

Comparative analysis of secondary implantation of Iris claw intraocular lens (ICIOL) & Scleral fixated intraocular lens (SFIOL) in terms of visual outcome and complications

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Abstract:

Background: The modern cataract surgery involves implantation of posterior chamber intraocular lens (PCIOL) when the posterior capsule is intact. However, in case of weak or no capsular support, PCIOL implantation is not possible. In such situations, implantation of secondary Iris claw lens (ICIOL) or Scleral fixated IOL(SFIOL) remains as treatment options. The aim of this study was to compare the efficacy of ICIOL and SFIOL in terms of visual outcomes and complications in aphakic patients. **Methods:** This prospective longitudinal randomized study was done from January 2019 to December 2019. Forty aphakic patients fulfilling inclusion criteria, who attended the ophthalmology outpatient department of VVPF's Medical college and hospital, Ahmednagar were included in this study. These patients were randomly divided into two groups such as Group 1 included 20 patients who underwent ICIOL implantation and Group 2 included 20 patients who underwent SFIOL implantation. The preoperative and postoperative evaluation was done with visual acuity, slit-lamp examination, IOP, fundus examination for the follow up period of 6 months. Results were analysed with Chi square test and t-test using SPSS software. **Results:** 85% ICIOL and 80% of SFIOL patients had final Best Corrected Visual Acuity (BCVA) of 6/18-6/6. Surgical time in ICIOL was significantly less than SFIOL group ($p=0.00$). Suture related complications were

significantly more in SFIOL group. However, oval pupil and pigment dispersion were seen more in ICIOL group but were harmless. One patient in SFIOL group developed Cystoid Macular Edema (CME) which persisted till final follow up and 1 haptic of ICIOL was disencavated which was re-encavated. **Conclusion:** Comparable final visual outcome was found between ICIOL group and SFIOL group. However, Implantation of ICIOL required less surgical time with fewer complications and hence is a better alternative to SFIOL implantation in correction of aphakia.

Key words: Cataract, Iris claw intraocular lens, Scleral fixated intraocular lens, Aphakia

Introduction:

Any metabolic disturbance in the lens results in localized or diffuse opacification in the lens or its capsule, called cataract. The opacity within the clear lens inside the eye reduces the amount of incoming light and results in deterioration of vision. Cataract develops from variety of reasons. Formation of cataract in human beings is mostly considered to be a multifactorial disease. Although it has various causes, ageing is the commonest one. Senile cataract is the most common cause of severe vision loss and blindness worldwide, affecting approximately 20 million people.¹⁻⁴ Lens capsule is a thin, transparent, hyaline collagenous membrane which surrounds the lens completely. Capsule is secreted anteriorly by basal cell area of the lens epithelium and posteriorly by the basal area of elongated fibres. Lens capsule is the thickest basement membrane in the body. The thinnest part of the capsule is located in the posterior pole.⁵

The surgical treatment of Cataract has evolved with time with various modifications and advancements. One of the goals of modern cataract surgery is to keep the posterior capsule intact and implant a posterior chamber intraocular lens (PCIOL) in the bag, which provides a more physiological placement of lens as it is closest to the nodal point of the eye.⁶

Cataract surgery is associated with variety of complications and posterior capsular tear is one of them. If sufficient amount of posterior capsule remain even after posterior capsule rupture, implantation of a PCIOL in the ciliary sulcus is technically feasible.⁷

However, in cases of aphakia secondary to trauma or complicated surgery, there is inadequate capsular support to place PCIOL in sulcus. There are many procedures for correcting the aphakia in such patients. The indication for such surgical procedure depends upon status of the iris and anterior chamber depth. These procedures include sutured scleral fixation IOL, angle-supported IOL and anterior chamber or retro pupillary iris-claw IOLs.⁸

IC-ACIOLs were first introduced by Worst et al, to correct the refraction in aphakic eyes.⁹ These iris-claw lenses were biconvex polymethylmethacrylate IOL fixated above the iridal plane at the mid-periphery of the iris. Since decrease in the endothelial cell count was observed in these anterior placed lenses, so an alternative to this procedure was thought. Amar L¹⁰ published the retropupillary implantation technique using an iris-claw IOL in 1980, which was then modified clinically by Mohr et al.¹¹ in 2002 and later this approach gained the popularity.

