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Exploring the Clinical Outcomes of Retro Fixated Iris Claw Lens Implantation – An Interventional Study

Dr. Vudi Sai Srinija[1], Dr. Mandava Manogna[2*], Dr. Shankar Chokkalingam[3], Dr. Rajakumari Murugesan[4], Dr. Trisha Govindaraju[5]

[1]Fellowship Resident, Sankar Foundation Eye Hospital, Visakhapatnam, 530047, Andhra Pradesh, India.
[2*]Postgraduate, Department of Ophthalmology, Chettinad Hospital and Research Institute, Chettinad Academy of Research and Education, Kelambakkam, 603103, Tamil Nadu, India.
[3]Professor, Department of Ophthalmology, Chettinad Hospital and Research Institute, Chettinad Academy of Research and Education, Kelambakkam, 603103, Tamil Nadu, India.
[4]Professor, Department of Ophthalmology, Chettinad Hospital and Research Institute, Chettinad Academy of Research and Education, Kelambakkam, 603103, Tamil Nadu, India.
[5]Postgraduate, Department of Ophthalmology, Chettinad Hospital and Research Institute, Chettinad Academy of Research and Education, Kelambakkam, 603103, Tamil Nadu, India.
Email: [2*]mandavamanogna5@gmail.com.

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ABSTRACT:

Background: Cataract is the most prevalent and major cause of reversible blindness across the world. This study focuses on the best corrected visual acuity after surgery and the secondary post-operative complications at various intervals following surgery for 180 days, thereby doing all the required interventions to prevent and treat problems. **Materials and Methods:** An interventional study conducted among 50 patients. We selected patients according to the inclusion and exclusion criteria. After a detailed history and examination, the preoperative assessment was done for all intraoperative complicated surgery and planned secondary IOL implantation cases. The postoperative examination included best corrected visual acuity (BCVA), intra ocular pressure (IOP), endothelial cell count (ECC), Central macular thickness (CMT) and other complications. The observations were made on the following postoperative days - Day 1, Day 7, Day 30, Day 90, and Day 180. **Results:** The BCVA postoperatively improved in 35 eyes (70%). The mean post-operative IOP by the end of 180th day was within normal range. Endothelial cell count and central corneal thickness were reduced in all the patients post operatively which was significant, but the cornea was still healthy. The central macular thickness measured by OCT macula was increased in five patients postoperatively, which was normal by the 180th POD. **Conclusion**: Our study demonstrated that retro fixated iris claw lens implantation is a safe procedure with good visual outcome in the majority of patients with fewer complications.

Keywords: Iris Claw Lens, Cataract, Retro Fixation, Visual Acuity

1. Introduction

Cataracts are the most prevalent eye disorder and the leading cause of curable blindness globally. Here, the clear crystalline lens of the eye turns opaque. This haze may cause a decrease in eyesight, even blindness[(1)]. About 17.6 million persons (39%) of the approximately 45 million blind people in the globe are blind due to cataract[(2)]. According to the results of a national survey on blindness, the widespread presence of blindness among those aged 50 and over is 8%. The number of people who are blind on both eyes is somewhere between 9 and 12 million, and 62.6% of all blindness is caused by cataracts[(3)]. It is believed that each year in India, 20 million new instances of cataract are diagnosed[(4)].

Cataracts can be caused by a variety of causes, including heredity, age, trauma, infection, and metabolic disorders. Following cataract surgery, intraocular lens implantation in the capsular bag is an excellent technique to recover vision. Glasses for aphakia, contact lenses, intraocular lenses implanted in the anterior chamber, lenses fixed to the iris, and scleral fixated intra ocular lenses are all effective methods for restoring sight in patients who have had surgery without adequate

capsule support. These intraocular lenses can be inserted as a primary or secondary therapy[5].
Since Jan Worst's 1971 discovery of the iris claw lens, several modifications and procedures have been devised to secure the lens in the posterior chamber. Bullous keratopathy, corneal endothelial damage, angle structural damage, pupillary block glaucoma, and other eye illnesses are mostly minimized[6].
Throughout the 6-month follow-up period, this research monitors patients' best-corrected visual acuity (BCVA), endothelial cell count, central macular thickness, intraocular pressure (IOP), and any secondary complications that may arise at regular intervals following iris claw lens fixation.

