Assessment of refractive outcomes in eyes that underwent intraocular lens implantation in the posterior chamber but not "in-the-capsular bag:" A comparative retrospective study

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Abstract:

PURPOSE: The purpose of this study was to report visual and refractive outcomes in eyes that underwent intraocular lens (IOL) fixation in the absence of capsular support.

METHODS: This was a retrospective chart review of cases undergoing posterior chamber iris-fixated IOL (IFIOL) and scleral-fixated IOL (SFIOL) implants from June 2014 to March 2020 with more than 3 months of follow-up and having a preoperative best-corrected visual acuity of 20/80 and more.

RESULTS: Records of 120 eyes of 112 patients were reviewed. The mean age of the patients was 46.9 ± 22.3 (14.4–98.0) years, and 62% (n = 70) of participants were male. Most of the eyes (102: 85%) were aphakic at the time of surgery. The mean follow-up was 22.95 ± 17.1 months. The efficacy index of sutured IFIOL and glued SFIOL outperformed sutured SFIOL at 3 months and final visits postoperatively (P < 0.001). All techniques studied here resulted in a similar safety index at 3 months (P = 0.4). The mean predictive error (postoperative spherical equivalent refraction minus intended target refraction) was +0.07 ± 1.5 D and −0.12 ± 1.4 D at 3 months and the final postoperative visit, respectively.

CONCLUSION: The studied techniques have relatively good visual and refractive outcomes in this series. In addition, techniques involving a small corneal incision with foldable IOL fixation to the iris or scleral tissue have superior efficacy and safety indices compared to creating large corneoscleral wounds for rigid IOL fixation techniques.

Keywords:

Aphakia correction, refractive outcome, retrospective cohort, secondary intraocular lens implantation, visual outcomes

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Introduction

Posterior chamber lens implantation with surgical fixation to adjacent structures is used in cases with inadequate capsular support.[1] Various techniques have been developed for such cases, and each technique has its advantages over the other in certain situations. Generally, the most commonly performed techniques nowadays are sutured scleral-fixated intraocular lenses (SFIOLs), sutureless SFIOLs, and iris-fixated intraocular lenses (IFIOLs).[2,3]

Refractive surprises can occur in cataract surgery, refractive surgery, and correction of aphakia. Any discrepancy in the predicted and the actual refractive outcome after surgery in diopters can be considered a refractive surprise.[4] Several factors associated with refractive surprises include older age, ocular comorbidities, intraocular lens (IOL) calculation formula used, and pre-, intra-, postoperative factors.[4-6] One of the issues during IOL calculation is the accurate estimation of the effective lens position (ELP). Many factors can influence this important parameter. Furthermore,

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the ELP can vary based on the surgical technique used and the type of IOL chosen for iris or scleral fixation. The current IOL formulas were designed to estimate the IOL power while assuming the IOL will be placed in the capsular bag or in the sulcus. The data regarding the accuracy of IOL calculations where iris fixated IOL (IFIOL) or scleral fixated IOL (SFIOL) implantation is scant.

Therefore, the current study aims to report the refractive and visual outcomes in cases that underwent IFIOL and SFIOL in our tertiary eye care center.

Methods

The institutional review board approved this retrospective cohort, which was conducted according to the Declaration of Helsinki. We reviewed the records of cases that underwent IOL fixation in the absence of capsular support from June 2014 to March 2020.

Out of 330 cases performed during the before mentioned period, we included eyes with uneventful fixation (i.e., absence of intraoperative complications such as iridodialysis or intraoperative IOL dislocation) of three-piece Sensar AR40e or Alcon MA60AC IOL or a poly (methyl methacrylate) (PMMA) IOL. Furthermore, only patients with preoperative corrected distant visual acuity (CDVA) of 20/80 or better and patients who had one postoperative manifest refraction at least 90 days after the surgery were included in the analysis. In addition, we excluded cases with any severe media opacity precluding examination of the ocular structures and reliable assessment of refractive errors postoperatively, such as advanced glaucoma and corneal and retinal pathology. Furthermore, cases undergoing concurrent surgical interventions such as keratoplasty or retinal detachment repair were excluded. Additionally, cases with <3 months of follow-up were excluded. The collected variables are summarized in Table 1.

