Comparative evaluation and analysis of sutured Scleral fixating intraocular lens (SFIOL) versus Retro pupillary iris claw lens implantation in the management of post cataract surgery aphakia in a tertiary care, teaching hospital in central Maharashtra.

[1]Dr Ajay Tammewar, [2]Dr Valay Parekh , [3]Dr Anjali Kapase , [4]Dr Anil Singh.

[1]Professor , [2]Junior Resident , [3]Assistant Professor ,[4]Senior Resident
Department of Ophthalmology,
Dr. Vitthalrao Vikhe Patil Foundation's Medical college and memorial hospital , Vilad ghat ,Ahmednagar, Maharashtra ,India. 414111

Abstract : Introduction : In modern ophthalmology, when executing a cataract surgery, a Rigid or a foldable intraocular lens (IOL) is implanted in the patient's eye while still rendering the posterior capsule intact. Posterior chamber intraocular lens (PCIOL) implantation is not viable if the capsular support is insufficient or non-existent. A supplementary Iris claw lens or Scleral fixed IOL may be implanted if the condition warrants it.
Aim : To assess and compare the visual acuity and sequelae (comprising of complications) of sutured Scleral fixating intraocular lenses (SFIOL) versus Retro pupillary iris claw lens implantation in the management of post cataract surgery aphakia.
Methods : A retrospective comparative analysis of 120 aphakic eyes (post cataract surgery) was done where one group underwent sutured Scleral fixating intraocular lens implantation and the other group had undergone retropupillary iris claw lens implantation with a minimum follow up period of 6 months.
Results : Improvement in UCVA (uncorrected visual acuity) and BCVA (best corrected visual acuity) was significantly seen in both SFIOL as well as Iris claw lens implantation($p<0.001$). Time required for surgical implantation of Iris claw lens was remarkably less compared to SFIOL($p<0.001$).(iris claw = 22.21 ± 4.56 minutes, SFIOL= 45.23 ±4.93minutes). Average intraocular pressure post operatively was almost similar in both the groups. Increased incidence of iritis (post operatively) (15%) was seen in retropupillary iris claw lens implantation compared to sutured SFIOL (10%). Frequent rise in intraocular pressure was seen in 12% of eyes fitted with iris claw lens and 18% of the same group also experienced oval shaped pupil.
Conclusion : Both the groups retropupillary iris claw lens vs sutured SFIOL had approximately similar visual rehabilitation of 6/18-6/6(BCVA) for post cataract aphakia. In the SFIOL group Cystoid Macular Edema(CME) lasted until the final follow up in 3 cases and had no problems linked to sutures. Advantage of Iris claw implantation is that it required lesser surgical time whereas oval shaped pupil and immediate inflammation post operatively were the notable drawbacks.

Index Terms- Sutured SFIOL, Retropupillary Iris Claw IOL, PCIOL, Aphakia.

Introduction

Any localised or generalised opacification in the lens or its capsule, is known as cataract [(1)]. The cataract inside the eye limits the amount of incoming light, causing eyesight to deteriorate. Cataract formation in humans is often regarded as a complex illness. Although there are several reasons, the most prevalent is ageing. Age related cataract, which affects nearly 20 million people globally, is the most prevalent cause of serious vision loss and blindness[(2)].Phacoemulsification with implantation of posterior chamber intraocular lens has become the gold standard treatment for cataract surgery universally[(3)]. Excellent visual prognosis is achieved if the IOL is implanted in the capsular bag which ensures lens centration. Damage to the capsular bag occurs in about 2-4% of cases making it very laborious to implant a lens in the bag[(4)]. Various techniques like Scleral fixated IOL's (SFIOL) [(5)] , Anterior chamber intra ocular lenses (ACIOL) or iris fixated IOL's can be used in cases where there is deficiency of capsular support.[(6)]
There has been a substantial use of scleral fixating IOL's for aphakia correction, yielding amazing results and are most commonly used. A great amount of shift in the technique has happened in the past 10 years from sutured SFIOL's to Suture less SFIOL implantation. But still sutured SFIOL implantation is the standard, time tested and conventional method of correcting aphakia.[(7)]
IOL fixation to the iris has also been previously described [(8)]. Haptic fixation on the anterior surface of the iris, such as the Binkhorst [(9)], and suturing the IOL haptics to the iris using sutures have all been documented in the literature. Retro-pupillary Iris claw lens fixation was first done by Andres Mohr back in 2002 [(10)]. Recently there has been a rejuvenated interest in retro-pupillary fixation of the Iris claw lenses considering how easy it is as well as good visual prognosis along with keeping the integrity of the Anterior Chamber intact[(11)(12)].
In this research, we compared the complications and outcomes of these two intraocular lens (IOL) implantation techniques for the surgical correction of aphakia in a tertiary teaching eye care centre

