Original Article

Comparison of visual performance and after cataract formation between two monofocal aspheric intraocular lenses following phacoemulsification for senile cataract: A randomized controlled study

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Purpose: Monofocal aspheric intraocular lenses (IOLs) provide better visual outcome compared to other available IOLs following cataract surgery. However, the imported IOLs are expensive and are not affordable by all subset of patients in low- to middle-income countries like India. The aim of this study is to compare the safety and efficacy of a relatively low cost indigenous IOL (Acriol EC) with an imported aspheric IOL (AcrySof IQ). **Methods:** A randomized controlled trial was conducted at a tertiary care centre. Two hundred and five eyes of 137 patients >45 years of age with uncomplicated age-related cataract were recruited. All cases underwent standard phacoemulsification and randomly assigned to one of the IOL implantations (Group I: AcrySof IOL; Group II: Acriol EC IOL). Primary outcome measure was best-corrected visual acuity (BCVA). Secondary outcomes included visual function (VF) score, spherical equivalent, contrast sensitivity, optical aberrations, and posterior capsular opacification. Independent *t*-test to compare two means; Mann–Whitney test; Pearson's Chi-square test, and McNemar's test were used for analyzing the nonparametric data such as incidence of posterior capsule opacification. **Results:** There was no significant difference in the mean postoperative BCVA at 1, 3, 6, and 12 months in either group ($P > 0.05$). The contrast sensitivity, wavefront aberrations, VF score, and posterior capsular opacification were comparable between the groups except for higher-order aberrations and spherical aberration, which were higher in Group II. **Conclusions:** Acriol EC IOL provides visual outcomes comparable to other commonly used aspheric IOLs with comparable safety and efficacy at an affordable cost.

Key words: Aspheric intraocular lens, cataract, intraocular lens, phacoemulsification

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Cataract surgery has become the most frequently performed surgical procedure with approximately 6 million surgeries being performed per year in India.[1] Out of these surgeries, 95% of the cases had intraocular lens (IOL) implantation.[1] Various designs, materials, and types of IOL have been introduced and evaluated for their safety and efficacy over the past few decades. The most popular among these is the modern foldable acrylic IOL.

The cost of foldable IOL and cataract surgery is often borne by the patients in a developing country like India. The expensive imported IOL with optimal optical qualities may not be affordable by a considerable proportion of patients with low socioeconomic status. There are only few aspheric IOLs of acrylic hydrophobic material with UV-blocking chromophore which are in the intermediate affordable range. Therefore, there is a need to introduce and evaluate the efficacy and quality of vision provided by a low-cost, indigenous IOL with similar properties.

Various studies have been done comparing spherical and aspheric IOLs or two aspheric IOLs in the past. The aspheric IOL, AcrySof IQ SN60WF (Alcon, Inc, Fort Worth, TX), has been compared with other IOLs in many studies. However, no studies have been done with the Acriol EC IOL (Care Group, India). The main objective of this prospective randomized study was to compare the safety and efficacy of AcrySof IQ SN60WF and the indigenous Acriol ËC IOL.

Methods

This prospective randomized controlled clinical trial was approved by the Institutional Review Board/Ethics Committee of All India Institute of Medical Sciences, New Delhi, India. The study complied with the tenets of the Declaration of Helsinki, and the trial was registered at www.ctri.nic.in (CTRI/2013/12/004198). Two hundred and five eyes (of 137 patients) that underwent phacoemulsification and IOL implantation between January 1, 2012, and May 31, 2012, were recruited for the study. All patients above 45 years of age with uncomplicated age-related cataract were recruited. Patients

