Original Article

A prospective, randomized, comparative clinical study to compare the safety and efficacy of different hydrophobic aspheric monofocal intraocular lenses

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Purpose: To report the 1-year clinical outcomes related to safety, efficacy, predictability, contrast sensitivity, patient satisfaction, complications, and overall results with Optiflex Genesis and Eyecryl Plus (ASHFY 600) monofocal aspheric intraocular lenses (IOLs) and compare the same with Tecnis-1 monofocal IOL. **Methods:** This prospective, single-center, single-surgeon, randomized, three-arm study included 159 eyes of 140 eligible patients who underwent cataract extraction with IOL implantation with any of the three study lenses. Clinical outcomes related to safety, efficacy, predictability, contrast sensitivity, patient satisfaction, complications, and overall results were compared at a mean follow-up of 1 year (12 ± 1.20 months). **Results:** Preoperatively, age and baseline ocular parameters of all the three groups were matched. At 12 months post-op, no significant differences were noted among the groups in terms of mean postoperative uncorrected and corrected distance visual acuity (UDVA and CDVA, respectively) sphere, cylinder, and spherical equivalent (SE; $P > 0.05$ for all parameters). Eighty-nine percent eyes in the Optiflex Genesis group as against 96% eyes in the Tecnis-1 and Eyecryl Plus (ASHFY 600) groups were within ± 0.5 D, and 100% of eyes in all the three groups were within ± 1.00 D of SE accuracy. Postoperative internal higher-order aberrations (HOAs) and coma, and mesopic contrast sensitivity at all spatial frequencies were comparable across all the three groups. Two eyes in the Tecnis-1 group, two eyes in the Optiflex group, and one eye in the Eyecryl Plus (ASHFY 600) group underwent YAG capsulotomy at the last follow-up. No eye in any of the groups showed glistenings or required IOL exchange due to any reason. **Conclusion:** At 1-year post-op, all the three aspheric lenses showed comparable results in visual and refractive parameters, post-op aberrations, contrast sensitivity, and posterior capsule opacification (PCO) behavior. Further follow-up is needed to evaluate the long-term behavior for refractive stability and PCO rates of these lenses. **Trial registry:** CTRI/2019/08/020754 (www.ctri.nic.in).

Key words: Aspheric, intraocular lens, monofocal

Access this article online

Website: www.ijo.in

DOI: 10.4103/ijo.IJO_1073_22

Quick Response Code:

While there is no ideal monofocal intraocular lens (IOL) available yet, significant improvements in the field of monofocal IOL technology have occurred in the past few decades to achieve an IOL design as close to perfection. A novel monofocal IOL design must offer an excellent optical performance without unwanted side effects, should be glistening free, have good capsular and uveal biocompatibility, possess optics that account for eyes requiring aspheric, spheric, or neutral corrections, and feature a design that fits through small corneal incisions to allow for optimal centration in the capsular bag.[1-3] Apart from these, the lens should include square edge technology to prevent posterior capsule opacification (PCO).[4,5] A new monofocal IOL is thus expected to fulfill all these properties.

In the present study, we compared the clinical performance of three different aspheric IOLs: Optiflex Genesis (Biotech Europe Meditech Inc Limited, Gallowstown, Co Roscommon, Ireland), Tecnis-1 (Advanced Medical Optics, Santa Ana, CA, USA), and Eyecryl Plus ASHFY 600 IOL (Biotech Vision Care Pvt Ltd, Ahmedabad, India). Optiflex Genesis and Eyecryl Plus (ASHFY 600) IOLs are two new, relatively recent entries in the field of monofocal IOL technology, and the clinical outcomes with these models of monofocal IOLs have not been evaluated yet.

In this study, we report the 1-year clinical outcomes related to safety, efficacy, predictability, contrast sensitivity, complications, and overall results with these new monofocal IOLs and compare the same with the Tecnis-1 monofocal IOL, the latter being considered as a benchmark and standard of care in the monofocal IOL technology.

Methods

This prospective, single-center, three-arm study was approved by the institutional ethics committee and was conducted in accordance with the principles of the Declaration of Helsinki. All patients provided written informed consent.

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Received: 29-Apr-2022 Revision: 28-Jul-2022
Accepted: 07-Dec-2022 Published: 03-Mar-2023

Cite this article as: Brar S, Vanga HR, Shah ML, Ganesh S. A prospective, randomized, comparative clinical study to compare the safety and efficacy of different hydrophobic aspheric monofocal intraocular lenses. Indian J Ophthalmol 2023;71:771-8.