Materials and Methodology

A retrospective comparative analysis was carried out with authorization by the ethics committee of the parent institution. All patients visiting the ophthalmology OPD of a tertiary care teaching hospital who underwent surgery for aphakia correction secondarily during the period of 2017 to 2021 and fit the inclusion criteria were taken into consideration. Prior to the surgery written informed consent was obtained from all the patients. 120 aphakic eyes with minimum 6 months post operative follow up period from January 2017 to December 2021 were included and put in 2 groups (SFIOL Implantation and Retro-pupillary iris claw implantation). Cases of lens drop and patients who had undergone PPV previously were also taken into consideration as all the cases were operated in the secondary sitting. The investigator measuring best corrected visual acuity (BCVA) was masked for the type of surgery and the patient also was not informed about the operative procedure.

Criteria for Inclusion

1. Participants between the ages of 40 - 75
2. Aphakia as a result of complicated cataract surgery.

Criteria for exclusion

1. Patients having pre-existing corneal conditions like keratitis, dystrophies, and corneal opacity in the optical axis.
2. Patients with retinal pathology such as Retinitis pigmentosa, ARMD, diabetic and hypertensive retinopathy, and any other irreversible maculopathy that compromises the visual outcome after the surgery
3. Extensive damage to the eye's iris as a result of chronic uveitis, iridodialysis or any other iris pathology
4. Glaucoma with or without glaucomatous optic nerve damage
5. PXF syndrome and associated abnormalities.

Preoperative examination was performed as follows prior to the procedure:

1. Universally accepted Snellen's chart visual acuity testing, both unassisted and with aphakic correction
2. Detailed Examination of the anterior segment using slit lamp biomicroscope.
3. Goldmann applanation tonometry and noncontact pneumo-tonometer (TOPCON)is used to monitor IOP.
4. In-depth examination of fundus with an indirect ophthalmoscope.
5. All patients' preoperative biometric parameters were examined, and IOL power was estimated using the IOL's A constant. SFIOLs were utilised with A constant 118.5(Aurolab ,biconcave with 2 eyelets) and retropupillary iris claw IOLs with A constant 115. (liberty, concavo-convex).

Surgical Techniques

Both surgical procedures were performed under peribulbar anaesthesia. Both surgeries were carried out by the trained surgeons. Iris claw IOL implantation was done by trained phaco surgeon (AKS) and sutured SFIOL implantaion (AMT) was done by a trained vitreoretina surgeon.

