Comparison of Outcomes of Primary Scleral-Fixated versus Primary Anterior Chamber Intraocular Lens Implantation in Complicated Cataract Surgeries

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Objective: To compare the visual outcomes and complication profiles of primary scleral-fixated intraocular lens (SFIOL) versus primary anterior chamber intraocular lens (ACIOL) implantation in cataract surgeries complicated by inadequate capsular support.

Design: Retrospective, interventional, comparative cases series.

Participants: Thirty-six eyes of 36 patients undergoing SFIOL implantation (group 1) and 46 eyes of 46 patients undergoing ACIOL implantation (group 2).

Methods: Retrospective analysis of medical records of a consecutive series of complicated cataract surgeries with primary SFIOL or ACIOL implantation.

Main Outcome Measures: Postoperative best-corrected visual acuity (BCVA), intraoperative and postoperative complications, if any, and postoperative corneal endothelial cell counts. A multiple linear regression model was constructed with postoperative BCVA as the dependent variable and with IOL group (SFIOL vs. ACIOL), preoperative BCVA, surgeon's operative experience, planned operation, and patient's age as independent variables.

Results: Fifty-eight percent (group 1) and 37% (group 2) of patients underwent phacoemulsification, whereas the rest underwent extracapsular cataract extraction. The mean postoperative follow-up was 33.4±17.9 months (range, 6–61 months). Postoperative Snellen BCVA of 20/40 or better was achieved in 47.2% (group 1) and 71.7% (group 2) of patients ($P = 0.038$). Regression analysis showed that primary ACIOL implantation was associated with a significantly better postoperative BCVA of −0.157 on the logarithm of minimum angle of resolution scale (95% confidence interval, −0.306 to −0.007; $P = 0.040$), compared with primary SFIOL implantation. Although both the number of eyes with complications and the total number of complications were higher in the SFIOL group, the differences in early ($P = 0.073$) and late ($P = 0.377$) complications were not statistically significant.

Conclusions: The results indicate that satisfactory results are achieved with primary implantation of current open-loop ACIOLs during cataract surgery complicated by loss of posterior capsule integrity. Eyes with these IOLs fared better than a cohort of eyes undergoing SFIOL implantation in a similar situation, at intermediate-term follow-up. Further prospective clinical trials with longer follow-up may help to evaluate the long-term visual outcomes and complication profiles after primary implantation of these lenses. *Ophthalmology 2007;114: 80–85 © 2007 by the American Academy of Ophthalmology.*

In the absence of adequate capsular support during cataract operation, the surgeon is faced with many decisions, including when to implant the intraocular lens (IOL) and which type of IOL should be implanted. Results of the few studies that have attempted to answer the first question indicate that secondary implantation of flexible open-loop anterior chamber IOLs (ACIOLs) after intracapsular cataract extraction seems to have a more favorable visual outcome than primary implantation in complicated extracapsular cataract extraction (ECCE) cases,[1] whereas our previous study found that similar visual outcomes may be achieved with primary and secondary implantation of scleral-fixated IOLs (SFIOLs).[2] However, results of the studies answering the second question have been conflicting, and most studies so far have focused on the comparison between secondary SFIOL and secondary ACIOL implantations.[3–7] A systematic review of both of these issues by the American Acad-

Originally received: July 4, 2005.
Accepted: November 8, 2005. Manuscript no. 2005-1081.

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Presented as a poster at: American Academy of Ophthalmology annual meeting, October 2005, Chicago, Illinois.

The authors have no proprietary interests related to the article.

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Published by Elsevier Inc.
ISSN 0161-6420/07/$–see front matter
doi:10.1016/j.ophtha.2005.11.024

emy of Ophthalmology indicates that currently there is little evidence available regarding the visual outcomes and complication profiles of primary implantation of these IOLs.[8]

Advantages of primary over secondary IOL implantation include the avoidance of a second operation, a shorter hospital stay, and a faster visual rehabilitation. With the aim to fulfill this literature gap in part, the present study was conducted to examine the visual outcomes and complication profiles of primary SFIOL versus primary ACIOL implantation.