Surgical techniques included in this study were described in previous reports.[7-10] Cases in this cohort were operated on by multiple surgeons (33 consultants and 11 fellows). For IFIOL, adjustment of the IOL power was made before implantation based on the assumption of in-the-sulcus position.[11] The assumption of the in-the-bag position was used for IOL power calculation in cases implanted using either sutured or glued SFIOL techniques.

Statistical analysis

Statistical analysis was performed using StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC. First, visual acuity was converted from Snellen units to the logarithm of the minimum angle of resolution (logMAR) equivalent as recommended.[12] However, to obtain efficacy and safety index, the visual acuity was converted to decimal equivalent. We used the postoperative spherical equivalent (SEQ) refraction minus the predicted refraction given by the IOL power chosen for implantation to calculate the prediction error. A negative result indicates more myopic refraction than the original predicted refractive error. We calculated the Efficacy index as the ratio of postoperative uncorrected distant visual acuity (UDVA) to preoperative CDVA after conversion to decimals equivalent and the safety index as the ratio of postoperative CDVA to preoperative CDVA after conversion to decimals equivalent. Next, we tested continuous variables for normality using the Shapiro–Wilk test, and then they were expressed as mean and standard deviation (SD). Next, categorical variables were summarized as frequencies and percentages. Finally, the associations between categorical and multiple continuous variables were tested using a one-way analysis of variance test. $P < 0.05$ was considered statistically significant.

Table 1: Summary of collected data in the study

Preoperative data
Age
Gender
Lens status
Systemic comorbidities
UDVA
CDVA
Manifest refraction
Axial length*
IOL calculation formula*
Predicted target refraction*
Intraoperative data
Surgeon's experience level (attending versus fellow)
IOL fixation technique used
Intraoperative complications
Postoperative data
UDVA
CDVA
Manifest refraction
Early and late postoperative complications

*Obtained from the IOL Master (IOL Master 500, Carl Zeiss Meditec AG) assuming "in-the-bag" IOL position. IOL: Intraocular lens, CDVA: Corrected distant visual acuity, UDVA: Uncorrected distance visual acuity

Results

Data from 120 eyes of 112 patients that met the inclusion criteria were analyzed. The mean age of the patients was 46.9 ± 22.3 (14.4–98.0) years. Sixty-two percent (n = 70) of participants were male, and 38% (n = 42) were female. The mean follow-up duration in this study was 22.95 ± 17.1 months. Table 2 shows the baseline data of cases included in this study.

Most of the eyes (102: 85%) were aphakic at the time of surgery. No cases of a dislocated crystalline lens were observed. Crystalline lens subluxation was reported in 6 (5%) eyes. Subluxation and dislocation of IOL were found in 8 (7%) and 4 (3%), respectively. In this series, only 12 eyes were associated with syndromes. Eight eyes were of patients with Marfan's syndrome, two eyes were associated with Weill–Marchesani syndrome, and the remaining two were associated with homocystinuria. Of 120 eyes, 32 (27%) had a history of trauma, while 33 eyes (27.5%) had a history of previous complicated cataract surgery. Congenital cataract with a history of lensectomy without IOL implantation was reported in 18 cases (15%). The cause of aphakia in the remaining cases was undocumented in the charts. Eleven eyes (9%) had a history of mild glaucoma controlled by medication. Out of these, only 5 cases were secondary to angle recession (3) or aphakia (2). Most of the eyes (103, 86%) had an unremarkable retinal examination.

