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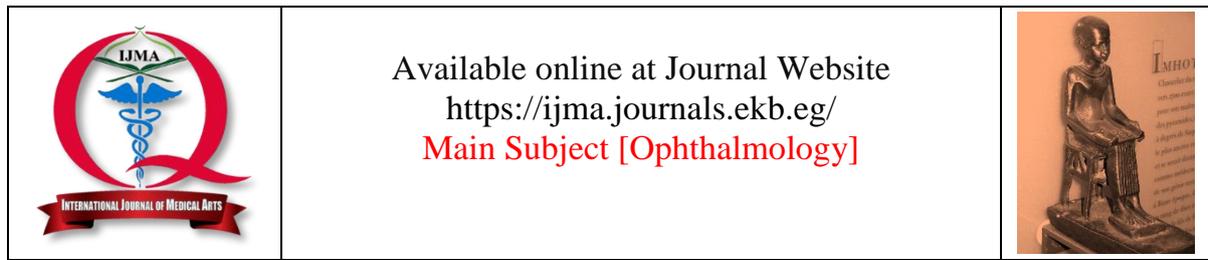


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## Original Article

# Safety and Efficacy of Retropupillary Fixation of Iris Claw Intraocular Lens versus Sutureless Scleral Fixated Intraocular Lens in the Management of Post Cataract Aphakia

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## ABSTRACT

### Article information

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**Background:** It is standard practice to implant a foldable, one-piece posterior chamber [PC] intraocular lens [IOL] into the capsular bag during uncomplicated cataract surgery. However, conditions like subluxated capsules, pseudo-exfoliation syndrome, and post-complicated cataract surgery can lead to aphakia without adequate capsular support.

**The aim of the work:** This study aims to evaluate the effectiveness of two intraocular lens [IOL] techniques for the treatment of aphakia: scleral fixation and iris claw fixation.

**Patients and Methods:** A prospective study of 40 eyes—20 were fixed with an iris claw IOL using the retropupillary technique and 20 were fixed with a PC IOL using the flanged scleral fixation technique.

**Results:** The most common indication for IOL implantation was posterior capsular rent [n=25, 65%]. Demographics and baseline factors were similar between groups. Uncorrected distance visual acuity significantly improved in both groups at 6 months [p>.001] with no difference at final follow-up. In the iris claw group, 25% developed ovalization. Excessive IOP occurred in 1% and 3% of scleral fixation and iris claw cases, respectively. Iris atrophy affected 30% of iris claw cases. Cystoid macular edema complicated 3 scleral fixation cases.

**Conclusion:** For aphakia, iris claw IOL fixation and scleral fixation provide good visual outcomes at 6 months with an acceptable safety profile.

**Keywords:** Aphakia; Flanged haptics; Scleral fixation; Iris claw.



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## INTRODUCTION

Intraocular lenses [IOLs] are most effective when implanted into a healthy posterior lens capsule that has adequate zonular support. Still, ophthalmic surgeons may encounter scenarios during cataract surgery where an unintentional, substantial tear in the lens capsule would eliminate the possibility of inserting the lens in the capsule and necessitate a different placement to achieve pseudophakia <sup>[1]</sup>.

The use of scleral-fixated IOLs, customized IOLs supported by the anterior chamber [AC] angle, or iris are among the surgical corrective approaches that have been detailed. The surgical repair of aphakia has made extensive use of scleral-fixated intraocular lenses [SFIOLs], which have proven to be highly effective. The conventional method for inserting an IOL has been suturing the SFIOL with non-absorbable threads <sup>[2]</sup>.

Implantation of an ICIOL, which stands for iris-claw-fixated anterior chamber, is still another option. Inadequate distance between the iris or corneal endothelial cells and the IOL was a problem with earlier models of iris-claw anterior chamber IOLs, which could cause damage to those tissues. A vaulted optic design was used in later generations of iris-claw-fixated anterior chamber IOLs to prevent iris chafing by creating enough space for aqueous flow between the IOL and the iris. The haptics are enclavated to the mid-peripheral iris stroma, and the lens was initially created for surgical correction of phakic myopic eyes, so it minimally interferes with the normal movement of the pupil. Reduced dispersion of iris pigment epithelium, a potential cause of chronic ocular inflammation <sup>[3]</sup>, is one benefit of this novel design. In a long-term comparison with Gabor's sutureless SFIOL placement technique, **Madhivanan et al.** <sup>[4]</sup> found that this method produced better results.