Materials and Methods

Institutional review board approval was not required for the present study. The medical records of all eyes receiving primary SFIOL (group 1) or primary ACIOL (group 2) implantation during cataract surgery for senile cataract, complicated by inadequate capsular support, were reviewed retrospectively. All cases were identified by the hospital computer database, which held a complete record of all the operations performed within the hospital. All operations were performed between January, 2000, and December, 2003, at the Hong Kong Eye Hospital, Hong Kong, a tertiary care ophthalmic center in the region. Exclusion criteria included: causes of poor visual function other than cataract (e.g., amblyopia, macular scar, etc.),[7] pathologic features that would dictate the choice of IOL implantation (e.g., ocular hypertension, glaucoma),[7] dislocated cataracts that required pars plana vitrectomy, incomplete operative medical records, and postoperative follow-up of less than 6 months.

Information collected from each case record included the type of cataract operation planned, anesthesia used, reason for failed capsular IOL implantation, surgeon's operative experience (classified as fellow or resident in ophthalmology), mean preoperative and postoperative (at patient's most recent visit) Snellen best-corrected visual acuity (BCVA), nature and number of intraoperative or postoperative complications, and corneal endothelial cell count at 3 months after surgery.

Surgical Technique

The Alcon CZ70BD (Alcon Laboratories International, Fort Worth, TX), a single-piece polymethyl methacrylate lenses with eyelets, was used for SFIOL implantation. The optic diameter was 7.0 mm and the overall diameter was 12.5 mm. The ACIOL used was the Pharmacia 351C ACIOL (Pharmacia International, Capelle aan den Ijssel, The Netherlands), a single-piece polymethyl methacrylate, open-loop, semiflexible lens with 4-point fixation. The size of the ACIOL was determined by adding 1 mm to the horizontal white-to-white corneal diameter.

In eyes undergoing surgery using topical anesthesia, supplementary sub-Tenon anesthesia was used to complete IOL implantation. In all patients with vitreous loss, a complete anterior vitrectomy was performed. The SFIOL or ACIOL was implanted through the original wound in planned ECCE procedures. For phacoemulsification procedures, the wound was enlarged to 8 mm for IOL implantation. For SFIOL implantation, all surgeons used a modified ab externo technique, originally described by Lewis,[9] in the following manner. A double-armed 10-0 polypropylene (Prolene, W1713, Ethicon, Dilbeek, Belgium) suture with straight needles was used. Two fornix-based conjunctival peritomies were made from 2 to 4 o'clock and from 8 to 10 o'clock, respectively. The entry sites were marked 1.0 to 1.5 mm posterior to the limbus, 1.0 mm above and below the 3- to 9-o'clock horizontal meridian. The straight needle was passed through the sclera at the superior marking on one side and was retrieved within the barrel of a 25-gauge needle inserted through the inferior marking on the opposite side. The same needle then was reinserted into the eye through the superior marking and was retrieved through the inferior marking on the other side. The sutures were withdrawn through the corneal or scleral wound using a Sinskey hook and were cut in the middle. The 2 cut ends on each side were passed through the corresponding eyelet of the SFIOL and their ends were tied. A square knot was made to join the 2 cut ends on each side and then rotated into and out of the eye through the superior marking on each side. After the SFIOL was inserted into the posterior chamber,[10] the sutures were tightened and tied with open knots. The corneal or scleral wound was closed with interrupted 10-0 nylon sutures (U7000 Ethilon; Ethicon). The open knots were converted to closed knots and then rotated through the inferior marking, which were the entry sites of the 25-gauge needle. The conjunctival peritomies were then closed.

For ACIOL implantation, the pupil first was constricted with acetylcholine (Miochol, Novartis Ophthalmics, Basel, Switzerland) and the anterior chamber was reformed with viscoelastics. The ACIOL was inserted into the inferior angle with or without the help of a Sheet's glide. The posterior lip of the wound then was retracted with tissue forceps and the superior haptic of the ACIOL was placed into the superior angle. A peripheral iridotomy then was performed. The corneal or scleral wound was closed with interrupted 10-0 nylon sutures (U7000 Ethilon; Ethicon).