Visual and refractive outcomes

The mean preoperative UDVA was 1.5 ± 0.6 LogMAR, and the mean preoperative CDVA was 0.3 ± 0.3 LogMAR. At the final postoperative visit, the UDVA was 0.5 ± 0.4 LogMAR for the IFIOL and 0.5 ± 0.3 LogMAR and 03 ± 0.1 LogMAR for the sutured and glued SFIOLs, respectively. Meanwhile, the CDVA was maintained at 0.3 ± 0.2 LogMAR, 0.2 ± 0.6 LogMAR, and 0.2 ± 0.2 LogMAR for the IFIOL, sutured SFIOL, and glued SFIOL, respectively. The details of the visual outcome, efficacy, and safety indices are summarized in Table 3. Figure 1 illustrates the difference between preoperative and postoperative visual acuities of all studied techniques.

IOL power calculation was performed using the Holladay 1 formula in all cases. As a result, the mean calculated intended target refraction for all cases was −0.7 ± 0.7 diopters (D), while the mean predictive error (postoperative SEQ refraction minus intended target refraction) was +0.07 ± 1.5 D and −0.12 ± 1.4 D at 3 months and final postoperative visit, respectively.

Table 2: Baseline preoperative data of the eyes included in the study

Preoperative data	Mean±SD
Axial length (mm)	24.2±1.8
K1 (D)	42.0±1.9
K2 (D)	44.4±2.0
Preoperative UCVA	1.5±0.6
Preoperative CDVA	0.3±0.3
Preoperative refractive error (sphere)	+10.7±4.5
Preoperative refractive error (cylinder)	2.0±1.4
Intended target refraction	−0.7±0.7

CDVA: Corrected distant visual acuity, UCVA: Uncorrected visual acuity, SD: Standard deviation

In cases undergoing sutured IFIOL, the preoperative cylindrical power was 2.46 ± 1.3 D and was maintained at 2.92 ± 0.9 D and 2.88 ± 1.4 D at 3 months and final visit, respectively. For sutured SFIOL, the cylindrical power preoperatively was 1.83 ± 1.5 D and then increased to 3.75 ± 1.9 D and 2.63 ± 1.2 D at 3 months and final visit, respectively, while the cylindrical power for glued SFIOL changed from 1.98 ± 1.2 D preoperatively to 3 ± 2.7 D and 2 ± 0.8 D at 3 months and final visit, respectively. The details of the refractive outcomes of all three techniques are illustrated in Table 4. Furthermore, the detailed comparisons of pre- and postoperative refractive astigmatism of all three studied techniques are shown in Figure 2.

Discussion

Many secondary IOL fixation techniques have been published advocating more IOL stability over time, ease of implantation, time-saving, and a less steep and short learning curve for the surgeon.[13] It is still controversial which technique is the best to implant an IOL in an eye with insufficient capsular support.

Our study is unique in many ways; it included several IOL fixation techniques with minimal coexisting ocular pathology, which can be very challenging in those eyes. This can only be achieved in a tertiary/referral center and over a long period, in our case, a span of 6 years.

To add to the difficulty, these eyes already have compromised visual potential secondary to sequelae of trauma or structural abnormalities and possible amblyopia.

Our data indicate that all techniques described here resulted in similar or better CDVA at 3 months after surgery compared to preoperative CDVA (P = 0.5). Furthermore, our data showed acceptable efficacy and safety indices of all techniques analyzed. Among the three techniques, glued SFIOL had the highest efficacy index at 3 months postoperatively, followed by sutured IFIOL and sutured SFIOL. At the final visit, all techniques showed an improvement in the efficacy index. Notably, eyes with sutured IFIOL had a sharp rise in efficacy index by 2.1. On

Table 3: Comparison of the visual outcome, efficacy, and safety index of different intraocular lens fixation techniques

