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Assesment Of Retropupillary Iris ClawVersus Scleral-Fixated Intraocular Lens In Post-Cataract Aphakia- A Comparative Study

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Abstract

Background: An ophthalmic surgeon is relatively frequently confronted with the situation to place an iol in aphakic eye without capsular bag in various conditions like trauma, complicated cataract surgery and different ocular diseases. Hence, the present study was conducted to compare Retropupillary Iris Claw Versus Scleral-Fixated Intraocular Lens In Post-Cataract Aphakia.

Material & Methods: The present comparative study was conducted on 60 aphakic patients. Patients were divided into two groups of 30 each randomly, Group 1 had patients with iris claw fixation IOL and Group 2 had patients with scleral fixated IOL. Data was recorded and analysed using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

Results: There was significant difference in vision between two groups at one month and 3 month post operative (P=0.001). There was significant difference in between the two groups (P=0.001) in pupil ovalisation also.More than half the iris claw IOLs were placed at the same time as primary cataract surgery as opposed to very few SFIOL done in primary setting.. Retropupillary iris claw IOL fixation is as safe as SFIOL for visual rehabilitation of post-cataract aphakia. Both primary (i.e. at the time of cataract surgery) and secondary approaches yield comparable visual results.

Conclusion: The study concluded that Retropupillary iris claw IOL fixation is better than SFIOL for visualrehabilitation of post-cataract aphakia acording to this study,

Keywords: Retropupillary, iris claw IOL fixation, SFIOL

INTRODUCTION

Aphakia comes from two Greek words: “a” meaning “none” and “phacos” meaning “lens.” In aphakia, there is no crystalline lens inside the eye.[1] Options available for the surgeon to correct aphakia are glasses, contact lens, keratorefractive surgery and intraocular lens (IOL). The various IOLs available are anterior chamber IOL (ACIOL), scleral fixated IOL (SFIOL) and iris fixated IOL(IFIOL), both anterior and posterior.[2] Some surgeons’ experience reveals that IFIOLs are more efficient than ACIOLs and even developed an ideal patient profile benefiting from them older, with average-sized anterior segments, especially if they have some remnants of capsule and vitreous that help stabilize the lens. The haptics have to be fixated to the iris as peripherally as possible. The iris claw lens does not need the angle of the anterior chamber, ciliary sulcus, sclera, or capsular bag for support. A modification of the classical design was made by Dr. Daljit Singh and was known as the Singh-Worst iris claw lens in late 1970s. This IOL was originally designed to be fixated to the anterior surface of the iris.However, anteriorly fixated iris claw lens implantation has been shown to cause slow and persistent endothelial cell loss. Therefore, this lens has started being implanted to the posterior surface of the iris, totally avoiding the anterior chamber. Fixation to the back

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surface of the iris is referred to as retropupillary fixation.[3,4] An IOL can be fixated at the sclera in several ways: with sutures, with no sutures by tunneling of the haptics and with fibrin glue. Suturing an IOL to the sclera is the most technically demanding procedure among the others discussed here, but it has two major advantages: durability and security.[3,4] To avoid the use of sutures, tunneling of IOL haptics was imagined.Another method to secure the IOL at the sclera is with fibrin glue. The pioneer of this technique advocates that it inhibits pseudophacodonesis better than the other variants.[3,4] Hence, the present study was conducted to compare Retropupillary Iris Claw Versus Scleral-Fixated Intraocular Lens In Post-Cataract Aphakia.

MATERIAL & METHODS

The present comparative study was conducted on 60 aphakic patients who were admitted in various wards or who came in OPD of Dept. of Ophthalmology in Guru Gobind Singh Medical College and Hospital, Faridkot. The study duration was 18 months. Patients who undergo iris claw or SFIOL for post-cataract aphakia, either as a primary (i.e. at time of cataract surgery) or secondary sitting were included in the study. Patients with preexistent glaucoma, pseudoexfoliation, cornealopacity in visual axis, patients with aphakia following trauma, penetrating keratoplasty, and such other procedures were excluded. An informed consent of the patients was taken. From the patients who signed the consent, a detailed history including data regarding demographic features, predisposing factors, associated ocular conditions and systemic diseases were taken and visual acuity at the time of presentation was recorded. Patients were divided into two groups of 30 each randomly
Group 1 had patients with iris claw fixation IOL

Group 2 had patients with scleral fixated IOL
Baseline demographic data like age, gender, and involved eye was noted. Preoperative characteristics including previous surgicalprocedure (cataract surgery, pars plana vitrectomy, lensectomy, etc.) and duration between previous cataract surgery and IOL implantation was recorded. Any preexisting corneal, retinal, or macular pathology, the technique to be used for IOL placement, and any intraoperative andpostoperative complications was also recorded.