Statistical Methods

Data were analyzed using the SPSS for windows program (version 12.0; SPSS Inc., Chicago, IL). Continuous variables were expressed as means (± standard deviations), and categorical variables are expressed as individual counts and proportions. The Snellen BCVA was converted into logarithm of the minimum angle of resolution (logMAR) units for analysis.[11] Visual acuity of hand movements and light perception were arbitrarily assigned the equivalent of 1.7 and 1.8 logMAR units, respectively.[11] Univariate analyses to determine the association between baseline demographics, operative details, preoperative and postoperative BCVA, complications, and treatment groups were performed using Mann–Whitney *U* tests, chi-square tests, and Fisher exact tests as appropriate. A multiple linear regression model was constructed with postoperative BCVA as the dependent variable and IOL group (SFIOL vs. ACIOL), preoperative BCVA, surgeon's operative experience, planned operation, and age of patient as independent variables. Colinearity diagnostics, using an averaged variance inflation factor of more than 5 as the cutoff, were included. There was no evidence of multicolinearity for any of the independent variables included in the regression model. The critical value of significance was set at $P<0.05$ for all tests.

Results

Of the 15 000 cataract operations performed at the Hong Kong Eye Hospital during the study period, 82 eyes of 82 patients fulfilled the inclusion and exclusion criteria and were included in the study. Nine eyes were excluded: 2 from patients with sight-threatening pathologic features other than cataract, 2 from patients with glaucoma, 1 from a patient with dislocated cataract that required pars plana vitrectomy, 3 from patients with incomplete operative records, and 1 from a patient who did not follow up beyond month 2 after the operation. The mean age was 76.7±8.3 years (range, 57–98 years). There were 36 and 46 eyes in groups 1 and 2, respectively. The mean postoperative follow-up was 33.4±17.9 months (range, 6–61 months). A total of 12 surgeons (8 fellows and 4 residents) were involved in the study.

Univariate Analysis

Fifty-eight percent (group 1) and 37% (group 2) of patients underwent phacoemulsification, whereas the others underwent ECCE. The most common reason for failed capsular IOL implantation was posterior capsular rupture, occurring in 50.0% and 63.0% of patients in groups 1 and 2, respectively. There were no significant differences between the operative details among the 2 groups except for the type of anesthesia used.

The mean preoperative logMAR BCVA was similar among the 2 groups ($P = 0.988$). The mean postoperative logMAR BCVA (± standard deviation) was 0.486±0.386 and 0.322±0.311 in groups 1 and 2, respectively. This difference was statistically significant ($P = 0.010$). Significantly ($P = 0.038$) more eyes in group 2 (71.7%) had a Snellen BCVA of 20/40 or better compared with group 1 eyes (47.2%). Apart from 2 eyes with retinal detachment in the SFIOL group, the rest (97.6%) had a Snellen BCVA of 20/200 or better. Patient demographics, operative details, and mean preoperative and postoperative BCVAs are summarized in Table 1.

No major complications were encountered during the insertion of either type of IOL. Table 2 shows the early (within 1 month) and late postoperative complications encountered. Early complications were noted in 26 eyes (72.2%) with a total of 40 complications in group 1 and in 24 eyes (52.2%) with a total of 30 complications in group 2. Transient corneal edema was the most common early complication, occurring in 42.9% of all eyes. However, there were no cases of pseudophakic bullous keratopathy, and corneal endothelial cell counts were not significantly different between the 2 groups at 3 months after surgery. Eight eyes (22.2%) had a total of 10 late complications in group 1, whereas 6 eyes (13.0%) had a total of 6 late complications in group 2. Intraocular pressure of 21 mmHg or more was the most common late complication, occurring in 68.8% of all eyes. Although both the number of eyes and the total number of complications were higher in group 1, the differences were not statistically significant for early ($P = 0.073$) and late ($P = 0.377$) complications.

To examine potential bias resulting from surgical complications on the choice of IOL, the complication profiles of patients undergoing ECCE and phacoemulsification also were compared. The number of eyes with early complications were 29 and 21 eyes in the ECCE and phacoemulsification groups, respectively ($P = 0.369$). The number of eyes with late complications were 8 and 6 eyes in the ECCE and phacoemulsification groups, respectively ($P>0.999$). It therefore seemed that the complication profiles of the 2 techniques did not have a significant influence on the IOL choice.