Inclusion criteria were healthy eyes besides senile cataract, corneal astigmatism ≤1.00 D, IOL power calculation resulting in values between +7.0 and +30.00 D, and in-the-bag implantation of the IOL. Exclusion criteria were patients with corneal astigmatism of >1.00 D, irregular astigmatism due to keratoconus, pellucid marginal degeneration or corneal scars, corneal dystrophy, severe ocular surface disorders, pupillary abnormalities, history of glaucoma, intraocular inflammation, macular degenerations or retinopathies potentially affecting the visual outcome, vulnerable subjects, neuro-ophthalmic diseases, intraoperative complications such as posterior capsule rupture, nucleus drop, or capsular bag loss precluding the implantation of the planned IOL, and unassured follow-ups.

Preoperatively, all patients underwent complete ophthalmic examination including measurement of uncorrected and corrected distance visual acuity (Early Treatment Diabetic Retinopathy Study [ETDRS] charts; Precision Vision, La Sella, IL, USA), manifest refraction, slit-lamp biomicroscopy, noncontact tonometry (NCT; Tomey, Nagoya, Japan), ray tracing aberrometry (I-Trace; Hoya, Japan), specular microscopy (Tomey), macular optical coherence tomography (OCT) (Optovue, Fremont, CA, USA), and dilated fundus examination. Biometric assessments were performed using a swept-source OCT-based optical biometer (IOL Master-700; Carl Zeiss Meditec, Jena, Germany) with the Barrett TK Universal II formula. All eyes were targeted at emmetropia. Optimized A-constants of 118.6, 119.1, and 118.4 were used for Optiflex Genesis, Tecnis-1, and Eyecryl Plus (ASHFY 600) for IOL power calculations, respectively.

Description of the study IOLs

Table 1 provides the details of the technical specifications of the three study IOLs. Both the Optiflex Genesis and Eyecryl Plus (ASHFY 600) IOLs are single-piece, hydrophobic, acrylic, aspheric IOLs with 360° square edge containing natural chromophore. However, they slightly differ from each other in terms of their refractive indices, recommended A-constants, and injector systems.

Surgical procedure

All surgeries were performed by a single experienced surgeon (S. G.) using a standard phacoemulsification technique under topical anesthesia, using the Centurion Precision system (Alcon Laboratories, Fort Worth, TX, USA). Through a temporal clear corneal incision of 2.8 mm, a 5.0–5.5 mm capsulorhexis was aimed and direct chop technique was used for nuclear deployment. After irrigation and aspiration of the cortex, the left side port was hydrated and BSS injected from the main wound to inflate the bag and form the anterior chamber. In the Tecnis-1 group, the UNFOLDER Platinum 1 Series Screw-Style Inserter (Johnson & Johnson, New Brunswick, NJ, USA) was used to inject the Tecnis-1 IOL through a 2.8-mm temporal clear corneal incision, whereas in the Optiflex Genesis and Eyecryl Plus (ASHFY 600) groups, BES22 and Hydroject R (BHC150C)-1 injectors were used, respectively, for IOL loading and implantation. Intraoperative unfolding time was recorded by an independent observer as the time taken from injection to complete unfolding of both the haptics of the IOL inside the capsular bag. Any device-related intraoperative complication such as haptic or optic breakage, or explantation of the IOL due to device damage or wrong IOL power, was recorded for all the three study groups.

Postoperative topical therapy included topical prednisolone (1%, Pred Forte, Allergan) six times for 6 weeks, tapering weekly, moxifloxacin (0.5%, Vigamox, Alcon) four times for 2 weeks, nepafenac (0.1%, Nevanac, Alcon) three times for 4 weeks, and lubricants four times or SOS for 4 weeks or more.

Table 1: Technical specifications and characteristics of the three study lenses

	Optiflex Genesis	Tecnis-1	Eyecryl Plus
Model	MFA6	ZCB00	ASHFY 600
Material	Hydrophobic acrylic containing natural chromophore	UV blocking hydrophobic acrylic	Hydrophobic acrylic containing natural chromophore
Optic type	Single piece, 360° square edge with aspheric optic	Biconvex, anterior aspheric surface, square optic edge	Single piece, 360° square edge with aspheric optic
Optic size	6.00 mm	6.0 mm	6.00 mm
Overall size	13.00 mm	13.00 mm	13.00 mm
Angulation	0°	0°	0°
ACD	5.28	5.72	5.28
Refractive index	1.52	1.47	1.48
Glass transition temperature (Tg)	5°	13.8°	3.5°
Recommended ultrasound A-constant	118.45	118.8	118.3
Recommended optical A-constant	118.85	119.3	118.6
Diopter range	+5.0 to+30.0 D (with 0.5 D step)	+5.0 to+34.0 D (with 0.5 D step)	+5.0 to+30.0 D (with 0.5 D step)
Asphericity	-0.20	-0.27	-0.20
Implantation site	Capsular bag	Capsular bag	Capsular bag
Sterilization	Irradiation	Irradiation	Irradiation
Delivery system	BES22	UNFOLDER Platinum 1 Series (DK7796)	Hydroject R (BHC150C)-1

UV=ultraviolet

Follow-up examinations were performed at 1 day, 2 weeks, 3 months, 6 months, and 12 months after surgery. Slit-lamp examination was performed on post-op day 1 to assess the corneal clarity, anterior chamber inflammation, and IOL position. From 1 month onward, in addition to the above, assessment of manifest refraction, uniocular and binocular uncorrected and corrected distance visual acuity (UDVA, CDVA), uniocular and binocular uncorrected and corrected near visual acuity (UNVA, CNVA), photopic contrast sensitivity using CSV-1000 (Vector Vision, Greenville, OH, USA), and defocus curve charting from +3.5 to −3.5 D were evaluated.

