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A PROSPECTIVE STUDY OF VISUAL OUTCOMES AND COMPLICATIONS OF PRIMARY AND SECONDARY RETRO PUPILLARY IRIS-CLAW INTRAOCULAR LENS IMPLANTATION

Dr. Lipika Panda[1*], Dr. Sasmita Sahoo[2]

[1*]Associate Professor, Department of Ophthalmology, PGIMER and CH, Bhubaneswar, Odisha, India.
[2]Senior Resident, Department of Ophthalmology, PGIMER and CH, Bhubaneswar, Odisha, India.

***Corresponding Author:** Dr. Lipika Panda
*Associate Professor, Department of Ophthalmology, PGIMER and CH, Bhubaneswar, Odisha, India.

ABSTRACT

Background: In cases where there is insufficient capsular support, retro pupillary iris-claw intraocular lens (RPICL) implantation is one of the treatment options. This lens can be implanted during primary cataract surgery or as a secondary procedure weeks after the primary cataract surgery. The aim of this was a comparative study on visual outcomes and complications of primary and secondary retro pupillary iris-claw intraocular lens (RPICL).

Methods: This prospective study was done from December 2023 to November 2024. 52 patients fulfilling inclusion criteria, who attended the ophthalmology department of PGIMER and CH, Bhubaneswar were included in this study. 21 patients underwent primary RPICL implantation and 31 patients secondary RPICL implantation. The preoperative and postoperative evaluation was done with visual acuity, slit-lamp examination, IOP, and fundus examination. Follow-up was done on postoperative day 1, 2 weeks, 4 weeks,8 weeks. Results were analyzed with SPSS version 20.0.

Results: There were 52 total of 52 eyes of 52 patients of which primary RPICL was implanted in 21 eyes and secondary RPICL in 31 eyes. Post-operative complications on day 1 were more in primary implantation. 52% of primary implantation had corneal edema on postoperative day 1. Pupil ovalization was found in 19% of both groups. 2% of cases had RPICL haptic displacement. Only one patient (2%) had developed cystoid macular edema.

Conclusion: This study aims to provide a comparative analysis of these outcomes to guide clinical decision-making

Keywords: Retropupillary iris-claw intraocular lens (RPICL), Primary, Secondary, Visual outcomes, Complications.

INTRODUCTION

Since the 1980s, a 4-point fixation flexible open-loop angle-supported anterior chamber intraocular lens (ACIOL) has been used to correct aphakia in eyes without capsular support. Other alternative methods have been developed, including iris-fixation with iris-sutured intraocular lens and iris-claw intraocular lens (ICIOL), and scleral-fixation by suturing of PCIOL or intrascleral haptic fixation of PCIOL.[(1)] The use of ACIOL has decreased during past decades because of its restrictions in younger

patients and patients with glaucoma or uveitis for a relatively higher rate of corneal edema, secondary glaucoma, and uveitis.[2] Scleral fixation requires superb and complicated surgical techniques and longer surgical times and is associated with more intraoperative and postoperative complications.[3,4] Suturing the intraocular lens (IOL) to the sclera or the iris risks suture breakage, resulting in IOL tilt or dislocation of the IOL into the vitreous.[5,6]

Worst et al. published a technique using an iris-clip IOL, which required sutures to be fixed to the iris, in 1972.[7] Amar 1980 published his technique using a modified iris-claw model to be placed in the retro pupillary.[8] Later Rijneveld et al. described their retro pupillary fixation ICIOL implantation either in the anterior chamber or by retro pupillary fixation became an effective and safe choice with relatively simple placement and better clinical outcomes compared with scleral-fixation intraocular lens or ACIOL.[9] To our knowledge less number study have been done comparing primary and secondary RPICL implantation. So we planned this study to understand the visual outcomes and potential complications associated with both approaches.

MATERIAL AND METHODS

A prospective interventional study was done on 52 eyes of 52 patients without capsular support in which primary and secondary retropupillary iris claw lens implantation was done. The study was conducted at PGIMER AND CH Bhubaneswar from December 2023 to November 2024. Informed consent was taken from all patients. The study got approval from the Ethical Committee of the Institute.

Inclusion criteria

Patients with inadequate posterior capsular support; with aphakia and with normal iris anatomy were included.

Exclusion criteria

Patients with gross iris abnormalities like aniridia, diffuse iris atrophy, rubeosis iridis, pro-found iridodonesis, active uveitis, any pathology in retina, traumatic mydriasis, and surgical aphakia with decompensated corneas were excluded.

