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Performance of a New-Generation Extended Depth of Focus Intraocular Lens—A Prospective Comparative Study

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Purpose: The aim was to study the visual performance of a new refractive extended depth of focus (EDOF) intraocular lens (IOL).

Design: Prospective, comparative study.

Methods: Consenting patients with age-related cataract willing for bilateral cataract surgery within 2 weeks were implanted with the Supraphob EDOF IOL and those willing for 1 eye surgery were implanted with a monofocal IOL. The uncorrected and best-corrected distance, intermediate and near visual acuity, and contrast sensitivity were evaluated at 1 and 3 months postoperatively. We also inquired about glare, halos, difficulties in night driving, requirement for spectacles, and overall satisfaction with vision.

Results: The Supraphob EDOF group (n = 72 eyes) and the monofocal IOL group (n = 54 eyes) were comparable with respect to all preoperative parameters including biometry, visual acuity, and cataract status. The mean age of participants was 58.4 ± 10.6 years. Both groups had similar distance vision but the EDOF group had significantly better intermediate (0.2 ± 0.2 logMAR vs 0.75 ± 0.19 logMAR, $P < 0.001$) and near vision (median = N6 vs N12, $P < 0.001$) compared to the monofocal group at 3 months. The contrast sensitivity was similar in both groups. Patients in the EDOF IOL group had much greater satisfaction for intermediate and near vision. Less than 10% patients reported glare, halos, and difficulty in driving at night in the EDOF group.

Conclusions: The Supraphob EDOF IOL was effective in improving the distance, intermediate and near vision in majority of patients, and retained good contrast sensitivity with most patients reporting excellent satisfaction.

Key Words: cataract surgery, contrast sensitivity, extended depth of focus, intermediate vision, IOL, refractive IOL

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In recent times, cataract surgical techniques have improved tremendously and along with smaller incisions and introduction of newer intraocular lens (IOL) technologies are considered a refractive surgery. Patient expectations have also increased and the demand for complete spectacle independence after cataract surgery has driven research into continuous development of newer IOLs. Multifocal IOLs (bifocal IOLs) of the refractive and diffractive designs lead to considerable improvement in near vision when they were introduced, but near vision came at the expense of reduced contrast sensitivity.[1–3] True accommodative IOLs did not live up to their potential either.[4] The latest IOL technologies not only help rehabilitate distance and near vision, but also incorporate a component of intermediate vision (ie, trifocal IOLs) to ensure spectacle independence in the real sense.[5–7]

Recently, a newer category of IOLs has been introduced that offers increased depth of focus across a continuous range, called the extended depth of focus (EDOF) IOLs.[8–14] These newer IOL designs address some of the drawbacks associated with bifocal IOLs such as reduced contrast sensitivity, photic phenomenon, and night vision problems. The Tecnis Symfony IOL (Johnson & Johnson Vision, Santa Ana, CA) was among the first to introduce the EDOF design and a lot of literature has accumulated on its visual performance, efficacy, and safety.[9,10] After the success of the Tecnis Symfony EDOF IOL, vigorous research is being performed globally to further improve the IOL design such that EDOF is provided without compromising contrast sensitivity. We report results from a study that evaluated the visual performance of a new refractive EDOF IOL design.

METHODS

The study was approved by the local ethics committee and was conducted as per the tenets of the declaration of Helsinki and good clinical practice guidelines. Informed consent was obtained from every patient before enrolment.

Lens Design

The Supraphob Infocus IOL (Appasamy Associates, Chennai, India), a proprietary newer-generation refractive EDOF IOL was evaluated for its performance in the study. The IOL is made of acrylic yellow chromophore material and has a small central zone for near vision (3.50 Dioptre add), larger mid peripheral zone for intermediate vision and outer zone for distance vision (Fig. 1A and B) allowing for significantly improved depth of focus without spectacle correction. The optical performance of the IOL was designed and validated using the FRED optical engineering software[15] (Fig. 2) and its EDOF ranges between +1 Dioptre and −2.5 Dioptre at different pupil sizes has been demonstrated