Sample size calculation

Sample size was calculated based upon the mean change in CDVA. At least 138 subjects were required to prove that the null hypothesis of mean change in CDVA for all the three investigational products is same versus the alternative hypothesis of unequal mean change in CDVA for all the three investigational products. To achieve 90% power with 5% level of significance and considering 20% drop-out rate, 166 subjects were required to be enrolled. In order to have 1:1:1 ratio, instead of 166 subjects, 168 subjects were recruited, of which 28 dropped out, and finally, we had 140 subject, for the final evaluation. Power was considered as 90%, and alpha error was 0.05. Randomization was done using block randomization method. As it was an open-label study, there was no masking on allocation concealment used for the surgeon.

Statistical analysis

Statistical Package for the Social Sciences (SPSS) software for Windows version 17.0.0 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. All values were expressed as mean ± standard deviation (SD). Data was checked for normality using the data analysis tool pack software available in Microsoft Excel, before being subjected to analysis. Both skew and kurtosis were analyzed through descriptive statistics. Acceptable values of skewness fall between −3 and +3, and kurtosis is appropriate from −10 to +10 when utilizing Structural Equation Modeling (SEM) (Brown, 2006). One-way analysis of variance (ANOVA) test was used for intergroup comparisons, and paired *t*-test was used for intragroup comparisons. A *P* value of 0.05 or less was considered statistically significant.

Results

One hundred and fifty-nine eyes of 140 patients were evaluated in the study. Table 2 shows the demographic profile and baseline preoperative parameters of the eyes included in the study. There was no significant difference among the study groups in terms of age, keratometry, corneal astigmatism, anterior chamber depth, axial length, IOL power, corneal thickness, endothelial cell density, corneal higher-order aberrations (HOAs), and spherical aberrations (SAs). Table 3 shows the visual and refractive outcomes evaluated for uncorrected and corrected vision at postoperative visits of 2 weeks and 12 months.

Table 2: Demographics and baseline preoperative parameters of all eyes included in the study

	Optiflex Genesis (*n*=53) Mean±SD	Tecnis-1 (*n*=53) Mean±SD	Eyecryl Plus (ASHFY 600) (*n*=53) Mean±SD	*P*
Age (years)	64.91±9.38	62.09±8.64	61.96±10.51	0.20
K1 (D)	44.24±1.24	43.83±1.54	44.09±1.19	0.28
K2 (D)	45.10±1.41	44.59±1.66	45.03±1.30	0.15
Astigmatism (D)	0.86±0.66	0.76±0.47	0.94±0.68	0.30
ACD (mm)	3.30±0.68	3.20±0.34	3.11±0.38	0.12
AL (mm)	23.32±0.69	23.50±1.12	23.28±0.82	0.37
IOL power (D)	21.29±1.56	20.82±2.54	21.10±2.02	0.50
ECD (cells/mm^2)	2361.58±179.11	2327.79±205.22	2316.11±233.28	0.50
CCT (µm)	520.06±29.96	525.57±31.98	523.89±29.77	0.63
Corneal HOA total (mm)	0.49±0.11	0.51±0.14	0.49±0.12	0.70
Corneal SA (mm)	0.29±0.03	0.30±0.09	0.29±0.09	0.63

HOA=higher-order aberration, IOL=intraocular lens, SA=spherical aberration, SD=standard deviation

Table 3: Visual and refractive outcomes obtained in the three study groups at 2 weeks and 12 months postoperatively

	2 weeks				12 Months			
	Optiflex Genesis (Mean±SD)	Tecnis-1 (Mean±SD)	Eyecryl Plus (ASHFY 600) (Mean±SD)	*P*	Optiflex Genesis (Mean±SD)	Tecnis-1 (Mean±SD)	Eyecryl Plus (ASHFY 600) (Mean±SD)	*P*
UDVA (logMAR)	0.15±0.09	0.13±0.13	0.11±0.09	0.70	0.13±0.07	0.09±0.08	0.10±0.08	0.09
CDVA (logMAR)	-0.04±0.07	-0.06±0.05	-0.04±0.05	0.69	-0.04±0.06	-0.07±0.05	-0.05±0.05	0.06
Sphere (D)	-0.13±0.30	-0.09±0.24	-0.07±0.32	0.57	-0.06±0.29	-0.05±0.29	-0.05±0.28	0.98
Cylinder (D)	-0.24±0.74	-0.20±0.48	-0.14±0.37	0.90	-0.17±0.38	-0.14±0.37	-0.16±0.36	0.90
Spherical equivalent (D)	-0.24±0.52	-0.21±0.41	-0.24±0.42	0.80	-0.15±0.33	-0.12±0.30	-0.12±0.29	0.91