Pre-operatively the investigations were performed. Best corrected visual acuity was taken using Snellen's chart; anterior segment examination using a slit lamp; posterior segment examination using 90 D lens in slit lamp or B scan; keratometry; biometry; IOP measurement using applanation tonometry. The IOL power was calculated using the SRK/T formula and an A constant of 116.5. The lens used was an Iris claw lens made of polymethyl methacrylate. During cataract surgery, a patient who had inadequate posterior capsular support on that eye Retropupillary iris-claw intraocular lens (IOL) was implanted termed as primary. When retropupillary iris-claw IOL was implanted 6 weeks or more after the first catarct surgery, it was termed as secondary.

Procedure

Small incision cataract surgery was performed among all study participants.

The anterior chamber was formed with a viscoelastic substance. If vitreous was noted in the anterior chamber, automated vitrectomy was done. Two side ports are made diagonally opposite, i.e. at 6 o′ clock and 12 o′ clock positions. Iris claw IOL was introduced into the anterior chamber such that haptics were in line with the side ports. Holding the optic of the lens with a lens-holding forceps, one haptic was pushed under the iris with gentle manipulation. Simultaneously, the dialer was passed through the paracentesis on the same side, and enclaving was done. The endpoint was noting the dimple at the site of enclavation Similarly, haptic encalvation on the other side was done and then peripheral iridectomy was done. The wound was sutured if required. Postoperatively, topical steroid antibiotics in a tapering schedule over 6 weeks were given. Immediate postoperative complications were noted on postoperative day 1. Follow-up done on 1 week, 4 weeks, 8 weeks. On each visit anterior segment was examined and Best corrected visual acuity (BCVA) was noted.

Statistical Analysis

Mean, frequency, percentage, and standard deviation are descriptive statistics used.

RESULTS

GENDER	**N= 52**	**%**
Male	24	46.1 %
Female	28	53.8 %
Types of Surgery		
Primary RPICL	21	40.3%
Secondary RPICL	31	59.6 %
AGE IN YEARS		
40 - 50	2	3.8 %
51 - 60	6	11.5%
61 - 70	36	69.2 %
> 70	8	15.3%
Table 1: Demographic characteristics of the study		

RPICL- Retropupillary iris-claw intraocular lens

There were 52 eyes with aphakia, and a retropupillary iris claw lens (RPICL) was implanted. RPICL was implanted during primary cataract surgery in 21 (40.3%) cases, whereas, in 31 (59.6%) cases, RPICL was implanted 6 weeks after cataract surgery. Among the study population, males were 24 (46.1%) and females were 28 (53.8%). Out of all patients, 36 (69.2%) were in the age group of 61-70 years, 15.3% were above 70 years old.

Clinical characteristics		
Primary	**N= 21**	**%**
Zonular weakness	6	28.5%
Phacodonesis	4	19.0%
Small pupil < 5 mm	2	9.5%
Pseudoexfoliation syndrome	5	23.8%
Surgical complication	4	19.4%
Secondary	N =31	%
Aphakia	25	80.6 %
IOL subluxation	6	19.3%
Table 2: Clinical characteristics of Primary and Secondary RPICL implantation		

We studied the clinical characteristics of primary and secondary RPICL implantation. Among primary implantation, the commonest cause was zonular weakness (28.5%) 23.8% of patients had pseudoexfoliation syndrome. The most common clinical characteristic of secondary RPICL was aphakia (80.6%).

BCVA	**One week**		**4 weeks**	
	Primary (n=21) %	Secondary (n=31) %	Primary (n=21) %	Secondary (n=31) %
6/6 -6/9	1 (4.7%)	4 (12.9%)	5 (23.8%)	8 (25.8%)
6/12 - 6/18	6 (28.5%)	18 (58.06%)	14 (66%)	2 (67%)
6/24 - 6/36	8 (38%)	4 (12.9%)	2 (9.5%)	2 (6.4%)
6/60	2 (9.5%)	5 (16.1%)	0	0
< 6/60	4 (19%)	0	0	0
Table 3: Best corrected visual acuity (BCVA) after one week and four weeks				

BCVA was recorded in all patients on day 1, one week, 4 weeks, 6 weeks, 8 weeks. In primary RPICL 4.7% had BCVA 6/6 to 6/9, 28.5% had 6/12 to 6/18 , 19 % patients had BCVA < 6/60. Whereas in secondary RPICL implantation cases, 58.6% of patients had BCVA from 6/12 to 6/18 in one week postoperative follow-up. But BCVA at 4 weeks of postoperative day vision was 6/12 to 6/18 in 66% of cases in both primary and secondary implantation.