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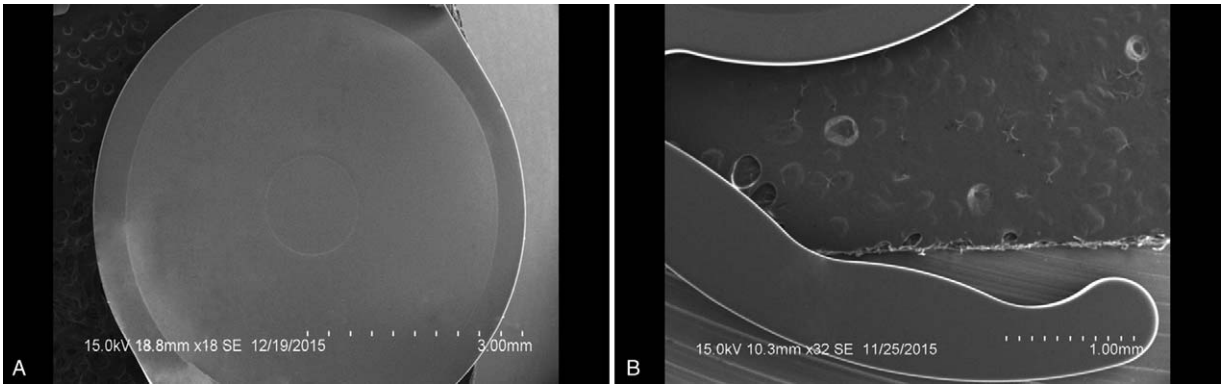

FIGURE 1. Electron microscope image of the optic design (A) and haptic (B) of the Supraphob extended depth of focus intraocular lens.

(Fig. 3). The IOL has an aspheric optical design with 360 degree enhanced square edges and is independent of pupil diameter of up to 4.75 mm.

Subjects

The study was conducted between February 2017 and October 2017. All patients with bilateral age-related cataract above the age of 40, presenting to the outpatient services of a tertiary eye care hospital in south India during the study period were offered study enrolment. Eyes with previous ocular trauma, coexistent ocular pathologies such as diabetic retinopathy, age-related macular degeneration, glaucoma, pseudoexfoliation, corneal guttae, among others, eyes with maximal pupillary dilatation $\leq$5 mm, and those with astigmatism $\geq$1 diopters were excluded from the study. Patients willing to undergo bilateral cataract surgery after 2 weeks of the first eye were implanted with the Supraphob Infocus whereas a group of patients who were implanted with the Superphob monofocal IOL (Appasamy Associates, Chennai, India) was considered as a control group. The Superphob monofocal IOL was chosen for implantation in the control group as it is similar in material and design and is marketed by the same company but only the Central add power zone which is a unique design of Supraphob Infocus is not available in Superphob.

Preoperative Evaluation

Consenting patients underwent a comprehensive ophthalmic evaluation before cataract surgery including uncorrected (UCVA) and best-corrected (BDVA) distance visual acuity using the ETDRS chart and near visual acuity [uncorrected near visual acuity (UNVA) and best corrected near visual acuity (BNVA)] at 33 cm using the Snellen near visual acuity charts monocularly. Dilated slit lamp evaluation was performed to grade the cataract using the LOCS III cataract grading system, intraocular pressure was recorded using Goldmann applanation tonometry, biometry was performed using the NIDEK optical biometry system, and IOL power calculation was done using the SRK-T formula.

Surgical Technique

All cataract surgeries were performed by a single surgeon via a 2.2-mm clear corneal incision (temporal/superior) using the Galaxy Pro phacoemulsification system (Appasamy Associates, Chennai, India). After the incision, an approximately 5 mm capsulorhexis was fashioned, nucleus fragmented using chopping techniques and emulsified, followed by cortical clearance and the appropriate power IOL was implanted in the bag. Thorough anterior chamber wash was done at the end of surgery to avoid residual viscoelastics.