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were excluded from the study if they had a history suggestive of ocular inflammation, trauma, diabetic retinopathy, uveitis, glaucoma, retinal pathology, or previous ocular surgery. These patients were assigned randomly to undergo cataract surgery with implantation of either the AcrySof IOL (Group 1) or the Acriol EC IOL (Group 2) using a computer-generated table. The Alcon AcrySof IQ is an acrylic foldable blue-blocking single-piece posterior chamber IOL with a 6.0 mm optic and 13.0 mm overall length. The posterior aspheric surface is designed with negative aberration to compensate for the positive spherical aberration of an average cornea with an added advantage of better contrast sensitivity. The Acriol EC IOL is a single-piece, foldable, hydrophobic acrylic posterior chamber IOL. It is a synchronized cast molded IOL with a biconvex optic of 6.0 mm diameter and overall length of 12.5 mm having a square edge optic. The optic is aberration neutral with both the anterior and posterior surfaces of optic being aspheric [Table 1].

The baseline demographic profile of all the study patients was recorded. A complete ocular examination was done using a slit lamp to evaluate the anterior segment and indirect ophthalmoscope to evaluate the posterior segement. B-scan ultrasonography was done in cases where fundus evaluation was not possible due to a dense cataract. Biometry was performed with the use of IOL Master (Zeiss, Version 5.0; Carl Zeiss Meditec, Inc., Dublin, CA, USA). Best-corrected visual acuity (BCVA) was recorded using the Snellen chart, and this was converted into logMAR (logarithm of minimum angle of resolution) acuity for statistical analysis. All patients underwent phacoemulsification by a standard surgical technique and IOL implantation using the recommended injectors for each of the IOLs through a temporal clear corneal incision (2.8 mm) under topical or local anesthesia. A single surgeon (NS) experienced in phacoemulsification performed all the cases. Postoperatively, all patients received topical antibiotic eye drop (moxifloxacin hydrochloride 0.5%) 3 times a day, topical steroid (prednisolone acetate 1%) 4 times a day for 1 week followed by tapering over subsequent 4 weeks, and tropicamide hydrochloride (1%) three times a day for 1 week. Primary outcome measure was BCVA. Secondary outcomes included visual function (VF) score, spherical equivalent (SE), contrast sensitivity, optical aberrations, and posterior capsular opacification (PCO). The investigator doing the postoperative assessment for all the patients was blinded for the type of IOL implanted.

Table 1: Characteristics of the intraocular lenses used in the study

Characteristic	AcrySof IQ SN60WF	Acriol EC
Optic material	Hydrophobic copolymer acrylate/methacrylate	Hydrophobic copolymer acrylate/methacrylate
Optic design	Biconvex; square edges; posterior aspheric surface	Biconvex; square edges; anterior and posterior aspheric surface
Optic diameter	6.0 mm	6.0 mm
Length (mm)	13.0	12.5
Haptic material	Modified L	Modified C-flex
Hapticangulation (degrees)	0	0
Ultraviolet filter	Yes (blue-light filter)	Yes (blue-light filter)
ACD (mm)	5.37	5.10
A constant	118.7	118.8

ACD: Anterior chamber depth

Patients were followed up and examined at baseline, 1 week, 1 month, 3 months, 6 months, and 12 months after the surgery. To evaluate the visual performance of patients implanted with the two IOLs, the following tests were done. The Pelli-Robson contrast sensitivity test (Clement Clarke International, London, United Kingdom) under photopic (85 cd/m^2) and mesopic (3 cd/m^2) conditions and wavefront aberrations using Zywave IIz aberrometer (Bausch and Lomb, St. Louis, MO, USA). The VF-14 score was recorded using "VF-14 Quality of Life" Questionnaire preoperatively and at 3, 6, and 12 months. The patients answered a self-administered questionnaire which consists of 14 questions related to behavioral patterns in daily life such as reading, doing fine handwork, cooking, watching television, and driving at day and night. Higher scores represent better visual functioning. At each follow-up, the pupil was dilated and the posterior capsule was evaluated for development of any PCO using digital retroillumination photodocumentation at a fixed illumination and magnification by a single examiner.