	Iris-fixated intraocular lens (sutured) (n=21)	Scleral-fixated intraocular lens (sutured) (n=76)	Scleral-fixated intraocular lens (glued) (n=23)	*P*
UDVA preoperatively*	1.5±0.7 (20/640†)	1.6±0.6 (20/800†)	1.4±0.7 (20/500†)	0.3
UDVA at 3 months*	0.6±0.2 (20/80†)	0.7±0.4 (20/100†)	0.6±0.3 (20/80†)	0.06
UDVA at final visit*	0.5±0.4 (20/63†)	0.5±0.3 (20/63†)	0.3±0.1 (20/40†)	0.05
CDVA preoperatively*	0.5±0.5 (20/63†)	0.3±0.2 (20/40†)	0.3±0.2 (20/40†)	<0.001
CDVA at 3 months*	0.4±0.2 (20/50†)	0.3±0.2 (20/40†)	0.3±0.1 (20/40†)	0.5
CDVA at final visit*	0.3±0.2 (20/40†)	0.2±0.6 (20/32†)	0.2±0.2 (20/32†)	<0.001
Efficacy index at 3 months‡	0.7±0.7	0.5±0.3	1.1±1.5	<0.001
Efficacy index at final visit‡	2.8±3.3	0.8±0.3	1.7±1.3	<0.001
Safety index at 3 months§	1.1±0.8	1.0±0.6	1.2±0.9	0.4
Safety index at final visit	2.7±3.6	1.1±0.5	2.0±1.3	<0.001

*LogMAR, †Snellen equivalent, ‡Ratio of postoperative UDVA to preoperative CDVA after conversion to decimals equivalent, §Ratio of postoperative CDVA to preoperative CDVA after conversion to decimals equivalent. CDVA: Corrected distant visual acuity, UCVA: Uncorrected visual acuity, LogMAR: Logarithm of the minimum angle of resolution