Postoperatively, patients were treated with tapering dose of topical steroids for 1 month and antibiotics for 1 week. At 1-month and 3-month follow-up period, patients underwent visual acuity testing as mentioned before. Additionally, intermediate visual acuity was tested at 66 cm using the Goodlite intermediate visual acuity chart and scotopic contrast sensitivity was recorded using the Mars contrast chart.[16] At the third-month follow-up, patients were shown standard photographs to demonstrate glare and halos and were asked whether they experienced any glare and halos in the postoperative period. They were also asked whether they were having driving difficulties at night. Finally, patients

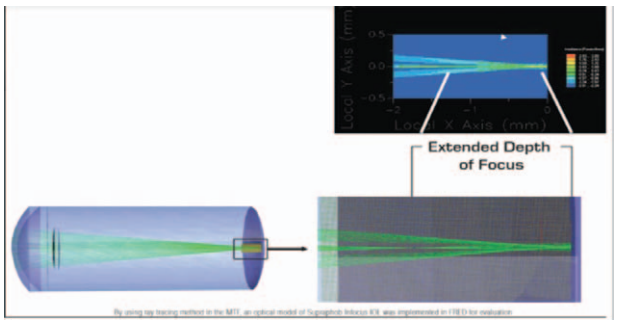

FIGURE 2. Optical performance of the intraocular lens using the FRED optical engineering software.

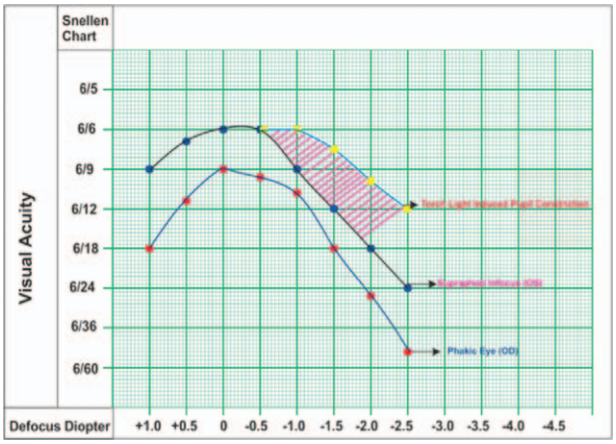

FIGURE 3. Defocus curve showing extended depth of focus of the intraocular lens.

were subjectively asked to grade their satisfaction ranging from very good to not satisfied on a 5-point Richter scale separately for far, intermediate and distance vision and spectacle dependence for daily activities from not at all to sometimes and all the time.

Statistical Analysis

All data were recorded in Microsoft Excel and were analyzed using STATA 12.1 I/C (Forth worth, T). All continuous variables were presented as means with standard deviation or median with interquartile range (IQR) and group differences between the IOL types were analyzed using the Student *t* test or rank sum test for nonparametric variables. Categorical variables were presented as proportions and group differences were analyzed using the χ^2 or Fisher exact test. Differences in parameters before and after surgery were analyzed using the paired *t* test. All *P* values ≤ 0.05 were considered statistically significant.

RESULTS

We included 72 eyes of 36 patients in the Supraphob EDOF Infocus group and 54 eyes of 54 patients in the monofocal IOL group during the study period. The mean age of participants was 58.4 ± 10.6 years (range=40–88 years), 39 (42%) were men, and the right eye was operated in 63 cases (50%). A comparison of baseline characteristics of those in the Supraphob EDOF Infocus and monofocal IOL groups is shown in Table 1. Eyes were comparable with respect to all parameters including demographics, biometric, visual acuity, and cataract status.

In the Supraphob EDOF Infocus group, the UCVA improved from 0.82 ± 0.5 logMAR to 0.16 ± 0.16 logMAR at 3 months' follow-up ($P < 0.001$). The BDVA also improved significantly from 0.53 ± 0.5 to 0.06 ± 0.1 logMAR ($P < 0.001$). The uncorrected intermediate visual acuity was 0.2 ± 0.2 logMAR (median = 0.1, IQR = 0–0.6 logMAR) at 3 months. Similarly, the median UNVA improved from N24 to N6 and BNVA also improved from N12 to N6 ($P < 0.001$ for both). The contrast sensitivity at 3 months was 1.45 ± 0.12 logCS (median = 1.44, IQR = 1.42–1.52 logCS, range = 0.96–1.8 logCS).