CDVA=corrected distance visual acuity, logMAR=log of minimum angle of resolution, SD=standard deviation, UDVA=uncorrected distance visual acuity

Visual outcomes

At 12 months, the mean UDVA for the Optiflex Genesis group was 0.13 ± 0.07, Tecnis-1 group was 0.09 ± 0.08, and Eyecryl Plus (ASHFY 600) group was 0.10 ± 0.08 log of minimum angle of resolution (logMAR), which was comparable and not statistically significant (P = 0.09). The mean CDVA for the Optiflex Genesis group was − 0.04 ± 0.06, Tecnis-1 group was − 0.07 ± 0.05, and Eyecryl Plus (ASHFY 600) group was − 0.05 ± 0.05 logMAR, which was not statistically significant (P = 0.06) [Table 3]. Thirty-eight percent eyes in the Eyecryl Plus (ASHFY 600) group had postoperative UDVA of 20/20 or better versus 36% eyes in the Tecnis and 19% eyes in the Optiflex Genesis group. These values were 92%, 94%, and 91%, respectively, for postoperative CDVA. All eyes in all groups had a minimum CDVA of 20/32 [Fig. 1].

Refractive outcomes

The mean values of sphere, cylinder, and spherical equivalent (SE) were not statistically significant among the three study groups (P > 0.05) for all parameters. The mean SE was − 0.15 ± 0.33, −0.12 ± 0.31, and − 0.12 ± 0.29 in the Optiflex Genesis, Tecnis-1, and Eyecryl Plus (ASHFY 600) groups, respectively [Table 3]. Eighty-nine percent eyes in the Optiflex Genesis group as against 96% eyes in the Tecnis-1 and Eyecryl Plus (ASHFY 600) groups were within ±0.5, and 100% of eyes in all the three groups were within ±1.00 D of SE accuracy [Fig. 2]. Similarly, 89% eyes in the Optiflex Genesis group as against 92% eyes in the Tecnis-1 and Eyecryl Plus (ASHFY 600) groups were within ±0.5 D and all (100%) eyes in all the three groups were within ±1.00 D of post-op refractive astigmatism at the end of 12 months [Fig. 3].

Aberrations

Pre-op corneal HOAs and SAs, measured at 4-mm scan size, were comparable among the groups [Table 4]. Postoperatively, at 1 year, the internal coma aberrations were comparable across all the three groups, with no statistically significant difference in their mean values (P > 0.05). However, the internal SA and HOAs were significantly higher in the Tecnis-1 group, compared to the other two groups.

Contrast sensitivity

Photopic contrast sensitivity evaluated binocularly at 12 months post-op did not show any significant difference between the mean log values for any spatial frequency compared (P- values for all spatial frequencies >0.05) [Table 5 and Fig. 4].

Defocus curve

Defocus curves were charted with correction using defocusing lenses from +3.50 to −3.50 D. At 12 months post-op, the defocus curve showed a single prominent peak for all three IOLs corresponding to 0.00 D, with an abrupt decline of the slope in the intermediate range of vision (−1.50 D) and near vision range (−2.50 D) [Fig. 5]. The average values of visual acuity were, however, higher for Optiflex Genesis and Eyecryl