Multivariate Analysis

Table 3 shows the regression model summary for postoperative logMAR BCVA. Primary ACIOL implantation was associated with a significantly better postoperative logMAR BCVA compared

Table 1. Patient Demographics, Operative Details, and Mean Preoperative and Postoperative Best-Corrected Visual Activity

	Intraocular Lens Type			
	Scleral Fixated	*Anterior Chamber*	***P* Value (2-Tailed)**	**Total**
Demographics				
No. of patients	36 (43.9%)	46 (56.1%)		
Age of patient (yrs) at the time of operation*	76.9±7.7	76.6±8.7	0.848†	76.7±8.3
Gender				
Male	12 (33.3%)	25 (54.3%)	0.058‡	37 (45.1%)
Female	24 (66.7%)	21 (45.7%)		45 (54.9%)
Surgeon's operative experience				
Fellow	13 (36.1%)	16 (34.8%)	0.901‡	29 (35.4%)
Resident	23 (63.9%)	30 (65.2%)		53 (64.6%)
Planned operation				
Phacoemulsification	21 (58.3%)	17 (37.0%)	0.054‡	38 (46.3%)
ECCE	15 (41.7%)	29 (63.0%)		44 (53.7%)
Anaesthesia				
Retrobulbar	28 (77.8%)	44 (95.7%)		72 (87.8%)
Topical then sub-tenon	4 (11.1%)	2 (4.3%)	0.029‡	6 (7.3%)
General	4 (11.1%)	0 (0.0%)		4 (4.9%)
Main reason for failed capsular IOL implantation				
Posterior capsular rupture	18 (50.0%)	29 (63.0%)		47 (57.3%)
Loose zonules	11 (30.6%)	13 (28.3%)	0.305‡	24 (29.3%)
Unplanned ICCE	7 (19.4%)	4 (8.7%)		11 (13.4%)
Mean postoperative follow-up (mos)*	32.8±18.2	33.8±17.9	0.765†	33.4±17.9
Preoperative BCVA				
Mean (logMAR)*	1.315±0.448	1.300±0.435	0.988†	1.306±0.438
Postoperative BCVA				
Mean (logMAR)*	0.486±0.386	0.322±0.311	0.010†	0.394±0.354
≥20/40 (Snellen)	17 (47.2%)	33 (71.7%)		50 (61.0%)
<20/40 & ≥20/200 (Snellen)	17 (47.2%)	13 (28.3%)	0.038‡	30 (36.6%)
<20/200 (Snellen)	2 (5.6%)	0 (0.0%)		2 (2.4%)
BCVA change (preoperative BCVA − postoperative BCVA)				
Mean (logMAR)*	−0.829±0.504	−0.978±0.510	0.147†	−0.913±0.510

BCVA = best-corrected visual acuity; ECCE = extracapsular cataract extraction; ICCE = intracapsular cataract extraction; IOL = intraocular lens; logMAR = logarithm of the minimum angle of resolution.
*Mean ± standard deviation.
†Mann–Whitney *U* test.
‡Chi-square test.

Table 2. Postoperative Complications after Primary Scleral-Fixated Intraocular Lens or Anterior Chamber Intraocular Lens Implantation

	Intraocular Lens Type			
	Scleral Fixated	*Anterior Chamber*	**P Value (2 Tailed)**	**Total**
No. of patients	36 (43.9%)	46 (56.1%)		
Early complications (within 1 mo)				
Transient corneal edema	15 (37.5%)	15 (50.0%)	0.398†	30 (42.9%)
Vitreous hemorrhage	5 (12.5%)	3 (10.0%)	0.290‡	8 (11.4%)
Intraocular pressure >30 mmHg	3 (7.5%)	4 (13.3%)	0.474‡	7 (10.0%)
Residual lens matter	5 (12.5%)	1 (3.3%)	0.082‡	6 (8.6%)
Severe uveitis (AC cells ≥3+)	4 (10.0%)	1 (3.3%)	0.163‡	5 (7.1%)
Fibrin	3 (7.5%)	1 (3.3%)	0.315‡	4 (5.7%)
Hyphema	1 (2.5%)	3 (10.0%)	0.627‡	4 (5.7%)
Vitreous incarceration at wound site	2 (5.0%)	1 (3.3%)	0.579‡	3 (4.3%)
IOL capture	1 (2.5%)	1 (3.3%)	>0.999‡	2 (2.9%)
Retinal detachment	1 (2.5%)	0 (0.0%)	0.439‡	1 (1.4%)
Total number of early complications	40	30		70
Total number of eyes with early complications	26 (72.2%)	24 (52.2%)	0.073†	
Late complications (after 1 mo)				
IOP > 21 mmHg	5 (50.0%)	6 (100.0%)	>0.999†	11 (68.8%)
Vitreous prolapse into anterior chamber	1 (10.0%)	0 (0.0%)	0.439‡	1 (6.3%)
Persistent uveitis (AC cells ≥1+)	1 (10.0%)	0 (0.0%)	0.439‡	1 (6.3%)
IOL decentration	1 (10.0%)	0 (0.0%)	0.439‡	1 (6.3%)
Pseudophakic CME	1 (10.0%)	0 (0.0%)	0.439‡	1 (6.3%)
Retinal detachment	1 (10.0%)	0 (0.0%)	0.439‡	1 (6.3%)
Total number of late complications	10	6		16
Total number of eyes with late complications	8 (22.2%)	6 (13.0%)	0.377†	
Postoperative corneal endothelial cell count at 3 mos (cell/mm^2)*	1695±695	1685±625	0.535†	