TABLE 1. Comparison of Baseline Characteristics Between the 2 Groups

Variable	Supraphob EDOF Infocus	Superphob Monofocal	*P* Value
Age	59.3 ± 11.2	57.3 ± 9.9	0.33
Male (%)	24 (44%)	13 (36%)	0.34
IOP preop	15.1 ± 2.7	14.9 ± 3.3	0.90
Axial length	22.9 ± 0.6	22.6 ± 1.2	0.22
K1, D	44.3 ± 1.3	44.5 ± 1.3	0.41
K2, D	44.1 ± 1.4	44.5 ± 1.4	0.21
IOL power inserted	21.7 ± 1.9	21.6 ± 1.6	0.85
UCVA, logMAR	0.82 ± 0.5	0.79 ± 0.6	0.52
BDVA, logMAR	0.53 ± 0.5	0.46 ± 0.5	0.27
UNVA (median)	N24	N24	0.55
BNVA (median)	N12	N10	0.32
Cataract (≥grade 3)	61%	57%	0.74
% PSC	54%	62%	0.28

BDVA indicates best corrected distance visual acuity; BNVA, best corrected near visual acuity; EDOF, extended depth of focus; IOL, intraocular lens; IOP, intraocular pressure; preop, preoperatively; PSC, posterior subcapsular cataract; UCVA, uncorrected distance visual acuity; UNVA, uncorrected near visual acuity.

TABLE 2. Comparison of Characteristics Between the 2 Groups at 3 Months

Variable	Supraphob EDOF Infocus	Superphob Monofocal	*P* Value
UCVA, logMAR	0.17 ± 0.16	0.17 ± 0.20	0.62
BDVA, logMAR	0.06 ± 0.1	0.06 ± 0.1	0.95
Sphere	$+0.14 \pm 0.50$	-0.14 ± 0.75	0.20
Cylinder	-0.43 ± 0.6	-0.36 ± 0.6	0.45
UCIVA, logMAR	0.2 ± 0.2	0.75 ± 0.2	<0.001
UNVA (median)	N6	N12	<0.001
BNVA (median)	N6	N6	0.76
Contrast sensitivity	1.45 ± 0.12	1.32 ± 0.13	0.54
Halos (%)	3 (8.3%)	0	0.32
Glare (%)	3 (8.3%)	0	0.32
Driving difficulty (%)	2 (5.5%)	1 (2%)	0.41
Spectacle dependence			
Not at all	0	54 (77%)	<0.001
Sometimes	0	10 (12%)	
All the time for reading	8 (11%)	54 (100%)	

BDVA indicates best corrected distance visual acuity; BNVA, best corrected near visual acuity; EDOF, extended depth of focus; IOL, intraocular lens; preop, preoperatively; PSC, posterior subcapsular cataract; UCVA, uncorrected distance visual acuity; UNVA, uncorrected near visual acuity; UCIVA, uncorrected intermediate visual acuity.

In the monofocal group, the UCVA improved from 0.79 ± 0.6 to 0.14 ± 0.14 logMAR at 3 months' follow-up ($P < 0.001$). The BDVA also improved significantly from 0.45 ± 0.5 to 0.05 ± 0.09 logMAR ($P < 0.001$). The uncorrected intermediate visual acuity was 0.75 ± 0.19 logMAR (median = 0.8, IQR = 0.6–1.0) at 3 months. Similarly, the median UNVA improved from N24 to N10 and BNVA also improved from N10 to N6 ($P < 0.001$ for both). The contrast sensitivity at 3 months was 1.32 ± 0.13 log CS (median = 1.44, IQR = 1.31–1.52 logCS, range = 0.96–1.8 logCS).