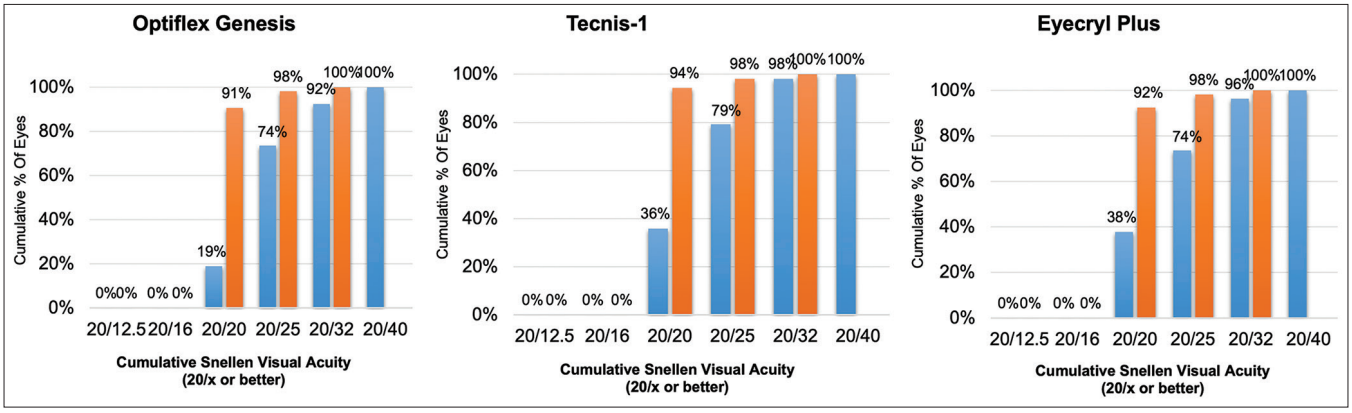

Figure 1: Histogram showing results for UDVA and CDVA obtained following implantation of the three study IOLs at 12 months postoperatively. CDVA = corrected distance visual acuity, IOL = intraocular lens, UDVA = uncorrected distance visual acuity

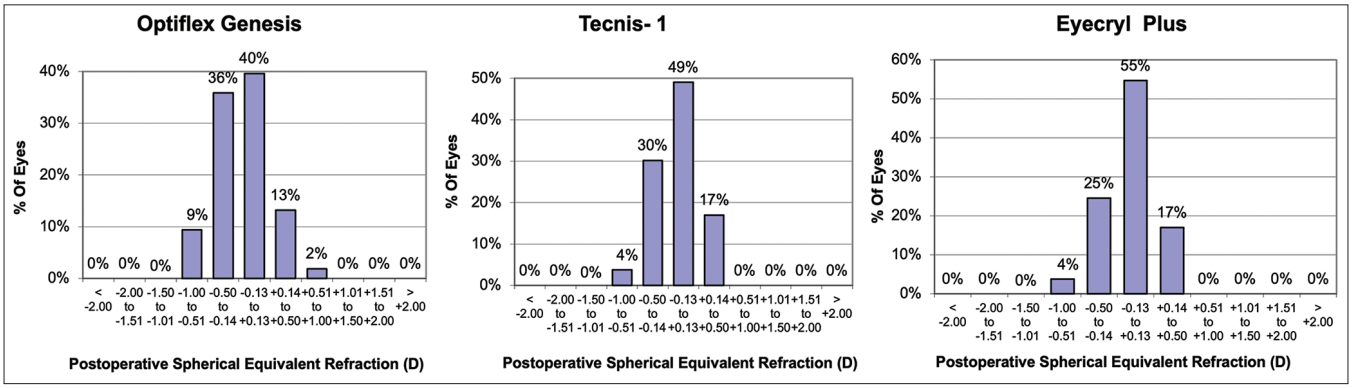

Figure 2: Histogram showing the accuracy to the intended spherical equivalent refraction at 12 months postoperatively

Table 4: One year postoperative internal and total HOAs for the three study groups

	Optiflex Genesis (Mean±SD)	Tecnis-1 (Mean±SD)	Eyecryl Plus (ASHFY 600) (Mean±SD)	*P*
Internal HOA (mm)	-0.210±0.14	-0.271±0.12	-0.222±0.16	0.04*
Internal SA (mm)	-0.207±0.01	-0.261±0.02	-0.210±0.03	<0.0001*
Internal COMA (mm)	-0.082±0.10	-0.062±0.04	-0.093±0.06	0.09
Whole eye HOA (mm)	0.099±0.04	0.105±0.05	0.095±0.03	0.53
Whole eye SA (mm)	0.015±0.03	0.008±0.02	0.014±0.03	0.50

HOA=higher-order aberration, SA=spherical aberration, SD=standard deviation, *indicates *P* value <0.05 is clinically significant