Statistical analysis

A sample size of 100 eyes for each group was calculated using 95% confidence interval and 90% power of the study. The data were recorded on a predesigned proforma and managed on a spreadsheet (Excel; Microsoft Corp., Redmond, WA). All the quantitative variables were assessed for the normal distribution and were summarized by mean and standard deviation and other variables which were nonnormative as median values at each time point for the patients. Qualitative data were represented in percentage. SPSS version 17 was used for analysis of the data. For the different parameters, the following analysis was performed; Independent *t*-test to compare two means; Mann–Whitney test to compare nonparametric continuous data; Pearson's Chi-square test to compare nonparametric categorical data; and McNemar's test were used for analyzing the nonparametric data such as incidence of PCO. Result was considered statistically significant if $P < 0.05$.

Results

Two hundred and five eyes with age-related cataract were included of which five were excluded due to posterior capsular rupture (two in the AcrySof group and three in the Acriol group). Thus, 200 eyes were available for analysis. The baseline characteristics, such as age, gender, uncorrected visual acuity (UCVA), BCVA, SE, and intraocular pressure (IOP) at presentation, were comparable between the two groups [Table 2]. The preoperative values of contrast sensitivity [photopic ($P = 0.49$) and mesopic ($P = 0.39$)], glare acuity ($P = 0.56$), ocular aberrations including spherical aberration ($P = 0.61$), root mean square (RMS) aberrations for 5 mm pupil ($P = 0.69$) and 6 mm pupil ($P = 0.73$), and higher-order aberrations (HOA) for 5 mm pupil ($P = 0.89$) and 6 mm pupil ($P = 0.78$) were not statistically significant ($P > 0.05$) between the two groups [Table 3].

Results of UCVA, BCVA, SE, and IOP at baseline and at 1, 3, 6, and 12 months after surgery are summarized in Table 3. There was no significant difference in the mean postoperative

BCVA at 1, 3, 6, and 12 months in either group ($P > 0.05$). About 84% gained UCVA and 94% gained BCVA of ≥0.2 on logMAR scale (Snellen's >6/9) in AcrySof group whereas 79% gained UCVA and 92% gained BCVA of ≥0.2 on logMAR scale (Snellen's ≥6/9) in Acriol EC group.

The mean refractive error in SE in AcrySof group in the preoperative period was −2.66 ± 2.8 D and in the Acriol group was −2.98 ± 3.9 D ($P = 0.52$). This decreased significantly in the postoperative 1-month period in the two groups in AcrySof group to −0.23 ± 0.6 D and in the Acriol group to −0.28 ± 0.56 D ($P = 0.001$) which was statistically significant. IOP was similar between both groups at 12 months ($P > 0.05$).

The VF-14 quality of life questionnaires were completed by all patients. The preoperative and postoperative mean VF-14 score between the two groups was statistically comparable ($P = 0.079$ and 0.157), respectively. However, there was a significant change in the vision-related quality of life postoperatively ($P = 0.001$) in the two groups. The patients reported drastic improvement in day-to-day activities such as doing fine work, cooking, driving at day and night, and so on [Fig. 1].

The contrast sensitivity was evaluated under photopic and mesopic conditions in all patients. The mean photopic and mesopic contrast sensitivity values at baseline and 1, 3, 6, 12 months postoperatively in the two groups are summarized in Table 3.

Wavefront analysis was performed using Hartmann–Shack aberrometer. Only 41 eyes in Group 1 and 39 eyes in Group 2 had cataracts less dense so that a waveform map could be captured. Ocular aberrations including RMS aberrations at 5 mm and 6 mm pupil, HOA at 5 mm and 6 mm pupil, and spherical aberrations (SA) at 6 mm pupil were evaluated pre- and post-operatively in the same group and also between the two groups in these 80 eyes. The postoperative values of all 200 eyes were also analyzed in between the groups. These values are shown in Table 3. The AcrySof IQ IOL showed statistically significant less total RMS mean values at 5 mm and 6 mm pupil ($P = 0.02$) than Acriol EC and also lower HOA mean values ($P = 0.02$) than Acriol EC IOL. The AcrySof IQ IOL obtained statistically significant less spherical aberration when compared with the Acriol EC ($P = 0.001$). Four eyes in the AcrySof IQ group and six eyes in the Acriol EC group showed Grade 1 IOL decentration. The wavefront analysis of these cases separately showed increased values of mean RMS, but it did not affect final visual acuity in any case.