Table 2 shows the comparison of postoperative parameters between the IOL types at 3 months. The mean uncorrected intermediate and near visual acuity were significantly better in the Supraphob EDOF Infocus group compared with the monofocal group without loss of contrast sensitivity. Figure 4 shows the differences in intermediate vision between the 2 groups. A significantly greater proportion of eyes in the SupraPhob EDOF Infocus group had uncorrected N6 and N8 vision compared to the monofocal group (Fig. 5). Both groups reported high levels of satisfaction with visual recovery for distance vision but patients with the Supraphob EDOF Infocus group had much greater satisfaction for intermediate and near vision (Table 3).

DISCUSSION

In this nonrandomized comparative study, we found that the Supraphob Infocus refractive EDOF IOL offered excellent distance, intermediate and near visual rehabilitation without compromising on the contrast sensitivity, when implanted bilaterally in patients with age-related cataract. Majority of patients reported excellent satisfaction levels for vision at all distances and <10% reported driving difficulty, glare, halos, and other photic phenomenon.

Newer IOL technologies are emerging rapidly and require rigorous laboratory and clinical testing before being accepted widely. The recently introduced EDOF IOLs use several different methods to increase the depth of focus across a continuous range,

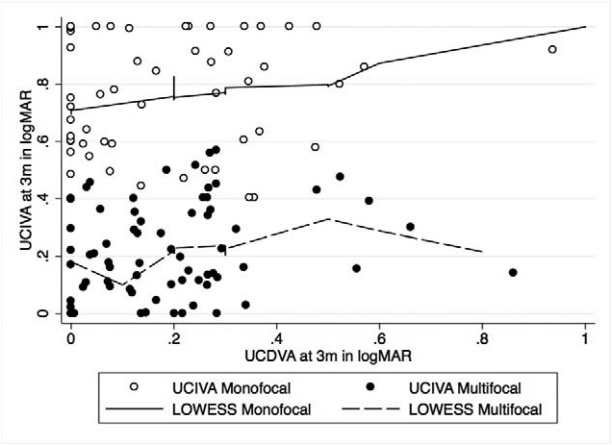

FIGURE 4. LOWESS curve showing comparison of uncorrected distance and intermediate vision in extended depth of focus and monofocal intraocular lens groups. UCVA indicates uncorrected distance visual acuity; UCIVA, uncorrected intermediate visual acuity.

TABLE 3. Patient Satisfaction for Far, Intermediate, and Near Vision at 3 Months

Variable	Supraphob EDOF Infocus	Superphob Monofocal	*P* Value
Uncorrected distance vision			
Very good	44 (61%)	35 (65%)	0.46
Good	23 (32%)	15 (28%)	
Satisfied	5 (7%)	4 (7%)	
Intermediate vision			
Very good	43 (60%)	3 (5%)	<0.001
Good	28 (38%)	1 (2%)	
Satisfied	1 (2%)	5 (9%)	
Not satisfied	0	45 (83%)	
Uncorrected near vision			
Very good	33 (46%)	0	<0.001
Good	36 (50%)	0	
Satisfied	3 (4%)	0	
Not satisfied	0	54 (100%)	

EDOF indicates extended depth of focus.

without restricting it to 2–3 focal points. The Tecnis Symfony IOL is based on the diffractive optics, whereas Lentis Mplus X is based on refractive optics, similar to the Supraphob EDOF IOL used in our study.[9,10] The EDOF IOLs are expected to overcome some of the drawbacks of the bi/trifocal IOLs including loss of contrast, improved intermediate vision, and lesser photic phenomenon.