Iris claw IOL implantation:

The optima iris claw IOL with optic size of 5.50 mm, length of 8 mm was used during the study period.SRK/T formula for all IOL power calculations was applied. Under peribulbar anesthesia conjunctiva was separated and superior sclero corneal tunnel incision was made. Anterior chamber was made free of any vitreous by staining with triamcinolone acetate anterior vitrectomy was performed, following which the pupil was constricted using intracameral pilocarpine. Two limbal paracentesis were made 180° apart and the iris claw IOL was placed over the iris, one haptic was guided below the iris and enclaved in the mid-peripheral iris using a blunt sinskey hook or ball dialer. The same procedure was repeated for the other haptic. Peripheral iridectomy was performed in every case. Finally, wound integrity was checked and wound sutured if required. Sub conjunctival steroids were injected in all cases.

Scleral fixated IOL implantation:

Under Peribulbar anesthesia, 5.0 mm conjunctival peritomy was done at the 2 o'clock and 8 o'clock positions. Then, 2 T-shaped incisions (1.5-2 mm long) were made 1.5-2.0 mm from the limbus and depth was half of scleral thickness, exactly 180 degrees apart diagonally. An0 infusion cannula or anterior chamber maintainer was inserted. To prevent interference with the creation of the T-shaped incision, infusion cannula was positioned at 4 o'clock.

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Sclerotomy was done parallel to the iris at the T-shaped incision with a 23-gauge angled micro vitreoretinal (MVR) knife and a scleral tunnel (3-3.5 mm long) wasmade parallel to the limbus at the branching point of the T-shaped incision. 2.8 mm keratome was used to make a corneal incision at 10 o'clock through which IOL, with overall diameter 13 mm and optic diameter 6 mm, (three-piece Foldable IOL) was implanted with an injector; the trailing haptic was left outside the incision. The tip of the haptic was then grasped with 24-gauge IOL haptic gripping forceps, pulled through the Sclerotomy, and externalized on the left side. After the trailing haptic was inserted into the anterior chamber and the haptic tip was grasped with a 24-gauge forceps, pulled through the second sclerotomy and externalized on the right side. The haptic insertion into the anterior chamber may be difficult depending on the material or shape of the haptics, which can cause the IOL to rotate clockwise and the leading haptic to slip back into the eye. To prevent such risks, the IOL optic can be pushed to the back of the iris and moved to the 2 o'clock position with a push-and-pull hook inserted through the side port at the 1 o'clock position. The tip of the haptic was subsequently inserted into the limbus-parallel scleral tunnel. A single 8-0 vicryl suturewas used to fixate the haptic to the scleral bed to prevent it from shifting immediately after surgery.

Statistical analysis

Data were described in terms of range; mean ±standard deviation (± SD), frequencies (number of cases) and relative frequencies (percentages) as appropriate. To determine whether the data were normally distributed, a Kolmogorov-Smirnov test was used. Comparison of quantitative variables between the study groups was done using Mann Whitney test. For comparing categorical data, Chi square ($\chi 2$) test was performed and fisher exact test was used when the expected frequency is less than 5. A probability value (p value) less than 0.05 was considered statistically significant. All statistical calculations were done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

RESULTS

Table 1: Distribution of case according to gender

		GROUP 1		GROUP 2		Total	Chi- square value	p-value
		No. of cases	%age	No. of cases	%age			
SEX	F	20	66.7%	22	73.3%	42	0.317	0.573
	M	10	33.3%	8	26.7%	18		
Total		30	100.0%	30	100.0%	60		

Comparing the two groups revealed no statistically significant differences (P=0.573).

Table 2: Comparison of age in between two groups

	GROUP 1		GROUP 2		Z	p-value
	Mean	SD	Mean	SD		
AGE	59.40	8.07	56.30	4.83	1.806	0.076

On comparison there was non significant difference in between two groups.

Table 3: Distribution of cases according to involvement of eye

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		GROUP 1		GROUP 2		Total	Chi- square value	p-value
		No. of cases	%age	No. of cases	%age			
EYE	L	13	43.3%	]12	40.0%	25	0.069	0.793
	R	17	56.7%	18	60.0%	35		
Total		30	100.0%	30	100.0%	60		

Comparing the twogroups revealed no statistically significant difference (P=0.793).

Table 4: Distribution of cases according to IOL placement at time ofsurgery

	GROUP 1		GROUP 2		Total	Chi-square value	p-value
	No. of cases	%age	No. of cases	%age			
IOL PLACED AT THE TME OF SURGERY	20	66.7%	7	23.3%	27	11.380	0.002

Due to less surgical time and less instrumentation there has been more IFIOL placement at time of surgery.

Table 5: Distribution of cases according to IOL placement insecondary sitting

	GROUP 1		GROUP 2		Total	Chi-square value	p-value
	No. of cases	%age	No. of cases	%age			
IOL PLACED IN SECONDARY SITTING	10	33.3%	23	76.7%	33	11.380	0.002

SFIOL implantation in secondary sitting more due to need of more surgical time and more instrumentation.