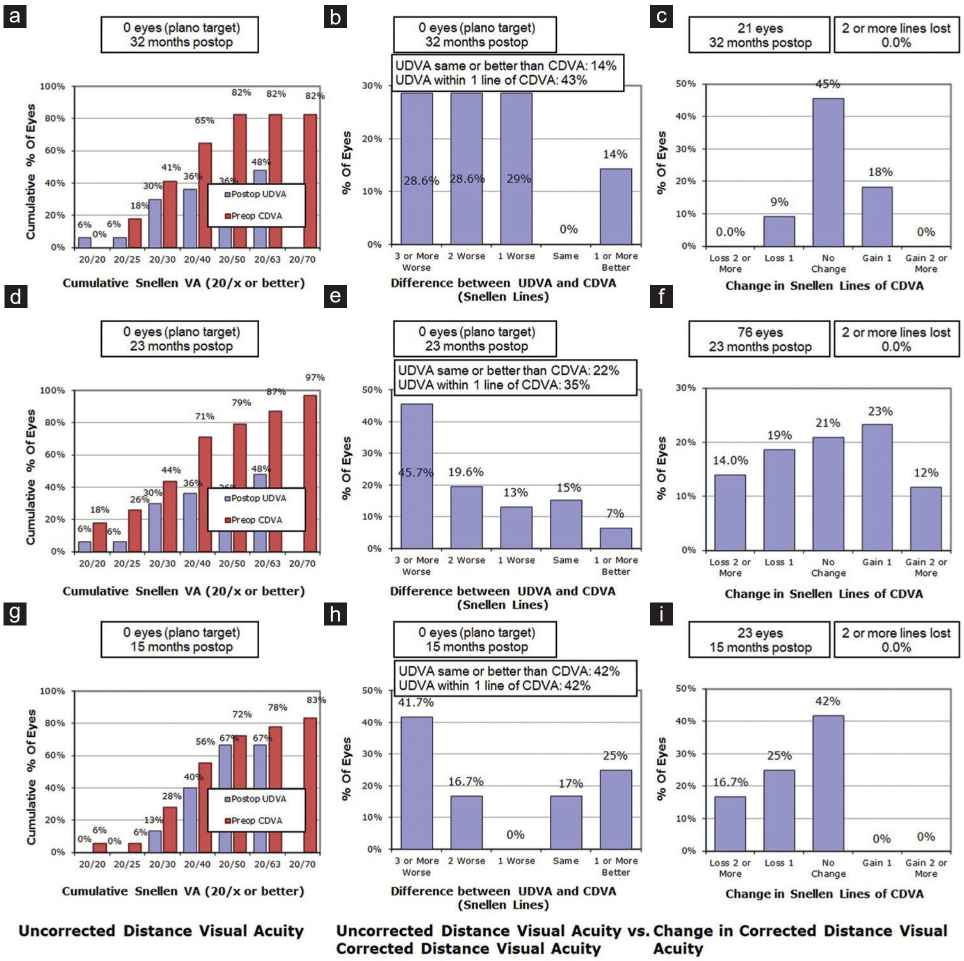

Figure 1: Preoperative and postoperative visual acuity of (a-c) Iris-fixated intraocular lens, (d-f) Sutured SFIOL, (g-i) Glued SFIOL. UDVA: Uncorrected distant visual acuity, CDVA: Corrected distant visual acuity, SFIOL: Scleral-fixated intraocular lens

Table 4: Comparison of the refractive outcome of different intraocular lens fixation techniques

	Iris-fixated intraocular lens (sutured) (n=21)	Scleral-fixated intraocular lens (sutured) (n=76)	Scleral-fixated intraocular lens (glued) (n=23)	*P*
Spherical power preoperatively	+11.03±3.4	+10.95±4.5	+9.20±5.5	0.2
Cylinder power preoperatively	2.46±1.3	1.83±1.5	1.98±1.2	0.6
Spherical power at 3 months	+0.92±0.7	+1.12±2.5	+1.17±1.2	0.003
Cylinder power at 3 months	2.92±0.9	3.75±1.9	3±2.7	0.08
SEQ at 3 months	−0.54±0.5	−0.73±2.2	−0.33±0.4	<0.001
Spherical power at final visit	+0.94±1.7	+0.13±1.5	+0.84±0.8	0.07
Cylinder power at final visit	2.88±1.4	2.63±1.2	2±0.8	0.3
SEQ at final visit	−0.5±1.4	−1.14±1.5	−0.15±0.8	0.07
RPE at 3 months†	+0.04±0.7	−0.05±1.8	+0.5±0.7	0.004
RPE at final visit†	+0.23±1.7	−0.41±1.4	+0.4±0.9	0.1

†Mean predictive error. CDVA: Corrected distant visual acuity, UCVA: Uncorrected visual acuity, SEQ: Spherical equivalent, RPE: Respiratory protective equipment

the other hand, the efficacy index of sutured SFIOL did not show as much improvement compared to the remaining two techniques throughout the postoperative follow-up visits. This seems to be correlated with induced astigmatism resulting from large incisions, the use of sutures to secure the corneoscleral wound, and the relatively anterior position of the IOL compared to the glued SFIOL technique.

Three months after surgery, the safety index was comparable between all techniques studied here. Alternatively, on the final postoperative visit, both sutured IFIOL and glued SFIOL techniques showed an evident increase in safety index compared to the postoperative 3-month visit, while the safety index of sutured SFIOL remained more or less the same. This would indicate a better complication profile and could also

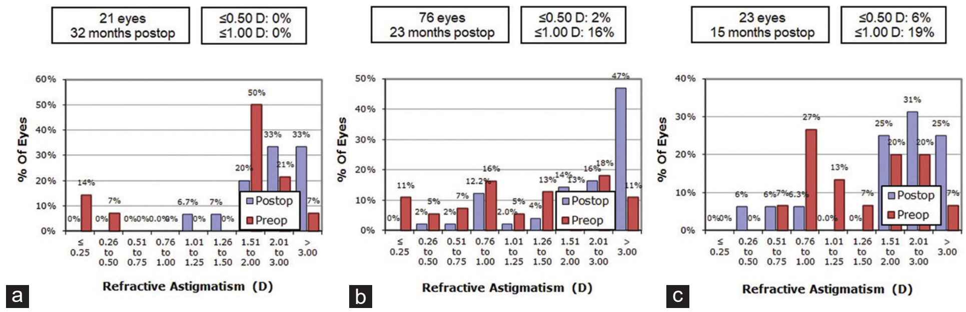

Figure 2: Pre- and postoperative refractive astigmatism of (a) Iris-fixated intraocular lens, (b) Sutured SFIOL, (c) Glued SFIOL. SFIOL: Scleral-fixated intraocular lens, D: Diopters

be related to the simplicity of both techniques compared to sutured SFIOL. Similarly, in their systemic review, Wong *et al*. found no difference between sutured SFIOL, glued SFIOL, and sutureless SFIOL in the major postoperative complications such as retinal detachment, choroidal detachment, and endophthalmitis except that sutured SFIOL was exclusively associated with suture-related complications such as exposure or breakage.[14] Similar findings were also reported regarding the comparison of IFIOL and SFIOL techniques in general.[15]