A novel method for sutureless intrascleral fixation of a PCIOL utilizing 27-gauge needles was detailed by **Yamane et al.** With this method, an IOL can be successfully fixed without the need for specialized tools, and the wound will close properly without leaking. The SFIOL approach, which includes a flange, has shown great promise in clinical settings and has been extensively used <sup>[5]</sup>.

So, this study aims to compare retropupillary fixation of an iris-claw intraocular lens versus Sutureless Scleral Fixated Intraocular Lens in the

Management of Post Cataract Aphakia without sufficient capsular support as regard to the surgical technique and the visual outcome.

## PATIENTS AND METHODS

This prospective interventional case series study included a total of 40 eyes of 40 patients of the age group 13-60 years attending at the Ophthalmology Department, Al-Azhar University Hospitals [New Damietta]. Approval of the ethical committee and a written informed consent from all the subjects were obtained. This study was conducted between March 2019 and April 2022.

**Inclusion criteria:** Patients with aphakia following complex cataract surgery, crystalline lens subluxation, or a second intervention in damaged eyes, with surgically corrected visual acuity of 4/60 or higher on the Snellen chart.

**Exclusion criteria:** Those who have undergone cataract surgery, have corneas that have not fully healed, as well as those who are aphakic and have posterior segment diseases such as cystoid macular edema, choroidal neovascular membrane, inadequate iris tissue, rubeosis iridis, or intractable glaucoma.

### Data collection

All patients underwent comprehensive ocular examinations, which included the following:

[A] Clear vision: We measured the CDVA and translated it to logMAR values.

[B] Examining the front segment using slit lamp biomicroscopy: 1] Cornea: Any signs of opacities, scars, keratic precipitates, or corneal edema were carefully investigated. 2] The anterior chamber was checked for any signs of inflammation, cells, or vitreous. We made sure that the depth was regular and that there were no anterior synechia. 3] A gonioscopy lens with three mirrors was used to assess the angle of the anterior chamber. The form, responsiveness, maximal dilatation, iridectomies, and presence of synechia of the iris and pupil were assessed. We took special care to inspect the areas surrounding the lens capsule, any remaining lens debris, and the front vitreous face.

[C] Evaluation of the fundus: slit lamp biomicroscopy with an auxiliary lens [+90 D], direct and indirect ophthalmoscopes, are utilized.

[D] To measure intraocular pressure before and after surgery, a Goldman applanation tonometer was used for tonometry.

[E] Autorefractometer results for keratometry.

[F] Biometry: We utilized an A-constant of 116.5 and the Sanders-Retzlaff-Krauff formula to determine the IOL power for retropupillary implantation, even though the manufacturer advised an A-constant of 115 for anterior chamber implantation site of the iris claw IOL.

[G] The subject gave their informed permission.

The implantation of IOLs was either performed as the first procedure with lens extraction or as a follow-up four weeks later. Under local anesthetic [a combination of lignocaine, bupivacain, and hylase injected into the peribulbar region], all cases were surgically treated. The exceptions to this rule were four patients who required sedation during the procedure and one who required general anesthesia.

The first group received topical drops five times a day for four weeks after surgery; these drops contained a combination of antibiotics and steroids.

Iris claw IOL [RP-ICIOL]: Vertical paracentesis at 9 o'clock and 3 o'clock, triamcinolone assisted anterior vitrectomy was performed before IOL insertion if required, acetylcholine chloride 1% [Miochol] was injected intracamerally, a 5.5-mm corneal incision was made at 12 o'clock position, sodium hyaluronate 1.0% [Healon] was instilled through the side port incision to maintain sufficient ACD for endothelial protection and to facilitate lens manipulation, the iris-claw IOL was then inserted upside down [with its convex surface placed posteriorly], rotated with to a horizontal position, and centered on the pupil, the optic of the reversed iris-claw IOL was held securely with a special forceps. The two haptics were then carefully positioned behind the iris, and the optic was moved slightly forward toward the back of the eye. This allowed the surgeon to see the haptic's claw configuration on the front of the eye. With the other hand, a long micro-spatula was inserted into the claw using a lateral paracentesis at 3 or 9 o'clock, depending on the surgeon's non-dominant hand.