The new generation of IC-IOLs are implanted in retro pupillary position with haptic enclavation at mid peripheral iris, because of less vascularity and less mobility in this area. This procedure provides good visual outcomes with less surgical time and helps in preserving the anatomy of anterior segment with respect to position of natural crystalline lens and has cosmetic benefit with low risk surgery. There are also few disadvantages such as dislocation of IC-IOL, pupillary deformity and iris atrophy.¹² Though SF-PCIOL offers better visual outcome, its implantation is technically difficult. It requires considerable operative time and is associated with complications such as IOL tilt, decentration, retinal detachment, CME and conjunctival erosion secondary to use of trans-scleral sutures.¹³ In spite of these complications, it is the method of choice in case of insufficient iris tissue and atrophic iris, where IC-IOL is contraindicated.

Having diverse options for correction of aphakia, many studies have been carried to know pros and cons of iris fixated and scleral fixated IOL. With the improved techniques and current knowledge the efficacy of each modality should be analysed. In this regard our present study was planned to analyse the efficacy of iris claw

IOL and Scleral fixated IOL in terms of visual outcomes and complications.

Methodology:

Sample size: It is a Prospective longitudinal interventional comparative study which included 40 patients who visited the outpatient department during study period from January 2019 to December 2019. These patients were divided into 2 equal groups, with 20 patients in each group such as

- Group 1 underwent ICIOL
- Group 2 underwent SFIOL.

Inclusion criteria:

1. Adult patients aged between 40 to 75 years were included.
2. Aphakia resulting secondary to surgery.
3. Aphakia following trauma

Exclusion criteria:

1. Patients with pre-existing pathologies such as Corneal disease like keratitis, dystrophies, corneal opacity in visual axis.
2. Retinal pathologies like retinitis pigmentosa, ARMD, diabetic and hypertensive retinopathy, irreversible maculopathy.
3. Recurrent uveitis, severe iris damage.
4. Uncontrolled glaucoma.

Method of collection of data: The study was conducted in a Tertiary care Centre after obtaining approval from the institutional ethical review board. Forty aphakia patients aged 40 to 75 years, presenting to OPD from January 2019 to December 2019, in whom vision was improving with aphakic correction were taken into the study. All the patients selected had undergone primary surgery 1 month back. A written informed consent was taken from all of the participants. These 40 patients were randomly divided into 2 groups with 20 in each.

1. Group 1 for ICIOL.
2. Group 2 for SFIOL

Before the procedure, preoperative evaluation was done as follows:

1. Visual acuity testing with standard Snellen's chart both unaided and with aphakic correction.

2. Anterior segment examination with slit lamp biomicroscope.
3. IOP measurement with Goldmann applanation tonometry.
4. Detailed fundus examination with indirect ophthalmoscope.
5. Preoperative biometric values were considered in all the patients and IOL power was calculated computing A constant of the IOL used.

ICIOLs were used with A constant 115 and SFIOLs were used with A constant of 118.5.

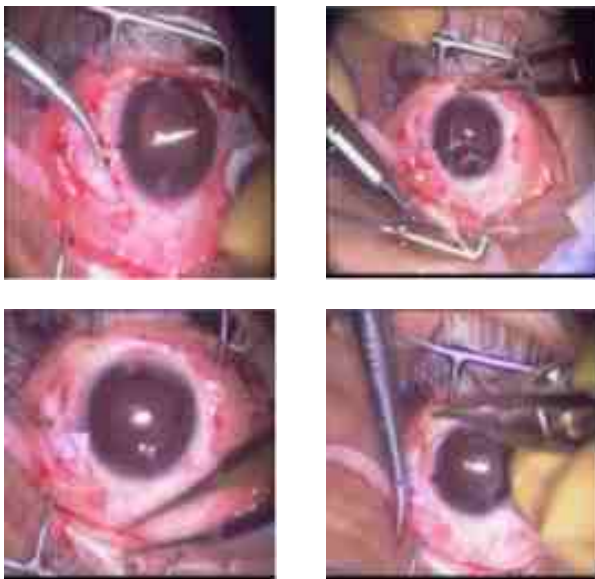
Both the surgical procedures were done under peribulbar block. Both the procedures were performed by a single surgeon.