Most eyes (75%) in this cohort, regardless of the technique used, achieved a SEQ within 1.0 D of the target refraction in our study, and 92% achieved an SEQ within 2.0 D. However, five cases of the sutured SFIOL group achieved three-dimensional (3D) from the target. This could be attributed to the surgically induced astigmatism of a larger wound needed to facilitate the rigid PMMA IOL implantation. Additionally, two cases of the sutured IFIOL group had their postoperative SEQ within 3 D from the target. One of these cases developed IOL tilt. In the other case, the patient was 18 years old at the time of implantation. Therefore, we assume instability of the refraction due to normal eye growth in the second case.

Our cohort shows that assuming "in-the-bag" IOL position to calculate the IOL power for sutured SFIOLs results in a postoperative prediction error that is slightly myopic from the preoperative intended target refraction (mean SD).[16]

Our data align with other studies that showed more myopic outcomes than intended, with gradual myopic progression occurring over time after surgery. The postoperative prediction error in Botsford *et al*.'s study of their cases using Gore-Tex suture and Akreos AO60 and CZ70BD IOLs was slightly myopic from the target (−0.19 ± 0.72 D), using the assumption of "in-the-bag" IOL position.[16] Hayashi *et al*. had a myopic prediction error in their study (mean SEQ − 0.65) among cases that underwent sutured SFIOL. They attributed this refractive error to a more anterior IOL position than assumed.[17] In their analysis for the group of eyes with good visual prognosis, Lockington *et al*. reported that the mean postoperative SEQ of −1.26 D was mainly affected by postoperative cylindrical error (−2.4 ± 1.9 D). In their study, the used IOL models were the PMMA IOL (CZ70BD, Alcon Laboratories, Inc.) and the aniridia IOL (type 67G, Morcher GmbH).[18] Therefore, larger incisions were created to facilitate the fixation of the IOL in their study cases.

On the contrary, glued SFIOL and sutured IFIOL had a slightly more hyperopic outcome than the preoperative intended refraction when the assumptions of "in-the-bag" IOL position and "in-the-sulcus" IOL position were used, respectively.

The refractive outcomes of secondary IOL can vary due to many factors. This presents a challenge given the unique anatomic position determined by the location of the point of fixation and the assumption of the IOL position when calculating its power. Other factors that play an important role in the postoperative refractive outcome are the wound location (whether it is scleral or corneal) and size (whether it is big or small), which is an important limiting factor in the sutured SFIOL compared to the glued SFIOL and sutured IFIOL. This is one of the limitations in our study, as it was not thoroughly investigated; nevertheless, the difference in the refractive outcome was still consistent with the smaller wound of glued SFIOL and IFIOL. Although the tendency for the myopic shift was minimal, this needs to be kept in mind when tailoring the IOL power selection, especially if sutured SFIOL will be performed.

The myopic shift we encountered with sutured SFIOL could have another explanation. Anterior vitrectomy is crucial to ensure the successful IOL placement in aphakic eyes because vitreous prolapse can lead to decentration of the IOL, cystoid macular edema, or even retinal detachment.[19-21] Many hypotheses for this myopic shift have been generated, including an increased postoperative axial length, a change in anterior chamber depth (ACD) and ELP, a change in keratometry values, and the effect of gas tamponade; however, none of these have been validated.[22-24] Hence, in vitrectomized eyes or when anterior vitrectomy is planned along with the sutured SFIOL implantation technique, a slightly more hyperopic IOL power should be chosen to overcome this expected myopic shift.