Table 2: Demographic profile and baseline characteristics of the patients in the two groups

Parameter	Acrysof IQ	Acriol EC	*P*
Age (years)	60.5±8.4	60.9±8.5	0.91
Sex (M/F)	46/54	44/56	
SE (D)	-2.66±2.82	-2.98±3.91	0.823
IOP (mm Hg)	14.66±3.45	14.14±3.41	0.285
AL (mm)	23.2±0.67	23.08±0.73	0.081
Km (D)	45.16±1.52	45.28±1.56	0.22
Mean IOL power (D)	21.68±1.65	21.92±1.5	0.29

SE: Spherical equivalent, IOP: Intraocular pressure, AL: Axial length, Km: Keratometry, IOL: Intraocular lens

The incidence of posterior capsular opacification in the two IOL groups at 6 and 12 months was statistically insignificant. At 1-year follow-up, 10% in the AcrySof group while 14% in the Acriol group showed PCO changes. Pigments on the IOL surface was noted in 37% cases in the AcrySof group and 44% cases in the Acriol EC group ($P = 0.529$).

There was no significant difference in the incidence of adverse surgical events during ($P > 0.05$) or after ($P > 0.05$) surgery. No problems were encountered during implantation of IOL in any of the cases. Rupture of the posterior capsule occurred in two patients in the AcrySof IOL group and in three patients in the Acriol EC group. A multipiece posterior chamber IOL implantation was performed in these cases. None of the cases in the two groups manifested an unusual inflammatory response in the early postoperative period. The postoperative course was uneventful in all the patients in both groups at the end of 1, 3, 6, and 12 months ($P > 0.05$).

Discussion

Modern cataract surgery routinely is combined with the implantation of an IOL. Surgical technique as well as IOL materials and designs have advanced extensively, and considerable attention has been given to improve the optical quality provided by IOLs. Advances in technology have brought about the use of silicone and acrylic components, both of which are soft foldable inert materials, and resulted in the development of aspheric IOLs to compensate the corneal aberrations.[2] Several studies have been done in the past to evaluate the efficacy of these newer generation IOLs.

In our study the mean BCVA significantly increased from the preoperative value at 1-month follow-up in both the groups which remained stable till the last follow-up.

The visual performance index that well depicts human spatial vision is contrast sensitivity function. Our study showed that photopic and mesopic contrast sensitivity in both IOL groups achieved near normal values postoperatively. We did not find any difference in photopic and mesopic contrast sensitivity between the two IOLs. The Pelli-Robson contrast acuity in log units was statistically comparable ($P > 0.05$) in both the groups in the postoperative period which was significantly higher than the preoperative value ($P < 0.05$). This result agrees with findings of Nabh *et al.*[3] who reported comparable

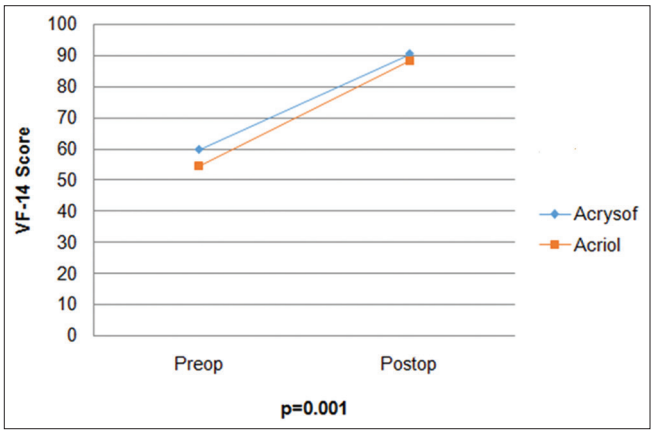

Figure 1: The visual function 14 quality of life questionnaires between the two groups