Operative procedure of ICIOL: Under peribulbar anaesthesia, painting and draping of the parts was done. Universal wire speculum placed. Conjunctival peritomy was revised. Sclerocorneal tunnel was revised from the previous incision. Two paracenteses were made 90° from the main incision. Anterior chamber was entered through the tunnel. Anterior Vitrectomy was done using 23G vitrectomy cutter through the main incision under the continuous irrigation from the sideport. Once the vitreous from AC was removed, 0.2 – 0.3ml of 0.5% Intracameral pilocarpine (aurocarpine 0.5%) was injected in AC to constrict the pupil. Viscoelastic substance (2% HPMC) was injected to reform AC following miosis of pupil. Iris claw IOL was introduced into the anterior chamber through main incision. Viscoelastic was injected at each stage to deepen the anterior chamber and maintain space. Holding the optic with iris claw lens holding forceps, one haptic is tilted down and pushed under the iris with gentle manipulation. Simultaneously a Sinskey hook is passed through the aracentesis on the same side. Once the haptic of the IOL is behind the iris, the haptic is tilted up to produce an indent on the iris. The iris is enclavated into the haptic claw with gentle push with the help of Sinskey hook. Then with similar manoeuvre the other haptic enclavation is done. Viscoelastic was aspirated with simcoe cannula. Main incision was sutured with 10-0 nylon. Anterior chamber was formed with balanced salt solution and conjunctiva repositioned. Subconjunctival dexamethasone and gentamycin was given.



Iris claw lens and technique of implantation of iris claw lens

Procedure for SFIOL: Under peribulbar anesthesia, painting and draping of the parts was done. Universal wire speculum was placed. Conjunctival peritomy was revised and extended to 1800. Two partial thickness scleral flaps 1.5 to 2 mm posterior to the limbus were made at the 3 o'clock and 9 o'clock meridians, 1800 apart. A double arm 10-0 prolene suture with straight needle was used. The needles were rail -roaded out of the eye through the bed of the opposite scleral flap using a bent 26g needle introduced through the scleral bed. A limbal section was fashioned and the sutures were drawn out of the eye, and cut into two halves. Each half of the sutures were passed through the fixation eyelet on the superior and inferior haptic of the IOL at the point of maximum haptic spread. A single piece, PMMA, large optic IOL (equiconvex 6.5mm optic, 13mm overall length) was used for scleral fixation. The IOL was introduced into the posterior chamber, and the sutures were tightened and tied. The suture knots were buried in the scleral bed and the sclera flaps were sutured. The viscoelastic substance was cleared from the anterior chamber. The sclerocorneal wound and conjunctival peritomies were closed with 10-0 nylon sutures. Subconjunctival gentamycin and dexamethasone 0.5cc was given at the end of the procedure.



Technique of implantation of SFIOL

Postoperatively, patients of both the groups were started on antibiotic with steroid combination drug topically, one drop hourly for the 1st day and gradually tapered over subsequent follow ups.

Postoperative evaluation: Postoperative evaluation was done on 1st day, 1st week, 1st month, 3rd month and 6th month. Uncorrected visual acuity (UCVA) followed by slit lamp examination and fundus evaluation was done on each visit to look for complications. Best corrected visual acuity (BCVA) was tested at 6th month follow-up.

Data analysis: The visual acuities were converted to the logarithm of the minimum angle of resolution (logMAR) units for the statistical analysis. The results were analyzed using the SPSS v10 statistical package, using chi-square test and t-test. A p value < 0.05 was considered as statistically significant.

Result:

Table 1: Age distribution

Age (in years)	Group		Total	P value
	Group 1	Group 2		
40-44	1	1	2	0.092
45-49	1	0	1	
50-54	2	2	4	
55-59	4	5	9	
60-64	8	7	15	
65-69	3	3	6	
70-74	1	2	3	
Total	20	20	40	

The patients included in the study were matched in terms of age. Majority of them were between 60-64 years.

Table 2: Sex distribution

Gender	Group		p-value
	Group 1	Group 2	
Male	14	16	0.30
Female	6	4	
Total	20	20	

No significant difference between the two groups. (p > 0.05)

Table 3: Preoperative vision

Vision	Group		Total	p-value
	Group 1	Group 2		
HM	2	3	5	0.513
CF 1m- CF 3m	17	17	34	
6/60	1	0	1	
Total	20	20	40	

Majority of the patients included in the study had pre-operative vision of counting finger 1m to counting finger 3m in both the groups. In Group 1, 1 patients had vision of 6/60 and 2 had hand movements whereas 3 patients in Group 2 had vision of Hand movements.

Most common etiology for aphakia in our study was complicated cataract surgery. 3 patients had traumatic lens drop and 1 patient had post cataract surgery IOL drop.

Table 4: Time taken for two surgeries

	Group 1	Group 2	p-value
Mean time	27.47 ± 4.21	42.93 ± 5.23	0.00

Mean time taken for Group 1 was less compared to Group 2, which was statistically significant. (p < 0.05)

Table 5: Post operative BCVA at 6months :

	Group 1	Group 2	p-value
6/18- 6/6	17	16	0.36
6/60- 6/24	2	4	
< 6/60	1	0	
Total	20	20	

85% of patients in Group 1 had vision better than 6/18 while 1 patient had less than 6/60. 80% of patients in Group 2 had vision more than 6/18.