To avoid postoperative pupillary obstruction, an appropriate iridectomy was performed, if not already present. In order to seal the corneal

wound, 10-0 nylon sutures were utilized. After the treatment was finished, the stromal hydration of the two paracenteses were performed to remove all ophthalmic viscosurgical device [OVD] material anterior to the intraocular lens [IOL].

Two milligrams of dexamethasone and twenty milligrams of gentamicin were administered sub-conjunctivally as part of GROUP II following the sutureless flanged SFIOL approach outlined by **Yamane et al.** [5].

At 4 o'clock and 10 o'clock meridians, 2 mm from the limbus, the conjunctival entrance points were indicated with a marker, 180° apart. In the anterior chamber, a foldable three-piece intraocular lens [IOL] Tecnis ZA9003 [Abbott Medical Optics, Santa Ana, CA, USA] and Sensar AR40e [Abbott Medical Optics] were initially implanted through a limbal or sclero-corneal tunnel after an appropriate vitrectomy, as previously stated.

To prevent injuring the ciliary body, a 27-gauge needle was inserted 2 millimeters from the limbus while maintaining it tangential to the iris plane, following the prior marking. To insert the leading haptic tip into the 27-G needle lumen, a 23-G end gripping forceps was used, which was introduced from a paracentesis.

Following Yamane's description, the haptic was externalized and a flange was created by heating the tip with a thermal cautery. The flange was subsequently attached intrasclerally. The trailing haptic was fixated by repeating the same approach at the 180° opposite meridian. A balanced salt solution was used to construct an anterior chamber after aspirating viscoelastic material.

After the procedure: At the end of the first week, the end of the first month, the end of the third month, and six months after surgery, patients were followed up with.

Every detail was double-checked: 1] Edema was checked on the cornea. 2] Anterior chamber: Flare or aqueous cells, which indicate an anterior chamber reaction, were checked for. Thirdly, the intraocular lens [IOL] was examined for tremulousness or stability at the conclusion of the six cardinal directions of eye movement by having the patient look in a new direction of gaze. Decentration includes checking for: a] vitreous hemorrhage, b] central macular edema, and c] retinal detachment in addition to

intraocular pressure, refraction, and visual acuity measurements.

**Statistical analysis:** All statistical analysis was done using the SPSS version 26 [IBM Corp., Armonk, NY., USA]. Continuous data were firstly examined for normality using the Shapiro–Wilk test. Continuous data were described as medians and IQR and absolute frequencies [N] with percentages [%] for categorical data. Categorical data were compared using the chi-square test. Continuous data were compared between study groups using the Mann-Whitney U-test. Additionally, within-group comparisons were done using the Friedman test and the post-hoc test comparison adjusted by Bonferroni's corrections was further evaluated by the Wilcoxon signed-rank test. P-values less than 0.05 were considered statistically significant.

## RESULTS

Data from 40 eyes of 40 patients satisfying the inclusion criteria were statistically analyzed. Retro pupillary iris claw IOL was fixated in 20 eyes [RP-IOL], and sutureless SFIOL was performed in 20 eyes [FSFT]. The iris claw and SFIOL groups were comparable in terms of demographics and baseline characteristics [Table 1].

In RP-IOL, the duration ranged from 20 to 60 min with a median of 28.5 min [IQR=8], and about 15 patients [75%] were operated within 25 to 35 minutes and 1 patient [5%] were Operated within 60 minutes because the iris claw IOL dropped during implantation and pars plana vitrectomy [PPV] done by a posterior segment surgeon at the same sitting and the same lens was re implanted again. In FSFT, ranged from 30 to 60 min with a median of 40.5 min [P-Value is < 0.001]. Comparing both groups, Iris claw lens implantation consumed less time than SFIOL implantation.

One case of dropped iris claw IOL [Figure 1] and pars plana vitrectomy [PPV] by a posterior segment surgeon was done at the same sitting and the same lens was re implanted again so the total time of operation was [60 min]. Minor intra-operative bleeding had also occurred in 3 cases of iris claw IOL.

In group II [FSFT], intraoperative complications were mainly related to IOL haptic manipulation. Kinking of haptic occurred in 2 cases; breakage occurred in one case, slippage occurred in two

cases. Intraocular bleeding occurred in one case during sclerotomy.

## Refractive outcomes

In RP-IOL the UCVA was improved from 1 Log Mar preoperative to 0.6 Log Mar postoperative] at 1<sup>st</sup> POD [P < 0.001] and improved further to 0.40 log MAR [IQR = 0.2–0.4 log MAR] at 1 month [P < 0.001 compared to baseline and was maintained at 3 and 6 months follow up.