AC = anterior chamber; CME = cystoid macular edema; IOL = intraocular lens; IOP = intraocular pressure.
*Mean ± standard deviation.
†Chi-square test.
‡Fisher exact test.

with primary SFIOL implantation (unstandardized β, −0.157; 95% confidence interval, −0.306 to −0.007; P = 0.040). None of the other independent variables were significantly associated with the postoperative logMAR BCVA.

Discussion

In the presence of inadequate posterior capsular support during cataract operation, the IOL can be placed in the sulcus if the capsule–zonular rim is intact. In the absence of adequate sulcus support, an SFIOL or an ACIOL may be implanted. There are certain advantages of SFIOLs over ACIOLs, such as less corneal endothelial damage, reduced aniseikonia if the contralateral eye is phakic, and suitability in eyes with large-sector iridectomy or peripheral anterior synechiae.[12,13] Disadvantages include the greater technical complexity, increased surgical time, entry tracks into the eye because of the suture, and surgical manipulations in the region of the ciliary body. Inaccurate placement and erosion of the scleral fixation sutures have been reported to be associated with lens tilt,[14] suprachoroidal hemorrhage,[15] retinal detachment,[16] and even endophthalmitis.[17,18]

In the present study, we compared the visual outcomes and complication profiles after the primary implantation of these 2 lens designs. Seventeen eyes (47.1%) in the SFIOL group and 33 eyes (71.7%) in the ACIOL group achieved a postoperative Snellen BCVA of 20/40 or better. Our SFIOL

Table 3. Postoperative Best-Corrected Visual Acuity Linear Regression Model Summary, with Unstandardized β Coefficients, 95% Confidence Intervals, and P Values

Dependent Variable	Independent Variable	Unstandardized β	95% Confidence Intervals	P Value
Postoperative BCVA (logMAR)	IOL group (SFIOL vs. ACIOL)	−0.157	−0.306 to −0.007	0.040
	Preoperative BCVA	0.155	−0.015 to 0.326	0.099
	Age of patient	0.008	−0.001 to 0.017	0.162
	Surgeon's operative experience	−0.124	−0.284 to 0.035	0.302
	Planned operation	−0.199	−0.372 to 0.026	0.587

ACIOL = anterior chamber intraocular lens; BCVA = best-corrected visual acuity; IOL = intraocular lens; logMAR = logarithm of the minimum angle of resolution; SFIOL = scleral-fixated intraocular lens.

results compared less favorably with those reported in the literature of 58.6% to 80.9%,[2,19,20] but our ACIOL results were similar to those reported of 62.1% to 82.0%.[1,21–24] After adjustments for other potential confounding factors, primary ACIOL implantation was associated with a significantly better postoperative BCVA of −0.157 on the logMAR scale (95% confidence interval, −0.306 to −0.007; $P = 0.040$), compared with primary SFIOL implantation (approximately 1–2 lines of Snellen acuity). We do not expect this difference to be explained by the postoperative complication profiles alone, because they were statistically insignificant. To test this hypothesis, we compared the visual outcomes in the complication-free subset of SFIOL and ACIOL eyes. The differences in postoperative logMAR BCVA ($P = 0.011$) and Snellen BCVA of 20/40 or better ($P = 0.035$) were still statistically significant.