In a study similar to ours in design, Pedrotti et al[17] compared visual outcomes between an aspheric monofocal IOL (Tecnis monofocal ZCB00, n = 30 eyes) and a new EDOF IOL (Tecnis Symfony, n = 50 eyes). Authors concluded that the EDOF IOL provided better distance, intermediate and near visual acuity than the aspheric monofocal IOL, while maintaining the same level of visual quality and contrast sensitivity. We also found similar results with excellent intermediate and near visual acuity in our cohort of patients, without compromising on contrast sensitivity. Similar encouraging results have also been reported after implanting the Lentis Mplus X which is the refractive EDOF IOL, similar to our IOL design.[10]

In another study on Indian eyes implanting the Tecnis Symfony IOL, Sachdev et al[14] reported high level of spectacle independence for distance, intermediate, and near vision. The incidence of photic phenomena observed was minimal with a high level of patient satisfaction. ALthough this was a noncomparative study, it provided insight into how these newer IOLs are performing in Indian eyes.[14] Another study comparing the PanOptix trifocal IOL with the Tecnis Symfony showed that both IOLs were comparable with respect to visual performance at distance and intermediate.[13] However, the PanOptix IOL provided better near and preferred reading distance vision and showed a more continuous range of vision than the Symfony IOL.

Cochener et al[18] have shown that near vision was statistically better for trifocal IOLs compared with the EDOF IOL. However Ruiz-Mesa et al[19] did not find any such significant differences in vision and contrast sensitivity of fine vision IOL and trifocal.

The Supraphob IOL underwent extensive laboratory testing with excellent results before being implanted into patients during this study. The FRED optical engineering software used to design and validate the IOL design is one of the most robust ways to design optical systems. The defocus curve is another good measure to compare multifocal and EDOF IOLs with each other and they indicate how forgiving an IOL is in terms of postoperative residual spherical equivalent. The defocus curve of the Supraphob IOL is comparable to most other IOLs available in its category.[10] Another encouraging finding was that the contrast sensitivity of the Supraphob EDOF IOL was slightly better than the monofocal IOL, although this was not statistically significant. This optimal performance of the refractive optic design could be attributed to the use of the FRED optical engineering used as well as the unique proprietary refractive design of the IOL. This was translated clinically in terms of very few patients reporting photic phenomenon, difficulty in night driving and minimal glare and halos.

The main limitation of the study is the lack of objective measurement of the higher order aberrations induced by the IOL. Previous studies have shown that most IOLs including the EDOF IOLs induced some amount of higher order aberrations such as coma and trefoil and these are pupil-dependent.[10] However, we have recorded the subjective feeling of patients in terms of glare, halos, and other photic phenomenon, which may be used as surrogates to indicate higher-order aberrations. Another limitation is that we did not compare the monocular and binocular defocus curves. Also, there are some standard questionnaires to record

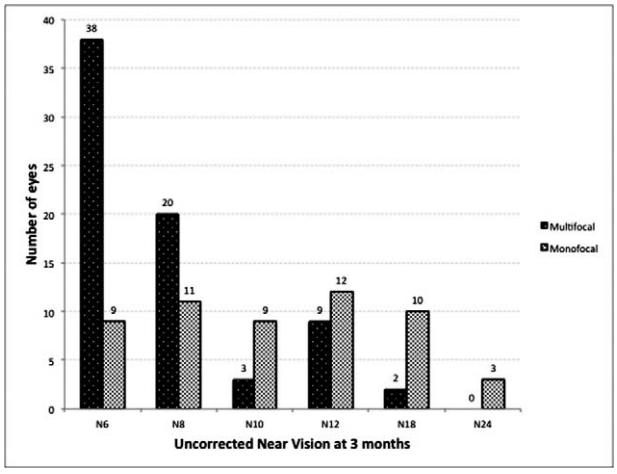

FIGURE 5. Comparison of uncorrected near vision in the extended depth of focus and monofocal groups.

glare and halos which could have been used for the study; unfortunately, we have not used it.

The strengths of this study are the comparison group which had a well-established identical IOL design except for the EDOF optics, follow-up to 3 months to see whether the EDOF persists beyond 1 month postop, and thorough laboratory testing of various aspects of the IOL before clinical testing.

In conclusion, we found that the Supraphob EDOF IOL was effective in improving the distance, intermediate, and near vision in the majority of patients and retained excellent contrast sensitivity compared with a monofocal IOL group. Patients reported excellent satisfaction levels with postop vision and few reported glare, halos and difficulty driving. Further studies are required to understand the higher-order aberrations induced by this new IOL on the visual system in the future.

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