2. Materials and Methods

An interventional study spanning for 18 months among 50 patients of pseudophakia with retro fixated iris claw lenses in a tertiary care hospital in the outskirts of Chennai district, Tamil Nadu, India.

INCLUSION CRITERIA:

Retro fixated iris claw lenses in Aphakic patients due to:

1.Primary implantation of iris claw lens during Intra operative complications like posterior capsular rupture during extra capsular cataract extraction, small incision cataract surgery, phacoemulsification, zonular rupture with or without vitreous loss.
2.Previous cataract surgery (secondary IOL implantation for correction of aphakia)
3.Subluxated or Dislocated lens (spontaneous or secondary to trauma)

EXCLUSION CRITERIA:

Patients with preexisting pathologies that intervened with the visual outcome such as

1.Aphakic bullous keratopathy,
2.Repaired corneal tears with aphakia
3.Inadequate iris support
4.Broad iridectomies
5.Iridodialysis with inadequate support

PROCEDURE:

It involved patients who were included according to the above inclusion and exclusion criteria. Detailed history and examination were done. Preoperative assessment was done in planned secondary IOL implantation. Informed and written consent was obtained from all patients posted for cataract surgery. The following steps were-

1.Once posterior capsular rupture was noted anterior vitrectomy was done with 23-gauge cutter.
2.Nuclear and cortical fragments were removed.
3.Intracameral Pilocarpine nitrate 0.5%w/v in the ratio of 1:4 with BSS was injected to constrict the pupil.
4.Two side port incisions preferably at 3 and 9 o’clock positions were made along with existing superior scleral incision.
5.Entry into the anterior chamber with the claw lens.
6.After balancing the lens with Shepard’s forceps, one haptic is fixed under the iris in alignment with the side port.
7.With reverse Sinskey hook, tucking of iris was done.
8.The same procedure was done in other side port and proper implantation confirmed by the presence of dimple at the site.
9.To prevent pupillary block, peripheral iridectomy was done at 12’0 clock position.

10. Main incision was secured with interrupted 10-0 nylon suture.
11. Patients were prescribed moxifloxacin and prednisolone eye drops, NSAIDs which were tapered over 6 weeks.

Our study focused on post-operative best corrected visual acuity, intra ocular pressure, endothelial cell counts and the secondary post-operative complications at these intervals – POD #1, 7, 30, 90 and 180, thereby doing all the required interventions to prevent complications.

Statistical Analysis:

Data was entered and coded using MS Windows Excel and statistical analysis was performed on the SPSS version 24.0 for Windows. Descriptive statistics such as frequency and percentage were done. Mean and standard deviation were calculated, and the means of parameters overtime were compared using repeated measures ANOVA to check for any significant differences. A p-value of < 0.05 was considered statistically significant.

3. Results

Table 1: Distribution of the study participants based on their demographics

Category	Subcategories	Frequency (n)	Percentage (%)
Age	41 to 50	3	6
	51 to 60	14	28
	61 to 70	28	56
	71 to 80	5	10
	Total	50	100
Gender	Male	18	36
	Female	32	64
	Total	50	100
Laterality	Right	23	46
	Left	27	54
	Total	50	100
Age Mean(±SD) - 62.6 ±5.64			

Among the study population about 56% were in the age of 61 to 70 years. 28% were in the age of 51 to 60 years. And 10% were between the ages of 71 to 80 years. Only 6% were at the age of 41 to 50 years. According to gender 36% were males and 64% were females. Based on laterality of the surgery among the study participants, 54% were left eyes and 46% were right eyes.