1- Sutured SFIOL- Painting and draping of the eye was completed under peribulbar anaesthesia. The universal wire speculum was positioned. At the 3 and 9 o clock meridian points, 180 degrees apart, two partial thickness scleral pockets as described by Hoffman in 2006 [(13)] starting from the limbus were created. Conjunctival peritomy (7-8 mm) was done superiorly at the limbus and conjunctiva was retracted. Scleral tunnel of size 6.5 to 7 mm was constructed superiorly using the disposable crescent knife. TCA assisted Anterior vitrectomy was done through two side ports using 23 g vitrectomy probe and a infusion cannula and anterior chamber was formed by visco (2% Hydroxy Propyl Methyl Cellulose- HPMC) injection. A double armed 10-0/9-0 prolene suture with two straight needles was utilised for two point scleral fixation of the IOL . Using a bent 26G needle introduced through the scleral pocket, 1.5 mm from the limbus of opposite side, a straight needle of the prolene suture intorduced through the scleral pocket 1.5 mm away from the limbus was rail-roaded out of the eye. The second straight needle of the 10-0 prolene suture was introduced through scleral pocket 1mm adjacent to previous suture entry point and was railroaded out of the eye through opposite scleral pocket 1mm adjuscent to previous suture using similar technique used for the first needle, so that we had two 10-0 prolene sutures parallel to each other across the eye (3-9 oclock hrs / 180 degrees opposite to each other) horizontally behind the iris. The anterior chamber was entered with the disposable keratome via the scleral tunnel and was formed with the Viscoelstic substance (2% HPMC) .The scleral tunnel incision was extended (6.5 - 7mm). Both the horizontal prolene sutures which were behind the iris across the anterior chamber were externalised through the scleral tunnel at 12 o'clock and cut in the middle. Both halves of the two prolene sutures were inserted into the IOL's fixation eyelet on the superior and inferior haptic at the point of maximal spread respectively and three knots were tied on each side. The cut ends of the prolene sutures were flanged by using the thermal cautery. Then this sutured IOL was introduced through the scleral tunnel and was positioned in the cilliary sulcus behind the pupil by retracting the prolene sutures. This sutured two point Scleral fixation was achieved using a rigid PMMA, IOL (equiconvex 6.5mm optic, 13mm overall length, (Aurolab). At this point we had two straight needles with prolene suture through scleral pocket on one side and a loop of prolene suture through scleral pocket on opposite side. The straight needles were seperated from the prolene suture after cutting it close to the needles and on the opposite side the loop of the prolene suture was cut in the middle. Both the prolene suture ends were hooked out of the scleral pocket with Sinskey hook and tied with each other using triple knot technique so that knot got burried in the scleral pocket once it is tightened and then the suture ends were cut. The same procedure was repeated on the opposite side. The anterior chamber was rendered free of viscoelastic material and was formed by balanced salt solution. 10-0 nylon suture was utilized to seal the scleral tunnel wound and the conjunctiva was reposited. Both the side port incisions were sealed by hydration. A mixture of 0.5cc of Gentamycin and Dexamethasone was administered subconjunctively at the conclusion of the operation.

2- Retropupillary Iris Claw lens implantation - Painting and draping of the parts were done under peribulbar anaesthesia. A universal wire speculum is mounted. Revisions were made to conjunctival peritomies. Sclerocorneal tunnel was revised from the previous incision. At a 90-degree angle from the primary incision, two paracenteses were performed. With the aid of continuous irrigation from the sideport, a 23G vitrectomy cutter was used for anterior vitrectomy. An injection of 0.5% Intracameral pilocarpine (aurocarpine 0.5%) with Triamcinolone acetate (aurocort 40 mg) was administered in AC just after vitreous had been removed,

which helps the pupil to constric and identify the strands of vitreous if any. A viscoelastic solution (2 % HPMC) was administered to reconstitute the AC after the pupil's miosis. The primary incision was used to insert the Iris Claw IOL into the anterior chamber. Anterior chamber depth and space were maintained by the injection of viscoelastic at each step. One haptic is gently manipulated beneath the iris while the optic is held with iris claw lens holding forceps. On the other side, a Sinskey hook is threaded through the paracentesis. At this point, the IOL's haptic was tilted up to create an indentation in front of the iris. With the assistance of the Sinskey hook, the iris was carefully and precisely nudged into the haptic claw. With a similar manoeuvre, the second haptic enclavation was completed. Using a Simcoe cannula, we were able to aspirate the viscoelastic. 10-0 nylon was used to sew the main incision shut. A balanced salt solution was utilized to construct the anterior chamber, and the conjunctiva was reposited. A mixture of Dexamethasone and gentamycin was administered subconjunctively at the completion of the procedure.

Post-operative evaluation-

Antibiotic and steroid combination medication was administered topically to both groups of patients, starting with one drop every 1 hour on the first post-operative day and tapered during subsequent follow-ups. Patients received 5 postoperative follow ups starting the day after surgery and continued for six months after they were discharged from the hospital (Post-op Day 1, Week 1, 1st, 3rd and the 6th month respectively). UCVA was evaluated at each visit, and slit lamp and fundus examinations were conducted to look for possible complications and sequelae. At the six moth follow-up, BCVA was measured subsequently.