Postoperative day one	**Primary (n=21) %**	**Secondary (n=31) %**
Corneal edema	11 (52%)	2 (6.4%)
Hyphema	2 (9.5%)	1 (3.2%)
IOP raised	8 (38.%)	4 (12.9%)
Vitreous in the anterior chamber	2 (9.5%)	0
Lens matter remnant	1 (4.7%)	0
Pupil ovalization	6 (28%)	8 (25.8%)
Postoperative 4 Weeks		
Pupil ovalization	4 (19%)	6 (19.3%)
RPICL displacement	1 (4.7%)	0
Cystoid macular edema	1 (4.7%)	0

Table 4: Complications

Complications were noted in both groups. On postoperative day one, 52% of primary RPICL implantation had corneal edema, and only 6.4% of patients in the secondary group had corneal edema. Pupil ovalization was found in 28.5% of both groups. After 4 weeks of surgery, the most common complication was ovalization of the pupil (19%) in both groups. RPICL one haptic was displaced in one patient of primary implantation. Cystoid macular edema was noted in one patient (4.7%) of the primary group.

DISCUSSION

While indisputably "in-the-bag" implantation is the location of choice for an IOL implant, lens implantation without adequate posterior capsular support is challenging for a cataract surgeon. At present, ACIOLs, SFIOLs, glued IOLs, and iris-claw IOLs are being used in the correction of aphakia in this scenario.[10-12] Endothelial decompensation is a known complication associated with ACIOLs.[13] ACIOLs are also associated with higher inflammatory reactions. In a study conducted by Marques *et al*., ACIOL-related inflammation has been the main indication for IOL exchange in 53% of cases.[14]

In a study published by Everekliogl*u et al*., SFIOLs were proved to have a better outcome than ACIOLs while another study by Bellucci *et al*. showed that SFIOLs had more intraoperative and postoperative complications.[12] In a study by Vote *et al*., SFIOLs were associated with a high complication rate and subsequent need for further surgery. Suture breakage was the main indication for 57% of re-surgeries.[15]

The rationale behind preferring posterior iris-claw IOL over anterior one is that posterior iris-fixated IOL is retropupillary and has a lesser risk of endothelial decompensation.[16 Posterior iris-claw lenses also have the advantage of a simpler procedure, positioning near the nodal point, and no need for extra sutures or glue.[16]

Our prospective study was 21 eyes where primary RPICL was implanted, on 31 eyes where secondary RPICL was implanted 6 weeks after primary cataract surgery.

In our study, BCVA after one week of postoperative 6/6 to 6/9 was found in 4.7% of primary implantation and 12.9% of secondary implantation. However, after 4 weeks of surgery, both primary and secondary RPICLimplantation BCVA was 6/12 to 6/18.

Forlin et al study BCVA was 6/12.[17] Helvaci et al study showed the mean BCVA was 6/18.[18] Jare et al study show mean BCVA was 6/9 to 6/12.[19]

In our study most common complication on post-operative day one was corneal edema, (52%) among primary RPICL implantation. IOP was raised in both groups but became normal after two weeks.

Pupil ovalization was found 28.5% and 25.8% respectively in primary and secondary implantation at post-operative day one. At postoperative 4 weeks pupil ovalization came down to 19% in both groups. According to Panchabai et al study, pupil ovalization was 25%.[20] Forlin et al study showing pupil ovalization was 5%.[18] According to Madhvinam et al study pupil ovalization was 16% [21]. In a study by Sugiarti et al 16.67 % of patients had pupil ovalization.[22]

In our study, 9.5% of primary and 3.2% of secondary implantation had hyphema at postoperative day one. According to Vidhya et al hyphema was found in 2.2% of the study population.[23] No hyphema was detected in a study by Sugiarti et al.[22]

Gonnermann et al reported 8.7% cystoid macular edema, hyphema 2.1%, and elevated IOP.[1]

In our study, one (2%) patient developed cystoid macular edema. In a study by Knekar et al a patient developed cystoid macular edema.[24] In a Study by Vidhya et al cystoid macular edema developed in 8% of patients.[23]

In our study, haptic was displaced from one side in 2% of the study population. A study by Sugiarti et al showed 1.85% of patients detached haptic.[22]

There was a significant improvement in postoperative vision in both primary and secondary RPICL implantation. The postoperative day one mean BCVA among primary RPICL was 6/24 due to corneal edema.

Positive aspects of this study are comparative analysis, as a prospective study design ensures systematic data collection, focus on real-world application, and detailed evaluation. The study tackles an important issue in cases with insufficient capsular support, contributing to the optimization of surgical techniques in such challenging situations.

LIMITATION OF THE STUDY

Limitations of this study are unequal distribution of cases between two groups, corneal endothelial cell count was not done, short follow-up period, and late complications not studied.

CONCLUSION

Although primary RPICL implantation was associated with a higher incidence of early postoperative complications, such as corneal edema, these issues were resolved within two weeks. At four weeks, there was no significant difference in BCVA between primary and secondary RPICL groups. This suggests that both implantation approaches are comparable in terms of long-term visual outcomes.

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