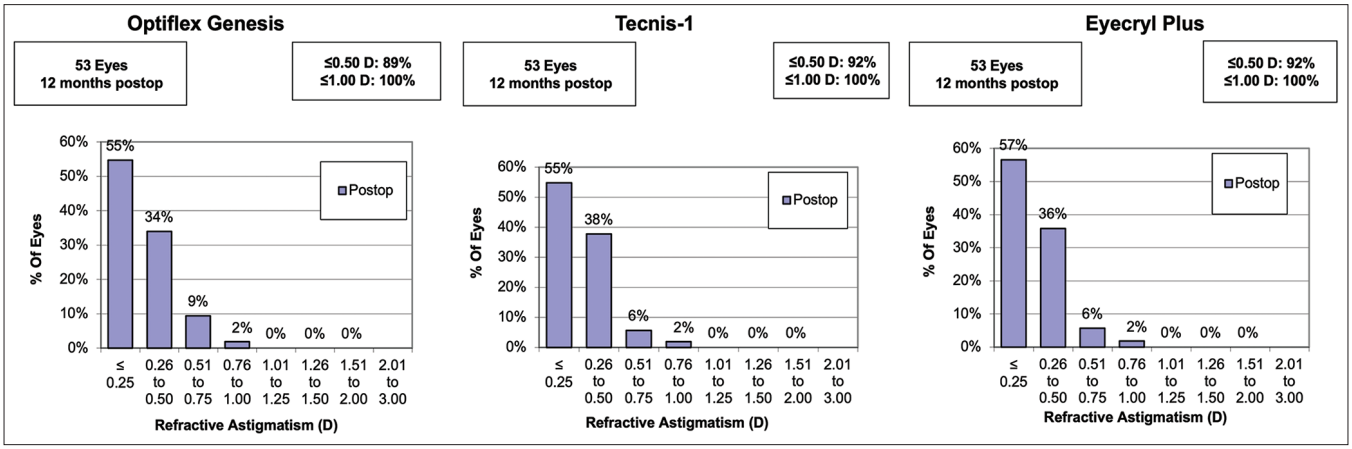

Figure 3: Histogram showing the accuracy to the intended refractive astigmatism at 12 months postoperatively

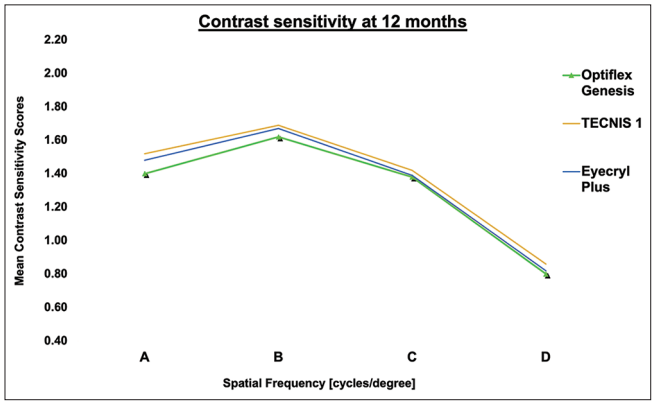

Figure 4: Photopic contrast sensitivity evaluated monocularly (with correction) at 12 months postoperatively

Plus (ASHFY 600) lenses in the intermediate and near range, with a slightly wider range of vision compared to the Tecnis-1 group.

Intraoperative unfolding time and events

The mean intraoperative unfolding time was highest (32.16 ± 10.40 s) in the Tecnis-1 group, compared to the Optiflex Genesis (12.15 ± 4.20 s) and Eyecryl Plus (ASHFY 600) (14.93 ± 3.80 s) groups, with the difference being statistically significant ($P < 0.001$). Intraoperatively, no eye in any of the study groups had any injector-related complication such as damage to the IOL, posterior capsule, zonules, or overriding of the haptic in the cartridge. However, seven eyes in the Tecnis group versus four eyes in the Optiflex Genesis and five eyes in the Eyecryl Plus (ASHFY 600) group had optic haptic adhesions, requiring separation with a Sinskey's hook.

Adverse effects and complications

Dilated clinical examination was performed at 12 months to assess optical clarity of the IOL and specifically to look for any discoloration, glistenings, opacification, calcification, or PCO formation. All eyes in all the three study groups had well-centered IOLs in the bag, with 360° overlap of capsulorhexis and without any significant tilt or decentration. None of the eyes had evidence of IOL glistenings or calcification. Two eyes in the Tecnis group (3.77%), two eyes in the Optiflex Genesis group (3.77%), and one eye in the Eyecryl Plus (ASHFY 600) group (1.88%) had evidence of visually significant PCO, requiring Nd:YAG capsulotomy at the end of the mean follow-up. No other vision-threatening complications occurred in any of the eyes included in the study. No eye in any group required IOL exchange or explantation due to any reason.

Discussion

The present study evaluated the clinical outcomes of three hydrophobic, acrylic, monofocal, aspheric IOLs – Optiflex Genesis, Eyecryl Plus (ASHFY 600), and Tecnis-1 IOLs, at 12-month follow-up. In terms of visual and refractive results, all the three study lenses showed comparable postoperative visual and refractive results at 12 months when compared to their 2 weeks values, with no significant differences in UDVA, CDVA, sphere, cylinder, and SE (Supplementary Table 1). This suggests that the all the evaluated IOLs exhibited good stability and similar behavior in the capsular bag after implantation. Similarity in the material, optic and overall size, consistent surgical technique (single surgeon), strict adherence to eligibility criteria, and use of the most advanced biometric techniques and formulae may have attributed to these favorable outcomes.