In FSFT the UCVA was improved from 0.9 Log Mar preoperative to 0.5 Log Mar at 1<sup>st</sup> POD [p value < 0.001] then improved to 0.42 logMAR which maintained at 3 and 6 months follow up [Figure 2].

As regards postoperative BCVA, we found that it was improved in both groups [Figure 2]. with no significant difference between them at 1st day, 1st week, 1st month, and at 6 months [p value= 0.6, 0.8, 0.4, and 0.5 respectively]. In RP-IOL the BCVA was improved from 0.55 LogMar preoperative to 0.33, 0.20 LogMar at 1, 6 months postoperative [p value < 0.003]. In FSFT the BCVA was improved from 0.56 LogMar preoperative to 0.32, 0.21 LogMar at 1, 6 months postoperative [p value < 0.004 and 0.008]. Also, we compared between all the follow-up periods in each group using the Friedman test and it was significant [p value < 0.001].

Figure [3] shows that CDVA was higher after surgery than before surgery in both groups, with the FSFI group exhibiting somewhat quicker improvement and the two groups reaching almost identical levels at 6 months.

**Spherical equivalence:** The goal refraction in our work was emmetropia or a slight residual myopia. In cases with high myopia the goal refraction was adapted to the refraction of the fellow eye. Mean preoperative SE refraction for RP-ICIOL group was 10 D [IQR=4D] this refraction decreased to a mean SE of -0.12 [IQR=2.1D] while for FSFT SE decreased from 8 D [IQR=5D] to -0.87 [IQR=1.9D]. FSFT group is more myopic in result may be due to its relative posterior position 2 mm from the limbus

**Post-operative IOP** [Figure 4]: As regards postoperative IOP, we found that no significant difference between groups at 1<sup>st</sup> day, 1<sup>st</sup> week, 1st month and at 6 months [p value= 0.8, 1, 0.3 and 0.5 respectively]. By comparing the follow-up

periods, we found no significant difference between the preoperative IOP and the postoperative IOP [p value > 0.05].

### Post-operative complications

During the trial, 9 [45%] of the RP-ICL and 10 [50%] of the FSFT groups were able to undergo the operation without any difficulties, as shown in Table 3. Eyes with RP-IOL [n=3] that were treated with topical antiglaucoma drugs for one month showed a slightly higher incidence of transient rise of intraocular pressure [IOP].

Two cases of RP-IOL were found to have post-operative wound leaking; one of these cases required restitching due to hypotony and shallow AC.

Figure 5 shows that the most common side effect in the iris claw group was ovalization of the pupil. Third case with FSFT observed corneal edema There was one instance of vitreous

hemorrhage in RP-IOL [5% of patients], while two cases of moderate vitreous hemorrhage in FSFT [10.0% of patients] were observed until they resolved on their own, with a maximum follow-up time of one month. Our viteroretinal unit performed PPV with silicon oil injection after one month, and only one case [5% of FSFTs] had RD.

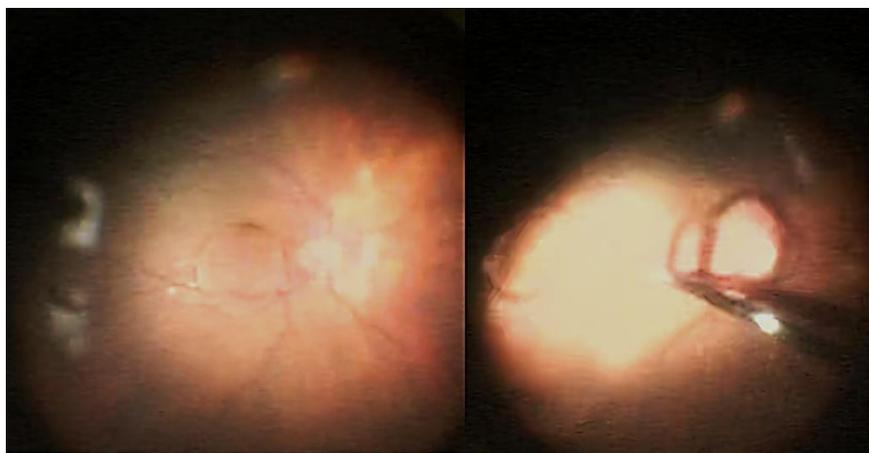
Optical coherence tomography revealed the presence of cystoid macular edema in 1 instance [5% of the total] involving RP-IOL and 3 cases [15%] including FSFT throughout the follow-up period. In other cases, patients experienced clinically unexplained visual loss. There was one case of IOL Decentration in RP-IOL [5% of cases] and two cases in FSFT [ 10% of cases]. Only after complete mydriasis in patients with regular pupils was IOL Decentration able to be measured. The presence of substantial astigmatism that is absent at the corneal level is indicative of IOL tilting. Figure 6 shows that there are two 10 percent incidences of IOL tilt in FSFT.