Table 6: Complications at Post-operative Day-1

Complications	Group 1	Group 2	p-value
Subconjunctival Haemorrhage	6	10	0.16
Striate keratopathy	18	16	0.32
AC reaction	19	17	0.29
Hyphema	2	2	1.00
Pupil ovalisation	4	0	0.032*
Raised IOP	1	0	0.309

At postoperative day1, striate keratopathy and AC reaction was seen in almost all the patients equally in both the groups. Subconjunctival Haemorrhage, Hyphaema and Raised IOP was not statistically significant between two groups. Pupil ovalization was seen more in Group 1 patients and it was statistically significant.

Table 7: Post-operative Complications at 1 week

	Group 1	Group 2	p-value
Striate keratopathy	7	5	0.195
AC reaction	8	7	0.715
Suture related	0	1	0.309
Pupil ovalisation	4	0	0.032*
Raised IOP	0	1	0.309
Pigment dispersion	4	1	0.142

At postoperative 1 week, striate keratopathy found to be persisted in 7 patients in Group 1 and 5 patients in Group 2. Suture exposure was noted in 1 patient of Group 2. Pigment dispersion was noted in 4 patients of Group1 and 1 patient of Group 2.

Table 8: Post-operative Complications at 1 month

	Group 1	Group 2	p-value
Striate keratopathy	1	0	0.309
IOL related	1	2	0.543
Suture related	0	3	0.153
Pupil ovalisation	4	0	0.032*
Raised IOP	0	1	0.309
Pigment dispersion	4	0	0.032*

At postoperative 1 month follow up, Striate keratopathy was seen in 1 patient in Group 1. Disenclavation of one haptic was noted in one patient in Group 1. It was re-enclavated and followed up. Suture related problems like scleral flap erosion and suture exposure resulted in IOL tilt, which caused an astigmatism of 3 diopters in 3 patients of group 2. 1 patient had raised IOP in Group 2. Pigment dispersion which was noted in 1 patient of Group 2 at 1st week was found to be resolved.

Table 9: Post-operative Complications at 6 months

	Group 1	Group 2	p-value
IOL related	1	3	0.543
Suture related	0	5	0.032*
Pupil ovalisation	4	0	0.032*
Raised IOP	0	1	0.309
CME	0	1	0.309
Pigment dispersion	4	0	0.032*

At the end of the follow up period of 6 months, pupil ovalization was found in 4 patients and pigment dispersion in 4 patients in Group 1. No such complications occurred in Group 2. Both the complications were found to be statistically significant ($p=0.032$). Whereas in Group 2, 5 patients had suture related complications, which was found to be statistically significant ($p=0.032$). IOL related complications like IOL decentration was noted in 1 patient of Group1 and IOL tilt was noted in 3 patients of Group 2, which was not statistically significant ($p=0.543$). CME found in 1 patient of Group 2.

Discussion:

Implantations of IC-IOL and SF-IOL are the mainstream operation methods in visual rehabilitation to treat aphakia in case of inadequate capsular support to hold an IOL in the posterior capsule and they avoid the need for aphakic spectacles or contact lenses. However choice of IOL in aphakia treatment is still debatable. There has been much discussion on the best method for secondary IOL implantation that offers the lowest complication rate and best possible visual rehabilitation over several years.¹⁴ Each of the available options has its own risks and complications, hence it is difficult to determine which is mostly suitable for the management of patients with inadequate capsular support. Thus, we conducted this study to compare the efficacy, safety and complexity between IC-IOL and SF-PCIOL implantations in correcting aphakia without sufficient capsular support.

Trans-scleral fixation of posterior chamber IOLs is an extremely technically demanding procedure with relatively high risk of intra-operative and post-operative complications and requires a large amount of dissection into the conjunctiva and the sclera.¹⁵ Reported complications associated with scleral fixated IOL, such as ciliary and choroidal body hemorrhage, vitreous prolapsed into the anterior chamber, retinal detachment, IOL dislocation, uveitis, and CME. Retro pupillary fixation of an iris-claw IOL has the advantages of true posterior chamber implantation, which results in a deeper anterior chamber and greater distance to the corneal endothelium. This procedure has a lower intraoperative and postoperative risk profile than anterior fixation.¹⁶

In our study, the mean surgical time taken for ICIOL was 27.47 ± 4.21 minutes and for SEIOL was 42.93 ± 5.23 minutes whereas it was 12 ± 4.71 minutes for ICIOL and 30.9 ± 5.81 minutes for SFIOL in a study by Mahajan et al¹⁷ and it is comparable to study done by Rashad et al¹⁸ which was 24.77 ± 4.8 and 67.09 ± 8.1 for ICIOL and SFIOL respectively. The mean surgical time was more in our study because of inclusion of anterior vitrectomy procedure, however this was found to be statistically significant same as the other studies.