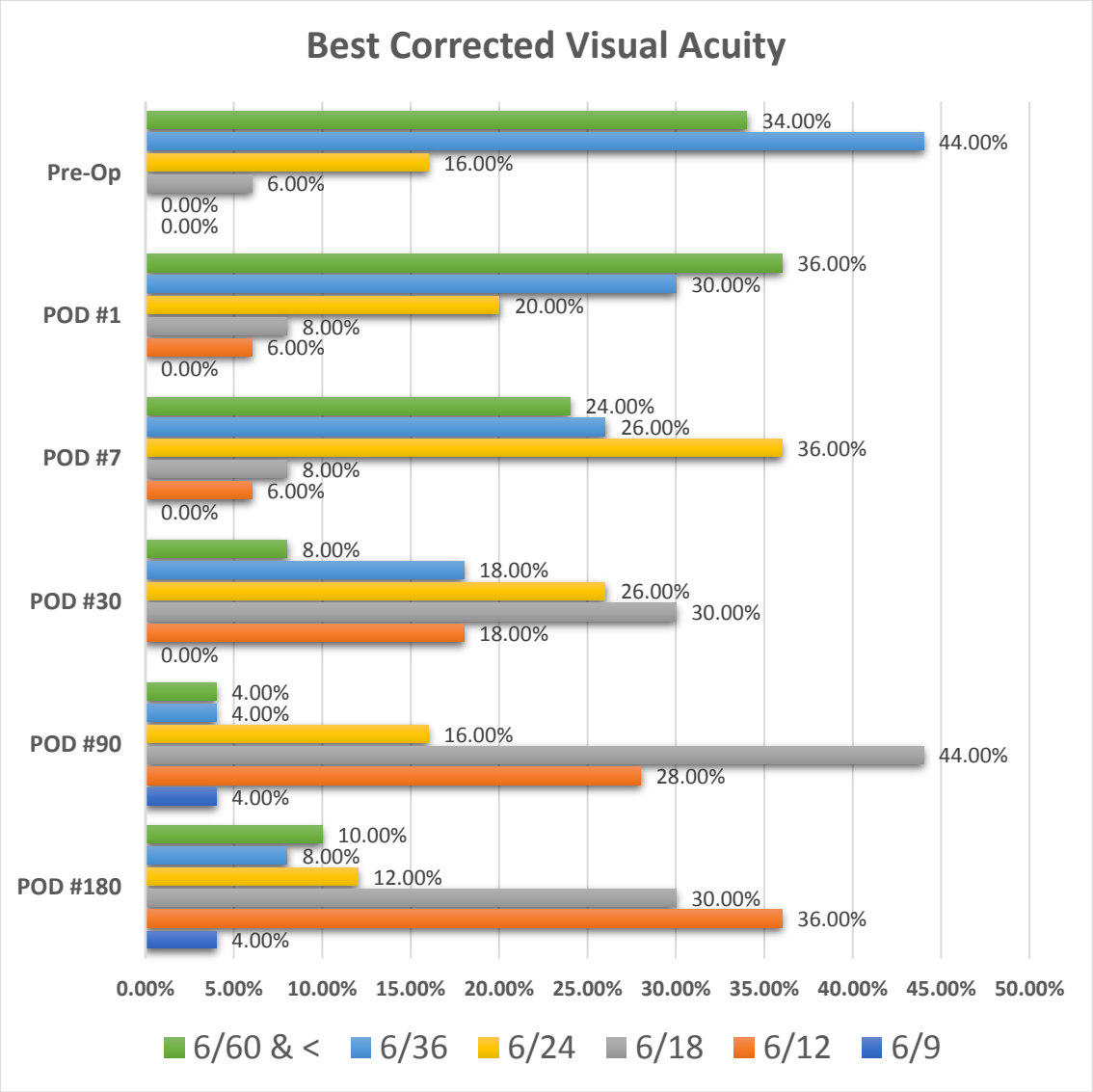

Figure 1: Comparison of BCVA pre and post operatively among the participants

This majority of participants in the preoperative period had their visual acuity at 6 /36, (44%) and on POD #1, 36% had visual acuity of 6 / 60 and less. On POD #7, 36% had visual acuity 6 /24 and 30% had visual acuity of 6/18 on the 30th POD 44% had visual acuity of 6/18 on 90th POD. On the 180th POD, most of the participants (36%) had visual acuity of 6 /12.