Statistical Data Analysis

Aided as well as unaided visual acuity was recorded at each follow up visit. Analysis of results was done with SPSS v10 statistics package and with application of chi-square test and student's t-test. A statistically significant p value <0.05 was taken into consideration.

Results-

Age range of the patients on which the study was done was from almost similar in both the groups.

Table 1-Distribution according to the age

Age (years)	Group SFIOL	IRIS CLAW	Total	P value
40-44	3	3	6	
45-49	3	3	6	
50-54	8	8	16	0.092
55-59	12	15	27	
60-64	24	23	47	
65-69	9	9	18	

Table 2- distribution according to sex

Gender	Group		p-value
	SFIOL	Iris Claw	
Male	42	48	
Female	18	12	0.3
Total	60	60	

p-value>0.05 as there is not much notable variance in both the groups.

Table 3 – preoperative Visual assessment

Visual Acuity	Group		Total	p-value
	SFIOL	IRIS CLAW		
Hand movements	6	9	15	
1/60 - 3/60	51	51	102	0.513
6/60	3	0	3	
Total	60	60	120	

Pre-operative visual acuity of the patients in both groups ranged mostly between 1/60 - 3/60 whereas few were having vision of Hand movements close to the face. Aphakia occurring after complicated cataract surgery in a teaching hospital being the most frequent diagnosis was our main reason for this study.

Table 4- Average Time taken for the respective surgical procedures

	SFIOL	IRIS CLAW	p-value
Time(minutes)	45.23±4.93	22.21±4.56	0

From the above data (table 4) $p<0.05$ indicates average time taken for SFIOL implantation was more as compared to retropupillary iris claw lens implantation which is significant statistically.

Table 5-BCVA at 6 month follow up

Vn	SFIOL	IRIS CLAW	p-value
6/18-6/6	48	51	
6/60-6/24	12	6	
<6/60	0	3	
Total	60	60	0.36

Around 82%-86% patients in both groups had visual rehabilitation ranging from 6/6-6/18 while the other patients ranged from 6/24-6/60

Table 6 – Complications on Post-op day 1

Complications	SFIOL	Iris Claw	p-value
Subconjunctival Haemorrhage	30	18	0.16
SK's	48	54	0.32
Anterior Chamber Reaction	51	57	0.29
Hyphema	6	6	1
Raised IOP	0	6	0.309
Pupil Ovalization	0	12	0.032

On Post-op day 1 both groups of patients showed identical amount of Anterior Chamber Reaction with striate Keratopathy. Subconjunctival hemorrhage was also seen in patients of both the groups. Ovalization of pupil was statistically significant and was seen in patients with iris claw implanted lens .Other complications like hyphaema and rise in IOP was not of much significance. Mild to moderate Vitreous Haemorhage was seen in three patients of SFIOL group which cleared within six to eight weeks after surgery.

Table 7- Complication on Post-op day 7

Complications		SFIOL	Iris Claw	p-value
SK's		15	21	0.195
Anterior Chamber Reaction		21	24	0.715
Suture Associated		1	0	0.309
Oval Shaped Pupil		0	12	0.032
Pigment Deposition		3	12	0.142
Raised IOP		3	0	0.309
Vitreous Haemorrhage		3	0	0.309

Table 8- Complication on Post-op day 30(1 month follow up)

Complications		SFIOL	Iris Claw	p-value
SK's		0	3	0.309
IOL Associated		6	3	0.543
Suture Associated		1	0	0.153
Oval Shaped Pupil		0	12	0.032
Pigment Deposition		0	12	0.032
Raised IOP		3	0	0.309

Vitreous Haem 3 0 0.309

Ovalization of pupil with deposition of iris pigments was most commonly noted in subjects implanted with the iris claw lens while the main complications noted in SFIOL implanted lenses were mild to moderate Vitreous haemorhage and transient rise in IOP in few cases at the end of four weeks postoperatively. Displacement of IOL was also seen in few patients in both the groups which was there at the end of six months follow up also.