Table 6: Comparison of BCVA score in two groups

	GROUP 1		GROUP 2		Z	p-value
	Mean	SD	Mean	SD		
BCVA PRE OP	1.84	0.22	1.90	0.09	-1.476	0.145
BCVA DAY 7	0.82	0.20	0.80	0.06	0.610	0.544
BCVA POSTOP I MONTH	0.63	0.12	0.76	0.09	-4.604	0.001
BCVA POST OP 3 MONTH	0.41	0.15	0.58	0.07	-5.569	0.001

Group 1 with IFIOL implantation acquires more visual acuity at 1 and 3 months than group 2 with SFIOL implantation. There was significant difference in between two groups at 1 month

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and 3 months post operative (P=0.001).

Table 7: Distribution of cases according to corneal odema

	GROUP 1		GROUP 2		Total	Chi-square value	p-value
	No. of cases	%age	No. of cases	%age			
CORNEAL ODEMA	1	3.3%	2	6.7%	3	0.510	0.554

Comparatively, the two groups differed non significantly from one another. (P=0.554)

Table 8: Distribution of cases according to spikes in IOP

	GROUP 1		GROUP 2		Total	Chi-square value	p-value
SPIKESIN IOP	No. of cases	%age	No. of cases r	%age			
	1	3.3%	2	6.7%	3	0.510	0.554

Comparatively, the two groups differed non significantly from one another (P=0.554).

Table 9: Distribution of cases according to severe iridocyclitis

	GROUP 1		GROUP 2		Total	Chi-square value	p-value
SEVERE IRIDOCYCLITIS	No. of cases	%age	No. of cases	%age			
	1	3.3%	0	0.0%	1	1.017	0.313

Comparatively, the two groups differed non significantly from one another (P=0.313).

Table 10: Comparison of pupil ovalisation in two groups

	GROUP 1		GROUP 2		Total	Chi-square value	p-value
PUPIL OVALISATION	No. of cases	%age	No. of cases	%age			
	16	53.3%	0	0.0%	16	21.818	0.001

There was significant difference in between the two groups (P=0.001).

Table 11: Comparison of decentration in between two groups

	GROUP 1		GROUP 2		Total	Chi-square value	p-value
	No. of cases	%age	No. of cases	%age			
DECENTRATION	4	13.3%	0	0.0%	4	4.286	0.112

Between the two groups, there was no statistically significant difference (p=0.112).

Table 12: Comparison of dislocation in between the two groups

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	GROUP 1		GROUP 2		Total	Chi-square value	p-value
	No. of cases	%age	No. of cases	%age			
DISLOCATION	1	3.3%	0	0.0%	1	1.017	0.313

There was no statistically significant difference between the two groups upon comparison (P=0.313).

Table 13: Comparison of resurgery in between the two groups

	GROUP 1		GROUP 2		Total	Chi-square value	p-value
	No. of cases	%age	No. of cases	%age			
RESURGERY	2	6.7%	0	0.0%	2	2.069	0.150
Total	30	100.0%	30	100.0%	60		

There was no statistically significant difference between the two groups upon comparison (P=0.150).

Table 14: Comparison of POST OP CME in both groups

	GROUP 1		GROUP 2		Total	Chi-square value	p-value
	No. of cases	%age	No. of cases	%age			
POST OP CME	2	6.7%	5	16.7%	7	1.456	0.424

There was non-significant difference in between the two groups (P=0.424).

DISCUSSION

Currently, ideal cataract surgery should end with the placement of an intraocular lens (IOLs) in the bag. However, in the clinical setting we have to manage cases without enough capsular support to allow the physiological IOL placement. Progress has been made in terms of IOL designs and implantation techniques. The options should be analyzed not only in accordance with surgeon's experience but also with patient's age, local and systemic comorbidities. Thus, in the absence of an appropriate capsule, IOL can be placed in the anterior chamber, fixated to the iris or to the sclera wall.[5]

The mean age in group 1 was 59.40±8.07 year and in group 2 was 56.30±4.83 year on comparison there was non-significant difference in between two groups.53 (51%) of the patients in the study led by Madhivanan N[6] were men, with a mean age of 63.6 10.8 years.[6]

In the current study, there were 20 (66.7%) and 22 (73.3%) females in groups 1 and 2, respectively. There were 10 (33.3%) and 8 (26.7%) males in group1 and 2, respectively. Comparing the two groups revealed no statistically significant differences (P=0.573).