Table 2: Comparison of parameters over different time periods

	IOP		SM (CCT)		OCT (CMT)		(ECC)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Pre-Op	15.76	2.12	567	67.12	211	22.3	1844	212.42
POD #1	16.60	1.68	580	66.24	212	24.24	1814	211.64
POD #7	17.81	1.22	543	45.82	214	26.56	1808	206.22
POD #30	18.12	2.34	512	36.54	342	21.46	1799	204.82
POD #90	11.2	1.21	556	22.14	220	22.61	1763	202.61
POD #180	10.1	1.3	512	26.54	218	21.68	1743	200.40
p-value	0.04		0.03		0.05		0.05	

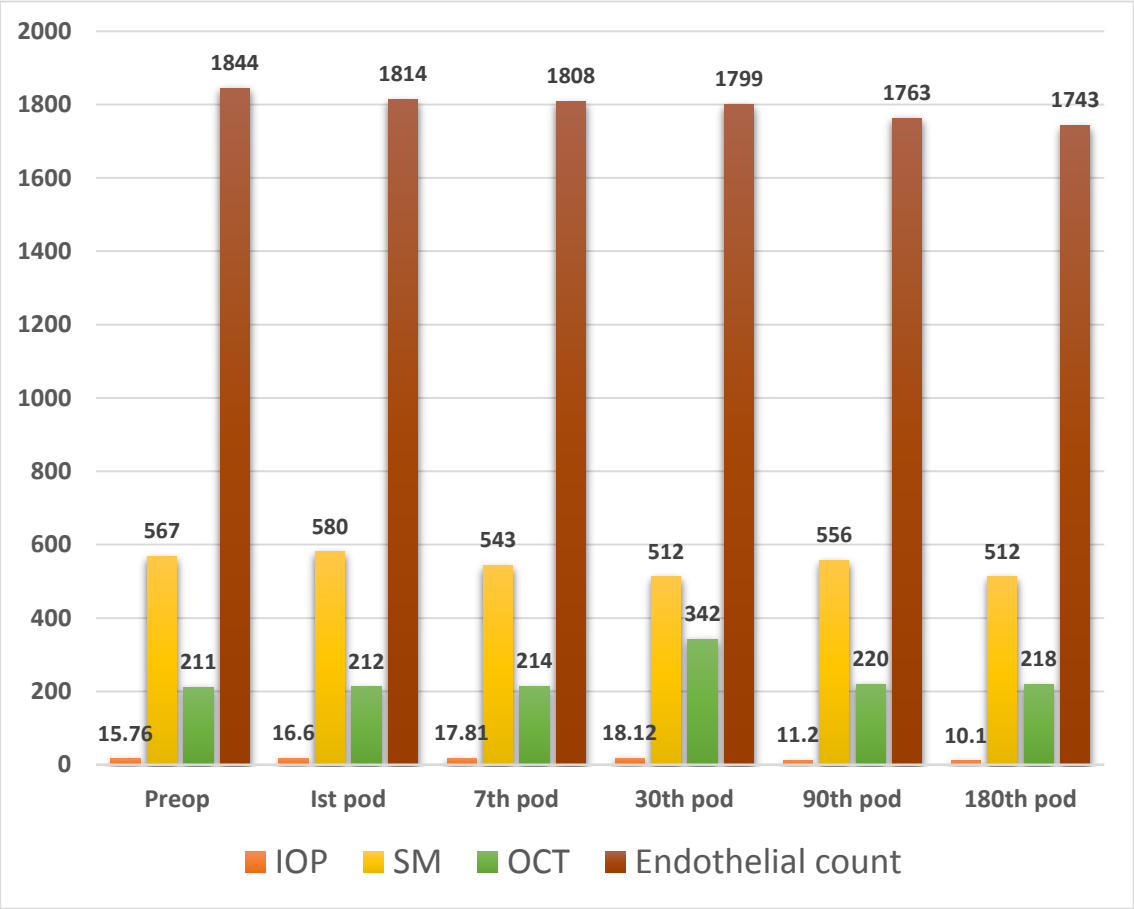

Figure 2: Comparison of parameters pre and post operatively among the participants

The changes of intra ocular pressure (IOP) measured by NCT (non-contact tonometry) are shown in the Fig.2. The mean preoperative was 15.76mmHg. Mean IOP gradually increased to 18.12mmHg and then started to decrease after POD #30 and was 10.1mmHg with standard deviation 1.3 by the end of POD #180. Clinically the IOP increased gradually and then came back to normal by the end of POD #180. As p-value was 0.04 (<0.05) this was statistically significant. The changes of endothelial cell count (ECC) show the mean value of ECC preoperative and postoperative day POD#180 were 1844±212.42 and 1743±200.40 respectively. A reduction in the ECC was seen from the preoperative day till the POD #180. Here the p-value was 0.05 which

means the reduction was statistically significant. Although there was reduction in ECC, cornea was still healthy postoperatively. Table 3 shows us the complications that were present during the post-op period among the participants.