There are at least 2 possible explanations for the better postoperative BCVA in the ACIOL group. Because SFIOL implantation takes considerably longer to perform,[3] prolonged phototoxicity from the operating microscope may play a role in light-induced retinal injury.[25] Such incidences have been reported in 0% to 28% of uncomplicated cataract surgeries.[26–28] In 1 report, angiographically proven light-induced macular damage was noted in 33% of eyes undergoing SFIOL implantation.[19] The operating time for the entire procedure in the present study was 89.5±27.6 minutes for SFIOL and 62.9±15.1 minutes for ACIOL. Another possible explanation for the outcomes noted in this report could be the occurrence of pseudophakic cystoid macular edema. The incidence of early pseudophakic cystoid macular edema has been reported to be 6.7% to 42.9% in primary SFIOL[2,20,29] and 5.7% to 22.2% in primary ACIOL[1,21–24] implantations after complicated phacoemulsification and ECCE. Because of the risk of pseudophakic lens capture, eyes with posterior capsular rupture implanted with SFIOL or ACIOL were not dilated routinely for fundal examinations in the early postoperative period, and hence the rate of this complication could not be determined in this retrospective analysis. The careful documentation of the clinical appearance of the macula, the use of fluorescein angiography, and the use of multifocal electroretinography may help ascertain the incidence of this complication.

Although the differences in the early and late complications were not statistically significant, we recognize that our study was insufficiently powered to detect such differences. The powers to detect significant differences, based on 36 eyes in the SFIOL group, 46 eyes in the ACIOL group, and $\alpha = 0.05$, for the number of eyes with early and late complications were only 48% and 19%, respectively.

The postoperative corneal endothelial cell counts were comparable between the 2 groups. We acknowledge that endothelial cell counts at postoperative month 3 do not provide a true reflection of the impact of these lenses on the cornea, unless comparisons could be made with reference to the preoperative cell counts. A recent study found that surgical trauma may be responsible for endothelial cell loss rather than the continued presence of an IOL in the anterior chamber,[30] and a longitudinal study of the endothelial cell counts and corneal thicknesses will be helpful to elucidate further the long-term effects of these IOLs on the health status of the cornea.

Limitations of this study include the nonrandom choice of SFIOL versus ACIOL implantation, which depended on factors such as the preference[7] and experience[4] of the operating surgeon, the patient's age,[7] and the surgeon's assessment of the ability of the patient to tolerate the prolonged, unanticipated surgical procedure. Ideally, a randomized controlled trial limited to a single surgeon would provide the highest level of evidence for this research question. However, if only 1 surgeon is involved, generalizability of the results may be limited because it would be heavily biased by the expertise of the operating surgeon. Involvement of multiple surgeons with different experience may account in part for the slightly less favorable visual outcomes in our SFIOL eyes compared with those reported in the literature.[2,19,20] To exclude potential bias resulting from surgical preference, we also examined the individual surgeon's choice of lens. No particular pattern was found. Specifically, for surgeons with 2 or more patients included in the analysis, at least 1 SFIOL and at least 1 ACIOL were used. We attempted to adjust for surgical experience and other confounding factors in our multivariate regression model. Although SFIOL implantation is more demanding technically, our regression model showed no significant difference (Table 3) in the final visual acuity between eyes operated on by fellows and eyes operated on by residents. Moreover, potential correlations between independent variables, such as patient's age and surgeon's operative experience, and the choice of IOL implantation were specifically tested, because these could bias our results. The fact that the observed univariate difference in BCVA remained in the multivariate analysis provides further support for the robustness of our findings.

Our results were based on a mean postoperative follow-up of over 2 years. Complications of SFIOL may occur earlier because of the magnitude and complexity of the procedure.[7] Indeed, a 10-year follow-up of secondary SFIOL patients showed that most of the complications for SFIOL patients tended to occur within the first 2 years of the study,[31] whereas complications associated with ACIOLs may result from slowly declining endothelial cell counts, which occur later.[7] As a result, the number of complications in the SFIOL eyes may be overrepresented. As we continue to follow up our patients, the long-term complication profiles of these lenses will be better understood.

In conclusion, in this retrospective analysis, it seems that intermediate-term outcomes of ACIOL implantation in eyes undergoing cataract surgery complicated by inadequate capsular support are encouraging. In this study, SFIOL implantation did not result in comparable outcomes. Despite the limitations of this study, it does provide information regarding the choice of IOL in these eyes and indicates the need for further prospective trials with longer follow-up.

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