Table 5: One-year contrast sensitivity (CSV-1000) values for all the three study groups

	A (1.5 cpd)				B (3 cpd)			
	Optiflex Genesis	Tecnis-1	Eyecryl Plus (ASHFY 600)	*P*	Optiflex Genesis	Tecnis-1	Eyecryl Plus (ASHFY 600)	*P*
12 months	1.40±0.18	1.52±0.20	1.48±0.17	0.08	1.62±0.28	1.69±0.35	1.67±0.33	0.51
	C (6 cpd)				D (12 cpd)			
	Optiflex Genesis	Tecnis	Eyecryl Plus (ASHFY 600)	*P*	Optiflex Genesis	Tecnis-1	Eyecryl Plus (ASHFY 600)	*P*
12 months	1.38±0.27	1.42±0.35	1.39±0.32	0.80	0.80±0.36	0.86±0.41	0.82±0.41	0.74

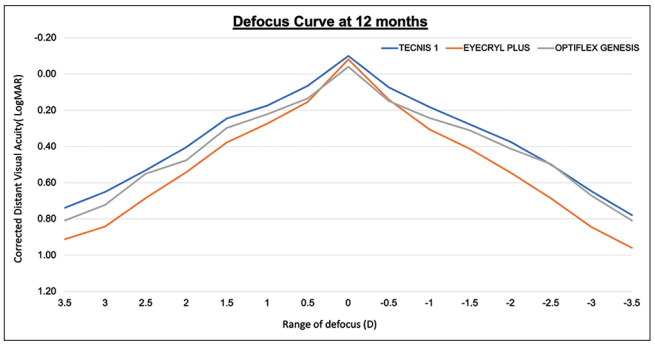

Figure 5: Monocular distance-corrected defocus curve evaluated from +3.5 to –3.5 D defocus at 12 months postoperatively

Recently, Ursell *et al*.[6] observed that, of all the five models of various IOLs compared, Tecnis-1 had a low PCO incidence (7%) after AcrySof IQ (4.7%) 3 years postoperatively. The acrylate material used in different hydrophobic lenses may have different fibronectin binding, which may also offer a rationale for the lower PCO associated with certain hydrophobic IOLs.[7] Edge design has also been shown to provide an important role in development of PCO, with previous studies demonstrating that IOLs with a square-edged optic profile are associated with less PCO than those with a round-edged profile.[8-10] While all the three IOLs assessed in this study possess a square-edged profile, it could be the case that the degree of sharpness of the posterior optic edge may have some bearing on the variation in the PCO-inhibiting properties displayed by different IOLs.[11] Even though the incidence of PCO was similar in all the study groups at 1 year, the long-term PCO rates still need evaluation due to the reasons discussed above.

From a theoretical viewpoint, IOL decentration >0.5 mm could limit or cancel the advantages of asphericity.[12,13] Holladay *et al*.[14] proposed that if an aspheric IOL was centered within 0.4 mm and tilted less than 7°, it would exceed the optical performance of a conventional spherical IOL. In the current study, we used the ray-tracing technology (I-trace) to measure postoperative internal coma arising from the lens optics, in order to evaluate the post-op IOL tilt and decentration. All the three groups had minimal and comparable values of internal coma, denoting good IOL centration in the capsular bag, due to a perfect optic–capsule overlap, which, in turn, is attributed to a meticulous and consistent surgical technique. However, the postoperative internal SA and HOAs were significantly higher in the Tecnis-1 group, possibly due to the higher value of asphericity incorporated in this lens compared to the other lenses.

Most analysis of whether aspheric IOLs have benefits over spherical IOLs has been performed by theoretical and physical eye modeling, and not with the measurements of the visual performance (visual acuity and contrast sensitivity) in eyes with these IOLs. A review study clearly showed the variability in results.[15] The main source of the discrepancies between studies of aspheric IOLs is attributed to the difference in corneal SA in the eyes with the IOLs. None of the studies reported here in the review had pre-op corneal SA computed to choose the best asphericity. In the present study, we computed the pre-op corneal SA and implanted the IOL considering the same. The whole eye postoperative SA, however, was not statistically

significantly different between the groups, even though the values for the same were least for the Tecnis-1 group of all, denoting a near-complete neutralization of the pre-op corneal SA in this group. The overall whole eye HOAs were also comparable at 12 months, suggesting a similar visual quality postoperatively. This also reflected in the results of contrast sensitivity at 12 months, showing no difference among the groups.

The perceived advantages of aspheric designs of IOLs have been shown to be influenced by pupil size before and after the surgery. A detailed analysis of values that are comparable (for the same pupil) showed a wide variation in postoperative ocular SA values. Even though the studies demonstrated residual SA with the Tecnis-1 IOL as approximately 0.0 mm (at 6 mm), the results may differ slightly in the real-world scenario due to variation in pupil sizes.[16-19]

All the three lenses exhibited a similar pattern of defocus curve, which was typical of monofocal lens technology, showing a single peak corresponding to the distance vision and a sudden decline in the intermediate and near range. The idea of performing a defocus curve was to mainly see if any of the groups exhibited a wider range of defocus and to see the vision in the intermediate and near range. As per the defocus curve obtained, Optiflex Genesis and Eyecryl Plus (ASHFY 600) IOLs appeared to have slightly wider range of vision (CDVA of 20/30 or better) and vision in the intermediate range (corresponding to the defocus of −1.50 D), compared to the Tecnis-1 IOL. This may be explained by the lower negative asphericity (−0.20 μm) of the former lenses compared to Tecnis-1 (−0.27 μm), resulting in slight residual SAs, possibly resulting in increased depth of focus. This, however, is a theoretical finding and needs to be verified subjectively in the clinical setting.