Table 3: Individual analysis of mean visual acuity, contrast sensitivity, wavefront aberrations for AcrySof IQ and Acriol EC groups

Parameter	Baseline	1 month	3 months	6 months	12 months
	Acrysof Acriol	Acrysof Acriol	Acrysof Acriol	Acrysof Acriol	Acrysof Acriol
UCVA	0.84 (0.32) 0.91 (0.35)	0.16 (0.14) 0.17 (0.12)	0.16 (0.12) 0.17 (0.1)	0.15 (0.13) 0.16 (0.1)	0.15 (0.14) 0.16 (0.11)
P	0.09	0.47	0.33	0.24	0.29
BCVA	0.56 (0.37) 0.64 (0.38)	0.02 (0.1) 0.03 (0.1)	0.02 (0.09) 0.02 (0.08)	0.02 (0.09) 0.02 (0.08)	0.02 (0.11) 0.02 (0.09)
P	0.16	0.58	0.44	0.44	0.47
Photopic contrast sensitivity (cd/m^2)	0.97 (0.45) 0.92 (0.47)	1.48 (0.16) 1.46 (0.19)	1.48 (0.1) 1.47 (0.1)	1.49 (0.1) 1.48 (0.1)	1.48 (0.1) 1.46 (0.1)
P	0.49	0.78	0.88	0.82	0.69
Mesopic contrast sensitivity (cd/m^2)	0.78 (0.38) 0.7 (0.43)	1.32 (0.19) 1.31 (0.2)	1.34 (0.1) 1.33 (0.1)	1.34 (0.1) 1.33 (0.1)	1.33 (0.11) 1.33 (0.1)
P	0.49	0.78	0.88	0.82	0.69
Root mean square (5 mm pupil)	1.75 (1.06) 1.64 (0.73)	0.94 (0.3) 1.13 (0.29)	1.01 (0.26) 1.22 (0.29)	1.1 (0.27) 1.31 (0.31)	1.19 (0.29) 1.42 (0.32)
P	0.60	0.017	0.015	0.02	0.013
Root mean square (6 mm pupil)	2.56 (1.33) 2.52 (1.09)	1.3 (0.44) 1.52 (0.56)	1.38 (0.36) 1.61 (0.5)	1.47 (0.33) 1.69 (0.47)	1.56 (0.32) 1.78 (0.44)
P	0.91	0.02	0.007	0.006	0.004
Higher order aberrations (5 mm pupil)	0.62 (0.33) 0.67 (0.29)	0.43 (0.18) 0.69 (0.16)	0.44 (0.17) 0.70 (0.15)	0.45 (0.16) 0.71 (0.15)	0.46 (0.15) 0.72 (0.14)
P	0.85	0.02	0.023	0.03	0.03
Higher order aberrations (6 mm pupil)	0.99 (0.55) 0.96 (0.51)	0.66 (0.21) 0.92 (0.27)	0.67 (0.18) 0.91 (0.23)	0.69 (0.17) 0.93 (0.23)	0.71 (0.17) 0.95 (0.18)
P	0.85	0.022	0.02	0.019	0.02
Spherical aberration	0.3 (0.14) 0.32 (0.19)	0.03 (0.29) 0.24 (0.27)	0.03 (0.25) 0.23 (0.22)	0.028 (0.23) 0.23 (0.18)	0.026 (0.22) 0.23 (0.16)
P	0.61	0.001	0.001	0.002	0.001

