0.0625 ± 0.05 and 0.0667 ± 0.04 ($P = 0.812$), respectively. All the time duration showed no statistically significant difference at $P > 0.05$. It was comparable to the results obtained in the study done by Hyuck *et al.*,^[8] in which they concluded that UDVA was similar in the two groups (Tecnis Eyhance ICB00 and EDof IOL’s [Tecnis Symphony ZXR00]) at 3 months postoperatively. Corbelli *et al.*^[9] also concluded that UDVA was excellent in three groups compared, i.e. Monofocal Tecnis ZCB00, Enhanced Monofocal Eyhance ICB00, and extended range of vision Symphony ZXR00 analyzed at 6 months postoperatively.

Comparison of logMAR corrected distance visual acuity (CDVA) by Mann–Whitney *U*-test at all the time durations showed no statistically significant difference at $P > 0.05$. The *P* values at day 1, 1st week, 4th week, and 3rd month were 0.440, 0.436, 0.723, and 0.812, respectively.

Similar observation was seen in the study done by Hyuck *et al.*,^[8] in which they concluded that CDVA was similar in the two groups (Tecnis Eyhance ICB00 and EDOF IOL's [Tecnis Symphony ZXR00]) at 3 months postoperatively. Mencucci *et al.*^[10] compared Tecnis Eyhance with Tecnis 1-piece IOL and found that distance visual acuities were similar in both the groups. Similar observation was also seen in study done by Ugur *et al.*,^[11] where postoperative monocular UDVA and CDVA results of Tecnis Eyhance group were similar to the Tecnis 1-piece group. Similarly, in a study done by Nivean *et al.*,^[12] they compared Supraphob EDOF IOL with monofocal IOL and found that both the groups had similar distance vision.

In our study, the comparison of logMAR uncorrected and corrected intermediate visual acuity (UIVA and CIVA) by Mann–Whitney *U*-test between the groups showed no statistically significant difference at $P > 0.05$ at all the time durations. The UIVA *P* values at day 1 were 0.512 and 0.963 at 1st week, 4th week, and 3rd month, respectively. The CIVA *P* values were 0.963 at all the time durations. Hyuck *et al.*^[8] also found that the UIVA was similar in the two groups (Tecnis Eyhance ICB00 and EDOF IOLs [Tecnis Symphony ZXR00]) at 3 months postoperatively. Corbelli *et al.*^[9] also observed that the similar UIVA was achieved by Tecnis Eyhance and Symphony group. Nivean *et al.*^[12] in their study found that the EDOF group achieved significantly better intermediate visual acuity compared to monofocal group at 3 months. Ugur *et al.*^[11] found that the monocular and binocular UIVA and CIVA were significantly higher in Tecnis Eyhance group than Tecnis 1-piece group ($P = 0.033$, $P = 0.038$, respectively). Mencucci *et al.*^[10] compared Tecnis Eyhance with Tecnis 1-piece IOL and found that UIVA and CIVA were significantly better in the Tecnis Eyhance group. In a prospective noncomparative case series done by Thomas *et al.*,^[13] it was observed that EDOF IOL provides excellent intermediate and far (<0.1 logMAR) visual acuity.

Comparison of logMAR UNVA by Mann–Whitney *U*-test at postoperative day 1, 1st week, 4th week, and 3rd month was analyzed. The mean logMAR UNVA at 1st day, 1st week, 4th week, and 3rd month in the EDOF and Tecnis Eyhance groups was 0.11 ± 0.02 and 0.17 ± 0.03 ($P = 0.0001$), 0.11 ± 0.02 and 0.17 ± 0.03 ($P = 0.0001$), 0.10 ± 0.02 and 0.16 ± 0.03 ($P = 0.0001$), and 0.10 ± 0.02 and 0.15 ± 0.03 ($P = 0.0005$), respectively. The comparison of UNVA with groups by Mann–Whitney *U*-test at all the time durations showed highly statistically significant difference at $P < 0.01$. Similarly, the mean logMAR CNVA at 1st day, 1st week, 4th week, and 3rd month in the EDOF and Tecnis Eyhance groups were 0.10 ± 0.02 and 0.16 ± 0.03 ($P = 0.001$), 0.10 ± 0.02 and 0.13 ± 0.04 ($P = 0.011$), 0.10 ± 0.02 and 0.13 ± 0.04 ($P = 0.027$), and 0.10 ± 0.02 and 0.11 ± 0.03 ($P = 0.262$), respectively. At 1st day, 1st week, and 4th week, there is statistical significant difference at $P < 0.05$, comparison in 3rd month shows no statistical significant difference at $P > 0.05$. Hyuck *et al.*^[8] found that monocular UNVA and spectacle independence for near distance were better in the Symphony group, whereas

binocular UNVA did not differ significantly in the two groups. Corbelli *et al.*^[9] also concluded that UNVA was highest in the Symphony group. Thomas *et al.*^[13] observed that the mean monocular and binocular UNVA (0.03 ± 0.145 logMAR and 0.22 ± 0.153 logMAR) and CNVA (0.30 ± 0.144 logMAR and 0.23 ± 0.126 logMAR) of EDOF IOL showed acceptable result. It was similar to the study conducted by Pedrotti *et al.* on the similar EDOF IOL; they also observed acceptable near visual acuity. Mencucci *et al.*^[10] compared Tecnis Eyhance with Tecnis 1-piece IOL and found that near visual acuities were similar in both the groups. Similar observation was also seen in study done by Ugur *et al.*,^[11] where postoperative monocular CNVA results of Tecnis Eyhance group were similar to the Tecnis 1-piece group.

Comparison of contrast sensitivity, patient satisfaction, and incidence of halos and glares with groups showed no statistical significant difference ($P = 0.617$, 1.000 , and 0.484 , respectively). However, two patients observed halos and glares in the EDOF group, but the incidence is zero among the Tecnis Eyhance group and this difference was statistically insignificant. Similar results were observed by Hyuck *et al.*^[8] and Corbelli *et al.*^[9]

There are a few limitations in the current study. The study had a 3-month follow-up period, which although gives a good idea of the short term postoperative visual outcome, an extended follow-up period would have provided additional information on long-term outcomes like rate of posterior capsular opacification.

CONCLUSION

In our study, we found that both the groups had similar distance and intermediate vision, but the near vision was significantly better in the EDOF group as compared to Tecnis Eyhance at 3 months. The contrast sensitivity and patient satisfaction were similar in both the groups. The incidence of halos and glares was present in the EDOF group, but it was statistically insignificant. We conclude from this study that the Tecnis Eyhance and Supraphob EDOF both were effective in improving distance and intermediate vision, but the near vision was significantly better in the EDOF group. Both the groups retained good contrast sensitivity and the majority of patients were satisfied.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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