From this cohort, we can conclude that it is possible to use the Holladay 1 formula to calculate IOL power and achieve the long-term outcome of emmetropia for sutured IFIOL and glued SFIOL, provided that a nearly half-diopter myopic target is chosen with the assumption of an "in-the-sulcus" IOL position and an "in-the-bag" IOL position, respectively. On the other hand, sutured SFIOL had a more myopic outcome than intended in the last visit using the same assumption of the “in-the-bag” IOL position. This could be related to the IOL having a more anterior position than expected, and this theory could be associated with the suture tension or the distance of the fixation points from the limbus.[17] Therefore, a less myopic target should be planned if the Holladay 1 formula is used to select the IOL power if the sutured SFIOL technique is sought.

Surgical-induced astigmatism is a common theme in intraocular surgeries.[25] In our study, it showed a decreasing trend over the follow-up period. Therefore, we hypothesize that the astigmatic effect of the wound also decreased in the last visit due to suture removal. However, no detailed analysis of the wound size, location, and suturing was available in our data, preventing a more precise conclusion. In the future, we recommend gathering clear data to improve our understanding.

At our institute, we favor SFIOL over IFIOL; this is related to the surgeon’s comfort level with the technique rather than the inferiority of the technique itself. Furthermore, from our past experience in the same institute, patients with preexisting uveitis or diabetes did not have a favorable outcome with IFIOL.[10] Another reason for our preference for the SFIOL technique over sutured IFIOL is the unique structural anatomy of the anterior chamber and the possibility that the ACD in our population is less than in Caucasians and Asians, making the technique more challenging.[26]

The main limitation of our study is its retrospective nature and the fact that only the patients who fully completed the follow-up were included. Therefore, it would be beneficial to conduct prospective studies using the same variables, especially addressing the issues related to refractive surprises in eyes with good visual potential. Also, the absence of timed consistent refractive error measurements for all included cases except for the three-month postoperative visit can be perceived as a limitation. This limitation is because these cases were managed at a governmental tertiary hospital that deals with a high volume of cases. Nevertheless, the cases included here had at least two refractive error measurements after surgery. Furthermore, patients were not randomized, and the IOL fixation technique was chosen based on the surgeon’s preference and the patient’s ocular comorbidities. The eyes included in this cohort were operated on by multiple surgeons. Therefore, surgical preferences and differences in surgical technique might have affected our results. However, our results confirmed reasonable visual improvement and refractive outcomes despite multiple techniques, different IOLs, and surgeons. Therefore, in future studies, the main point of focus should be the technique simplicity and the safety profile in determining the selection of optimal surgical technique for gold standard practice.

Another limitation of our study is that iris-clawed lenses were not looked at, although they are easier and more time-efficient. However, we could not find many of these cases for a good comparison. We suppose it would be interesting to compare our results with iris-enclaved IOL (Artisan) cases.

Conclusion

In cases with mild-to-moderate ocular morbidities and good visual potential (i.e., CDVA 20/80 and better), SFIOL and IFIOL can improve uncorrected visual acuity and maintain CDVA. In addition, IOL calculations using standard optical biometry intended for in-the-bag IOL implantation can be used for IFIOL and SFIOL with good reliability. However, further prospective studies are needed to refine the predicted refractive error using newer-generation IOL calculation formulas.

What is already known on this topic

- In eyes with poor capsular support, many techniques were described to correct aphakia, including anterior chamber IOLs, IFIOLs, and SFIOLs
- Although many studies reported complications associated with IFIOL and SFIOL, there are scant data on refractive outcomes.

What this study adds

- The degree of refraction predictive error varies with different IOL techniques, and this should be kept in mind when selecting IOL powers for patients with good visual potential
- There is no particular superiority to any techniques studied here regarding safety, efficacy, and stability over a long-term follow-up

How this study might affect research, practice, or policy

- Use of newer generation of IOL calculation formula in cases with deficient capsular support
- Help in selecting appropriate IOL power based on the surgical technique used to correct aphakia.

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Conflicts of interest

There are no conflicts of interest.

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