In our study, 85% (17 patients) of ICIOL group and 80% (16 patients) of SFIOL group achieved BCVA greater than 6/18 at the end of 6 months and 1 patient in ICIOL group got less than 6/60 which was same as preoperative vision because of intraoperative

endothelial damage and was not related to IOL implantation. 2 patients in SFIOL group had vision 6/60. This is because of development of CME in 1 patient and due to angle recession glaucoma in one more patient. Two more patients in SFIOL group had BCVA less than 6/18, it was attributed to the IOL tilt, which resulted in astigmatism of 3 diopters. In a study done by Mahajan et al¹⁷ 73% eyes with ICIOL and 70% with SFIOL achieved BCVA >6/18.

On the first postoperative day, striate keratopathy and Anterior chamber reaction was present in almost all patients of both the groups. At 1 week, anterior chamber reaction and corneal edema in ICIOL group persisted in 8 and 7 patients respectively, whereas in SFIOL group it was seen in 7 and 5 patients. However corneal oedema persisted beyond 1 week in 1 patient of ICIOL because of intraoperative endothelial damage. Iritis and striate keratopathy was found to be more in our study as compared to Mahajan et al¹⁷, where they found striate keratopathy in 4 patients of ICIOL group and in 5 patients of SFIOL group. Iritis was seen in 4 patients of ICIOL and 6 patients of SFIOL group. Similarly fewer incidences were found in a study by Rashad et al.¹⁸

Pupil ovalization was observed in 4 patients (20%) of ICIOL group and it remained the same till the last follow up day and no such complication was seen in any patient in SFIOL group. This complication can occur due to asymmetrical and very tight fixation of haptic. It was less than a study conducted by Gonnerman.¹⁹ Baykara et al¹⁶ found persistent ovalization of pupil after posterior iris claw IOL implantation in 12.7% of eyes. In a study done by Rashad et al, pupil distortion was seen in 4 cases in ICIOL group and 3 cases in SFIOL group.¹⁸

One patient had dis enclavation of ICIOL at 1 month follow up and it was repositioned back and followed up. Similarly subluxation was noted in 1 patient in the study by Mahajan et al.¹⁷ Three cases of spontaneous dis enclavation of one haptic occurred in study by Forlini et al²⁰, a complication that has been reported previously. It is a known complication and is corrected by surgical experience. 1 patient in ICIOL group had decentered IOL, which was because enclavation was not equidistant from the centre of pupil and no decentration was noted in SFIOL group whereas in a study by Rashad et al¹⁸, decentration was noted in 2 patients of ICIOL group and 4 patients in SFIOL group.

Cystoid macular edema was found in 1 patient of SFIOL group and no patients in ICIOl group. It was treated with steroids. However at final follow up it was found to be the same. Hazar et al reported two (8.3%) cases of CME in the retro papillary iris-claw group and one (3.2%) eye with CME in the scleral fixation group.²¹ Samantha and colleagues reported nine (7.7%) cases of CME in the retro pupillary iris-claw group.²² The cause for higher incidence of CME in ICIOl group when compared to SFIOL group in these studies is probably because of extensive anterior vitrectomy in these cases.

Retinal detachment was noted in 1 patient in a study by Dadeya and colleagues.¹⁵ Retinal detachments are seen more in secondary implantation of SFIOL.²³ Because of shorter period of follow up, complications such as retinal detachment and infection were not noted in our study. Although our study has reached its aims, there were limitations like small sample size and short duration of follow up.

The visual outcome after retro pupillary Iris claw Intraocular lens implantation was found to be comparable with that of the Scleral fixated intraocular lens. However, ICIOl had a higher percentage of patients with better visual acuity. ICIOl also had a shorter surgical time period with favourable outcome. ICIOl has lesser rate of complications, most common was pupil ovalization which was harmless and others were also treatable. So ICIOl can be a promising alternative to SFIOL in aphakic eyes with inadequate posterior capsular support.

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