Table 3: Distribution of complications over the post-operative period

Complications	**POD#1**	**POD#7**	**POD#30**	**POD#90**	**POD#180**
Striate Keratopathy	29	12	4	0	0
Corneal Edema	18	9	0	0	0
Vitreous Haemorrhage	0	0	4	4	4
Cystoid Macular Edema	0	0	5	0	0
Pos. Vitreous Detachment	0	0	2	2	2
Retinal Detachment	0	0	2	2	2
Pupillary Irregularity	6	6	6	6	6
Second time surgery	0	3	2	0	0
IOL Decentration	0	2	2	0	0
Anterior Uveitis	10	2	0	0	0
Suture Erosion	0	4	2	0	0
Increased IOP	12	3	0	0	0

4. Discussion

In managing intraoperative posterior capsular rupture or aphakia patients planned for secondary intraocular lens implantation, the ophthalmic surgeon's ultimate goal is to choose the best method of implantation of lens with minor complications. If the complications are prevented and treated properly, it is likely for the patient to regain good vision. In cases of posterior capsular rupture during cataract surgery in aphakia patients, planned for secondary intraocular lens implantation, we have many options like scleral fixated IOL, anterior chamber IOL, iris claw IOL, glued IOL. With anterior chamber IOL (ACIOL), though the haptics are flexible and easy to implant, there are problems like recurrent bleeding from angle of anterior chamber, increased intra ocular pressure post-surgery, decompensation of corneal endothelium, severe recurrent inflammatory reaction in the anterior chamber as mentioned by Marques FF (2007)[(7)].

Por YM (2005) stated from their research that scleral fixated IOL's are less invasive and takes less time in operating room with fast recovery but it requires tissue adhesives[(8)] and different suture methods for implantation. Agarwal A (2008) pointed out that it may lead to dislocation of IOL from breakage of polypropylene suture[(9)] and other complications such as tears in the retina, retinal detachment, vitreous haemorrhage, endophthalmitis. It has steeper learning curve, requires good surgical skills. When it comes to Glued IOL's many complications like decentration of IOL, extrusions of haptics and cystoid macular edema[(10)] have been reported by Divya Ashok Kumar (2013).

After the invention of iris claw lens by Jan Worst, it gained popularity in terms of less complications and easy implantation in intraoperative complicated surgery and aphakia patients 6. Posterior placement of iris claw lens has an advantage of not damaging the endothelium of cornea and positioned near nodal point. All the participants completed 180 days of follow up period. In our study around (56%) of the patients belonged to the age group of 61 to 70 years with mean age of 62.6 and standard deviation of 5.64. Around 64% participants were females. Among 50 eyes who were included in the study, 47 eyes underwent retro fixated iris claw lens implantation for

posterior capsular rupture intra operatively, whereas one patient after explanation of decentered PCIOL and two patients were aphakic patients (with nucleus drop and IOL drop).

Preoperatively 17 eyes (34%) had BCVA of less than or equal to 6/60. Of 50 eyes, the visual acuity improved in 35 eyes (70%) and worsened in 5 eyes (10%) due to postoperative complications like retinal detachment, vitreous hemorrhage. Vitreoretinal surgeon opinion was taken for the above complications.

Mean preoperative intra ocular pressure (IOP) was 15.76 mmHg with standard deviation 2.12. Whereas mean postoperative intraocular pressure (IOP) was 10.1mmHg with standard deviation 1.3. 12 patients (24%) had increased IOP postoperatively which was managed conservatively with tablet acetazolamide 250mg given orally three times a day which came back to normal. The increase in intraocular pressure could be due to retained viscoelastic material in the anterior chamber and vitreous loss. Surgical PI was done for all the patients' intra operatively. Mean postoperative IOP at the end of 180^{th} day was normal with p-value = 0.04 which was statistically significant.