It is known that the mechanical properties of most polymers, including acrylics, are affected by the temperature, and the glass transition temperature (Tg) of the polymer determines ideal temperature for optimal unfolding within the eye.[20] Chung *et al*.[21] compared the characteristics of five different preloaded and non-preloaded IOL delivery systems and found that the average time for non-preloaded systems was comparatively higher than the preloaded ones. MX60 had the highest IOL unfolding time in the capsular bag due to its high "Tg." In the present study, the mean intraoperative unfolding time was significantly high (32.16 ± 10.40 s) in the Tecnis-1 group, compared to the Optiflex Genesis (12.15 ± 4.20 s) and Eyecryl Plus (ASHFY 600) (14.93 ± 3.80 s) groups. The glass transition temperature of Tecnis-1 IOL being comparatively higher than the other two IOLs [Table 1] may explain the significantly shorter unfolding time of the latter, observed in the present study. The faster unfolding of the Optiflex Genesis and Eyecryl Plus (ASHFY 600) IOLs, however, did not lead to any undesirable consequences such as posterior capsule rupture, angle, or iris damage.

Seven eyes in the Tecnis-1 versus 4 eyes in the Optiflex Genesis and five eyes in the Eyecryl Plus (ASHFY 600) groups had optic haptic adhesions, requiring separation with a second instrument (Sinskey's hook) in our study. Intraoperative problems with acrylic IOL insertion or postoperative implications due to this have been previously reported.[22] Improper unfolding caused by one of the haptics sticking to the optic is known to occur due to inadequate OVD in the cartridge or rarely by the incorrect loading of the IOL.[23] These issues may also be encountered with preloaded IOLs. In a study evaluating the delivery characteristics of the AcrySof IQ SN60WS IOL injected via a preloaded AcrySert delivery system, 47 of the 85 eyes (55%) required additional rotational manipulation, management of trapped trailing haptic, haptic–optic adhesion, overriding of the plunger over the optic, and trauma to optic edge.[24] Appropriate surface modifications may potentially reduce the incidence of additional manipulations associated with implantation of single-piece acrylic IOLs.

Conclusion

In conclusion, all the three monofocal IOLs evaluated in the study delivered excellent and comparable outcomes in terms of visual and refractive results, long-term stability, induced aberrations, and optical quality. However, Optiflex Genesis and Eyecryl Plus (ASHFY 600) IOLs had significantly lesser unfolding time and smoother injection without any issues due to poor loading. Further studies with these lenses may be beneficial to understand their long-term safety, efficacy, optical quality, PCO behavior, and capsular bag stability, in comparison to other concurrent monofocal IOL technologies.

Financial support and sponsorship

Dr. Sri Ganesh and Dr. Sheetal Brar are consultants to Biotech Vision Care, Ahmedabad, India. The study was supported by a limited grant from the Biotech Vision Care Pvt Ltd.

Conflicts of interest

There are no conflicts of interest.

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Supplementary Table 1: Comparison between visual and refractive parameters of the study groups at 2 weeks and 12 months postoperatively

	Optiflex Genesis (*n*=53) Mean±SD			Tecnis-1 (*n*=53) Mean±SD			Eyecryl plus (ASHFY 600) (*n*=53) Mean±SD		
	2 weeks	12 months	*P*	2 weeks	12 months	*P*	2 weeks	12 months	*P*
UDVA (logMAR)	0.15±0.09	0.13±0.07	0.09	0.13±0.13	0.09±0.08	0.10	0.11±0.09	0.10±0.08	0.17
CDVA (logMAR)	-0.04±0.07	-0.04±0.06	0.46	-0.06±0.05	-0.07±0.05	0.10	-0.04±0.05	-0.05±0.05	0.15
Sphere (D)	-0.13±0.30	-0.06±0.29	0.20	-0.09±0.24	-0.05±0.29	0.50	-0.07±0.32	-0.05±0.28	0.20
Cylinder (D)	-0.24±0.74	-0.17±0.38	0.53	-0.20±0.48	-0.14±0.37	0.53	-0.25±0.58	-0.16±0.36	0.08
Spherical equivalent (D)	-0.24±0.52	-0.15±0.33	0.22	-0.21±0.41	-0.12±0.30	0.50	-0.24±0.42	-0.12±0.29	0.17

CDVA=corrected distance visual acuity, logMAR=log of minimum angle of resolution, SD=standard deviation, UDVA=uncorrected distance visual acuity