Table 9- Complications on 6 monthly follow up

Complications	SFIOL	Iris Claw	p-value
CME	3	0	0.309
IOL Associated	9	3	0.543
Suture Associated	0	0	0.032
Oval Shaped Pupil	0	12	0.032
Pigment Dispersion	0	12	0.032
Raised IOP	3	0	0.309

Notable findings in the 6 monthly follow up were no suture related complications like scleral flap erosion and suture associated granuloma due to the exposed sutures in SFIOL group since prolene suture knots on either sides were completely burried in the scleral pockets. In SFIOL implantation group IOL associated complications like tilting/ mild decenteration of the implanted lens were noted in 9 eyes whereas same were noted in 3 eyes of iris claw lens group . In the iris claw group similar results as 1 month follow up were present. Cystoid Macular Edema was noted in 3 patients of Scleral fixated group. No eye in the iris claw group showed de-enclavation or complete dislocation of the IOL in the vitreous cavity.

Discussion : A lengthy debate has been going on since years considering which technique is the best of IOL implantation for aphakia so that the need to wear thick aphakic glasses or contact lens doesn't arise after cataract surgery yielding excellent visual prognosis and least complications[14]. In this study Six monthly outcomes of eyes which had undergone sutured SFIOL implantation and Retropupillary iris claw fixation were compared and found to be safe for visual prognosis. None of the surgeries were done in a primary setting. Various studies have mentioned complication rates of sutured SFIOL surgical procedure ranging from 10% – 54%. [7,15,16]. Most common complications reported with sutured SFIOL were suture related (up to 24%.) [7] In our study, we did not encounter the suture related complications in SFIOL group since the suture knot was well burried in the scleral pockets. But in this group we had mild to moderate vitreous haemorhage without vision threatening sequelae in three cases. Surgically it was much easier to implant the Iris claw lens compared to implantation of SFIOL with sutures as well as it was less time consuming although the time required for making Hoffman's scleral pockets was lesser than making conventional scleral flaps in sutured scleral fixation of IOL group. Similar observation was reported by Rashad et al in their study[17].Oval shaped pupil was the most notable postoperative finding with retropupillary fixation of iris claw in our study. Ovalisation of the pupil was similarly noted in previous other studies as a most common postoperative problem in Retropupilaary iris claw lens group[18,19]. No any major changes were recorded in the average IOP of both the groups in this study.

In the beginning visual recovery of iris claw eyes took a little longer compared to SFIOL due to Iritis, striae keratopathy and pigment on the lens but improved at 1 month follow up and was maintained till 6 month follow up. Delayed Ocular complications

such as retinal detachment and IOL dislocations were not observed in our research which may be due to the shorter length of follow-up.

The optical result of retro pupillary Iris clawing lens was found to be equivalent to that of a sutured Scleral fixated intraocular lens. Iris Claw also had a reduced surgery time with a positive outcome. The most prevalent consequence with ICIOL was pupil ovalization, which was innocuous and others were equally manageable. In eyes with insufficient posterior capsular support, ICIOL may be a potential alternative to sutured Scleral fixated lenses. Also in eyes with weakly dilating pupils and no other iris abnormalities, iris clawing lenses can be recommended where sutured SFIOL implantation may worsen the condition.

The comparative design, relatively large sample size are benefits of our study. Although our study met its objectives, The shortcomings are the retrospective approach, short follow up period and the lack of data on endothelial cell counts. Future randomised, prospective control studies with a longer follow up duration and serial Anterior segment optical coherence tomography scans are necessary to demonstrate the efficacy of one Lens type over the other.

Conclusion

The six months corrected visual acuity in post cataract surgery aphakic patients is comparable with either of the techniques studied in this research. The retropupillary iris Claw IOL implantation can be a preferred choice of surgical procedure to correct aphakia because it is technically easy and faster procedure as compared to sutured SFIOL implntation, however the choice of the surgical procedure depends on surgeons comfort and expertise. Ovalisation of the pupil was the commonest postoperative finding in retropupillary iris claw IOL group whereas mild decentration was associated with sutured SFIOL group. Further studies with Prospective, randomised trials along with corneal endothelial study and anterior segment optical coherence tomography with long term follow up will guide appropriately regarding the choice of IOL implantation in post cataract surgery aphakia after complicated cataract surgey.

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