The mean preoperative central corneal thickness (CCT) was 567 micrometers with standard deviation 67.12 and mean postoperative CCT at the end of 180^{th} day was decreased to 512 micrometers with standard deviation 26.54. The exact reason for this is still not clear. Here p-value = 0.03, which was statistically significant. The mean post-operative endothelial cell count at the end of 180^{th} day was decreased with p-value 0.04(<0.05) which was statistically significant. Though the corneal thickness and endothelial cell count has decreased, cornea was healthy without any further intervention. We had not seen any case of bullous Keratopathy till our last visit. Though the most common cause for endothelial cell loss is iatrogenic surgical trauma like manipulation while delivering the nucleus, during anterior vitrectomy and iris claw lens implantation. Periodic follow ups were advised for the patients to check for the status of cornea and endothelial cell count.

The mean preoperative central macular thickness (CMT) was 211 micrometers with standard deviation 22.3 and mean postoperative CMT was 218 micrometers with standard deviation 21.68 by the end of POD # 180. By the end of Postoperative day 30, 5 (10%) patients were diagnosed with CME. The mean post-operative CMT by the end of POD # 30 was 342 micrometers with standard deviation 21.46. The p-value = 0.05, which was not statistically significant. The macular thickness was measured with OCT. CME was noticed in patients because of the prime cause of the aphakia or the vitrectomy procedure. Uncontrolled ocular inflammation leads to compromise of visual acuity. So, they were started on e/d Nepafenac 0.1% w/v three times per day for one month and asked for review. We observed gradual decrease in the macular edema by the end of 90 days.

From table 3 we see that in our study, 6 eyes (12 %) had irregular pupil postoperatively and the remaining were horizontally oval. 29 eyes (58%) had striate keratopathy on postoperative day1 (POD#1), 18 eyes (36%) had corneal edema on POD # 1, in addition to the topical steroids hourly and fourth hourly antibiotics, e/d Sodium chloride 5% w/v has been added one drop four times per day. 10 eyes (20%) with significant inflammatory reaction in the anterior chamber on POD # 1 were started on e/d Homatropine hydrobromide one drop two times per day for 5 days along with the regular medications. All patients improved with subsequent follow ups.

4 eyes (8%) had suture erosion at the end of POD#7 and no further intervention was needed. 3 eyes had decentered IOL in which one was PCIOL, which needed to be explained and an iris claw lens was placed. The other 2 were decentered iris claw lens which were repositioned again. Out of 50 patients 2 patients were aphakic with nucleus drop and IOL drop respectively. They had undergone posterior vitrectomy followed by iris claw lens implantation. One out of 50 eyes were

one eyed patient (phthisis bulbi), had BCVA 6/12 p by the end of POD#180 in fellow eye. The incidence of Cystoid macular edema was n=5 (10%) was less in our study which came back to normal after starting the patients on nepafenac eye drops. By the end of 180th day there were no patients with Cystoid macular edema (table 3, post-op complications).
Overall, the complications were less in our study. 2 eyes out of 50 had Retinal Detachment in which BCVA was 5/60 and 6/60 not improving with pinhole (NIP) respectively, 4 eyes out of 50 had vitreous hemorrhage in which two eyes had BCVA 6/60 and the other two BCVA 6/24. 2 eyes out of 50 had Posterior vitreous detachment in which BCVA was 6/18 and 6/24. 5 out of the above 8 eyes who had complications were pre-existing diabetic and hypertensive patients. 2 eyes out of 50 who improved to 6/36 and 2 eyes out of 50 who improved to 6/24 post operatively are amblyopic eyes. The BCVA has improved in 35 eyes (70%) of the patients following retro fixated iris claw lens implantation.

Limitations
Relatively smaller sample size and short follow up. Comparison group with Scleral fixated IOL, Glued IOL and Anterior Chamber IOL should be considered.
Studies with longer follow up and larger sample size are needed to see for the long-term complications and best corrected visual acuity.

5. Conclusion

Iris claw lens implantation is safe, time saving, and easy procedure compared to ACIOL, SFIOL and Glued IOL. Our study demonstrated that retro fixated iris claw lens implantation in patients without adequate capsular support and aphakia is safe and effective with good outcome in the vision with fewer complications. It has the advantages of a posterior chamber lens when implanted behind the iris plane. Therefore, it is a suitable alternative in eyes with insufficient capsular or zonular support, intraoperative complicated cataract surgery and secondary IOL implantation as in aphakia patients.

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