We compared the 3 month outcomes of eyes undergoing retropupillary iris claw IOL fixation and SFIOL implantation and found that more than half the iris claw IOLs were placed at the same time as primary cataract surgery as opposed to very few SFIOL done in primary

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setting.There were 10 (33.3%) cases in group 1 of IOL placement in secondary sitting and 23 (76.7%) in group 2. Implantation of the SFIOL using either the sutured or suture less procedure is substantially more challenging than implanting the iris claw IOL to the posterior surface of the iris. Furthermore, the iris claw IOL fixation is finished significantly faster than the SFIOL.[7]

With the exception of Forlini et al, who conducted the surgery in the primary sitting the majority of the time, authors have generally fixed the iris claw IOL as a later treatment. Given that Forlini et al. and our results with primary vs. secondary iris claw IOLs demonstrate no difference in complications or outcomes, primary fixation may be preferable in the majority of cases due to surgical simplicity and the benefit of avoiding a second surgery.[8-13]

The visual outcomes at seventh day following surgery of both groups were comparable but at one month following surgery, the SFIOL group's visual results were worse than those of iris claw group, at three months this difference also persisted. At seventh day results of iris claw were comparable because the factor that might have contributed to the delayed wound healing and stabilisation of vision is the fact that many of the iris claw lenses were fixed at the time of cataract surgery or very shortly after (at one month). The majority of SFIOLs, on the other hand,were carried out as scheduled secondary procedures in quiet eyes and had minimal inflammatory effects, resulting in faster wound healing and vision outcome. There have been many reports of visual outcomes of retropupillary iris claw IOL placement in the recent past in aphakic patients without capsular support.[14,15] In our study at one month and at three months following surgery, the SFIOL group's visual results were worse than those of iris claw group because there were more chances of post op CME due to more manipulation at the level of cilliary body and uveal tissue. There was significant difference in between two groups at one month and 3 month post operative (P=0.001).

In the current investigation, one case (3.3%) in group 1 had IOP spikes while group 2 had two cases (6.7%). The two groups differ non significantly from one another in comparison (P=0.554). Hazar and colleagues (2013) stated that the mean IOP was not significantly different at baseline between the two groups. Although the mean IOP was significantly higher in the SF-PCIOL group than in the RP-IFIOL group (P = 0.042) at postoperative 1 week, there was no difference in IOP between the groups at other follow-up visits. The rate of patients who had an IOP of 22 mmHg or more postoperatively was statistically higher in the SF-PCIOL group than in the other group at postoperative 1 week, whereas no differences were seen between the groups at the other follow-up visits**.**[16]

Compared to the research by Madhivanan N. and colleagues In comparison to SFIOL eyes, eyes that received the iris claw IOL had considerably more severe iritis cases and more transient IOP spikes throughout the postoperative period**.**[6]

In present study there were 16 (53.3%) cases of pupil ovalisation in group 1 and none in group 2. There was significant difference in between the two groups (P=0.001). Ovalization of the pupil is a consistent finding reported by all studies on retropupillary iris claw IOL fixation and can be as high as 33%. Distortion of the pupil may compromise quality of vision regained by patients, however, this phenomenon has never been adequately addressed in the literature. Additionally, enclavation of iris tissue may cause localized or generalized atrophic changes in the iris and thereby affect the physiological functioning of the pupil. Very few studies have followed up patients for > 1 year and, those which have, do not employ anterior segment OCT (ASOCT) to document changes in the iris architecture and pupil dynamics in bright and dim illumination.

Group 1 had two (6.7%) cases of resurgery due to IOL dislocation in the current

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investigation, whereas group 2 had none. When the two groups were compared, there was no statistically significant difference between them (P=0.150).

Our results in the iris claw group are very similar to that reported in literature. In contrast, there are very few studies comparing iris claw with SFIOL in the sitting of post-cataract aphakia. Rashad et al performed a randomized controlled study (without masking) of 21 eyes with iris claw vs. 21 eyes with sutured SFIOL and found no differences in best-corrected vision and complications.This study reported outcomes limited to 3 months postoperative period.[7]

We found a higher incidence of CME in the SFIOL group, which was surprising. It is possible that using triamcinolone-assisted vitrectomy in the iris claw group reduced the incidence of CME, as shown by Kelkar et al. recently.[17-19] Prospective studies in the future should address these issues with longer follow-up data. The advantages of our study are the comparative design, relatively good sample, and follow-up periods. The drawbacks are the retrospective design and lack of data regarding endothelial cell counts and dynamic changes occurring in theiris and pupil over the follow-up period.

CONCLUSION

The study concluded that Retropupillary iris claw IOL fixation is better than SFIOL for visual rehabilitation of post-cataract aphakia in this study but Sfiol is as safe as ifiol for visual rehabilitation .Visual rehabilitation following iris claw IOL might take longer than SFIOL and ovalization of the pupil is the commonest adverse effect reported with this type of IOL design. Lastly, as SFIOL implantation is much more technically challenging with a longer learning curve compared to iris claw IOL.

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