UCVA: Uncorrected visual acuity, BCVA: Best corrected visual acuity

visual performance and contrast sensitivity between Tecnis Z9003, AcrySof IQ SN60WF and Akreos Adapt AO after phacoemulsification.[3] Similar outcomes have been reported by Thiagarajan *et al*.,[4] Rodríguez-Galietero *et al*.,[5] Kurz *et al*.,[6] Pandita *et al*.,[7] Caporossi *et al*.,[8] Mester and Kaymak,[9] and Santhiago *et al*. in past.[10]

In our study the Hartmann–Shack spot patterns could only be appropriately measured and analyzed in all the patients after the surgery. The 1-, 3-, 6-, and 12-month postoperative wavefront analyses including mean total RMS values, mean HOA values, and spherical aberration for the two groups were found to be statistically significant ($P < 0.05$) than baseline. The AcrySof IQ IOL showed statistically significant less total RMS mean values ($P = 0.02$), lower HOA RMS mean values ($P = 0.02$), and lesser spherical aberration ($P = 0.001$) than Acriol EC IOL. These readings are consistent with the findings of Rocha *et al*.[11] Since we study an aspheric IOL that theoretically does not present negative spherical aberration, a higher amount of total ocular spherical aberration was found in our study compared with those previous studies that analyzed other types of aspheric IOLs, which have residual negative spherical aberration. Caporossi *et al.* conducted a study that compared an aspheric IOL that also does not generate internal negative spherical aberration, the SofPort AO (Bausch and Lomb, Inc), with a spherical IOL and also found lower values of spherical aberration with the aspheric IOL.[8]

The term "functional vision" describes the effect of sight on quality of life. The ability to recognize faces and facial expressions, read the newspaper, drive at night, perform vocational tasks, and participate in recreational pursuits is related to functional vision. In our study, the VF-14 score improved significantly in both the groups. Our results confirm those in previous studies of the benefits of cataract surgery with IOL implantation.[12,13]

Our study compared the PCO rates between two IOL models, both of which are single-piece hydrophobic acrylic

with angulated haptics of zero degrees. The PCO rate was 10% (10 of 100 eyes) in the AcrySof IQ group and 14.0% (14 of 100 eyes) in the Acriol EC group at the end of 1 year. These values were not statistically significant between the two groups (P = 0.38). The PCO was not significant in any of the cases, in either group, that could have necessitated Nd-YAG capsulotomy. Decreased visual acuity induced by PCO is reported to occur in 20% to 40% of patients 2–5 years after surgery.[14] It has been well established that an acrylic IOL is associated with significantly reduced degree of PCO as compared with silicone or polymethyl methacrylate IOLs.[15] In a study done by Bender *et al*. in 2004, the PCO rate of 16% was reported 1 year after hydrophobic single-piece Acrylic IOL (AcrySof) implantation.[16] In our study, the two aspherical IOLs yielded a similar incidence of PCO. This may be explained by the similar design configurations and material of the IOLs. It has been well documented that IOL edge design is an important factor in the pathogenesis of PCO.[17-20] Several studies have shown that a square-edged design results in a lower incidence of PCO than a round-edged design. Both the IOLs in our study have a square edge.[17-20]

Conclusion

This study showed that Acriol EC IOL was effective for the management of age-related cataract. The efficacy of an IOL can be judged by the visual outcomes and performance over a consistent follow-up period. The incidence of complications during and after the surgery was acceptably low in this study upto a follow up of 1 year suggesting that both the IOLs are equally efficacious for implantation after phacoemulsifaction.

The study suffers from the limitation of a relatively small sample size. In addition, a longer follow-up is required to compare the rate of PCO in any type of IOL. However, the result of this study suggests that Acriol EC IOL provides visual outcomes comparable to other commonly used aspheric IOLs with comparable safety at an affordable cost.

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Conflicts of interest

There are no conflicts of interest.

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