**Table [1]:** Demographic data of the patients

Variables		RP-IOL	FSFT
Age [years]		61 [9]	62 [12]
Gender [n %]	Male	13 [65%]	12 [60%]
	Female	7 [35%]	8 [40%]
Side [n %]	Right	12 [60%]	9 [45%]
	Left	8 [40%]	11 [55%]
UCVA [Log Mar]		1 [0.8]	0.9 [1.2]
BCVA [log Mar]		0.5 [0.2]	0.5 [0.1]
SE		+10 [4]	+8 [5]
IOP [mmHg]		15 [3]	14 [3]

**Table [2]:** Operative time

Operative time	RP-IOL	FSFT	P value <sup>a</sup>
Median and [IQR].	28.5 [8]	40.5 [6]	<b>0.001 *</b>
Range	20-60	30-60	



**Figure [1]:** Dropped Iris claw IOL during implantation

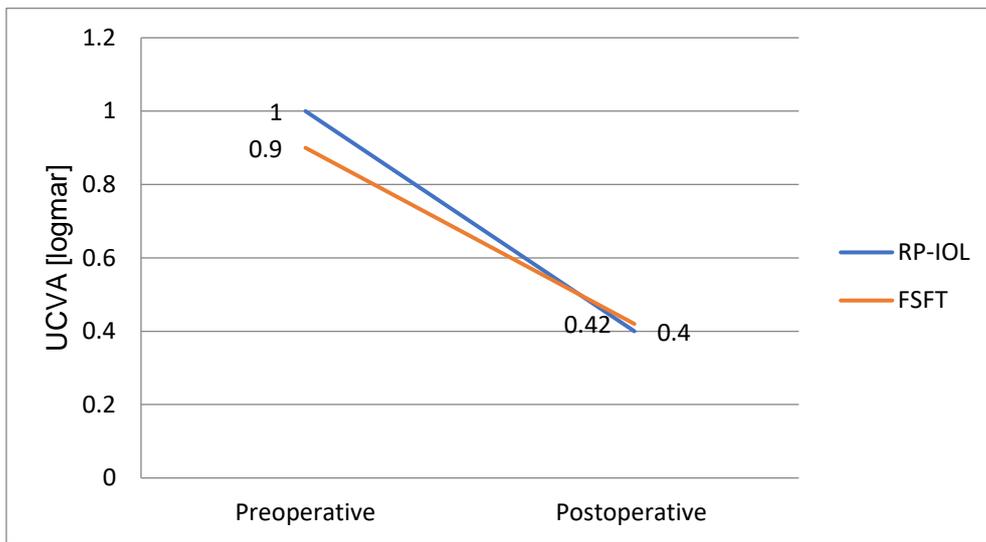


Figure [2]: Line chart between groups according to UCVA

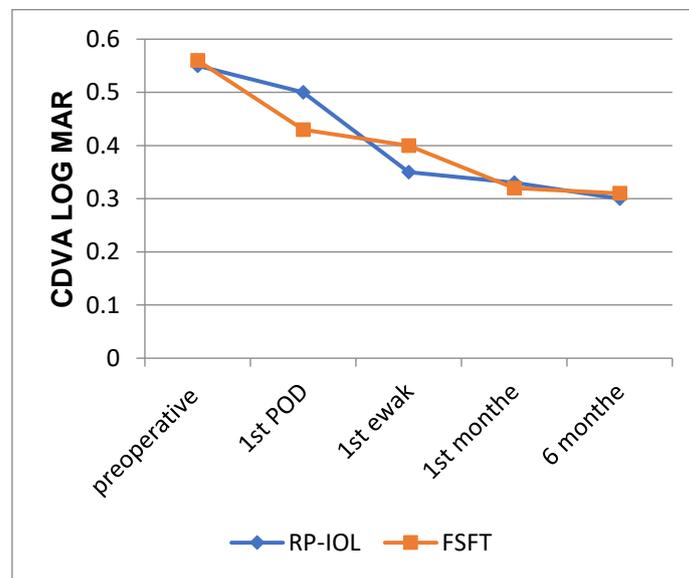


Fig [3]. The line chart comparing the two groups according to CDVA

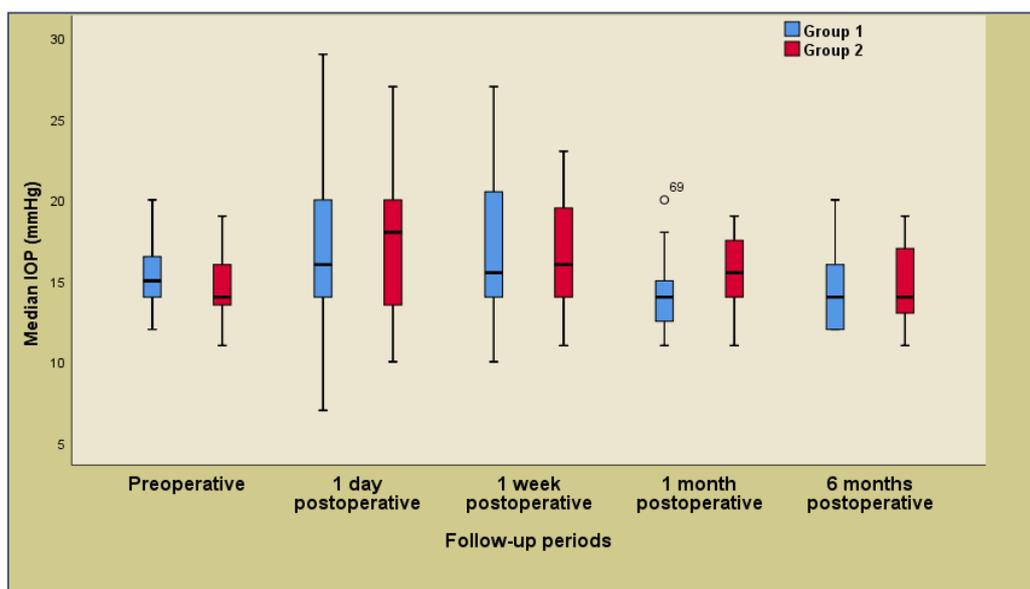
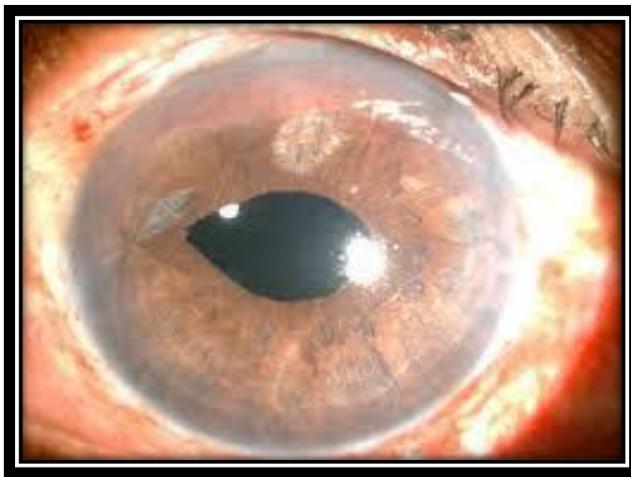
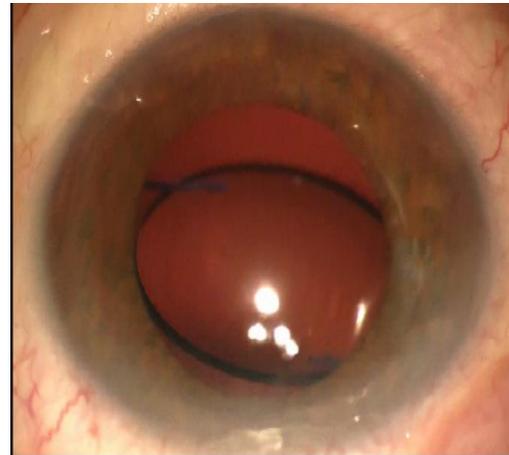
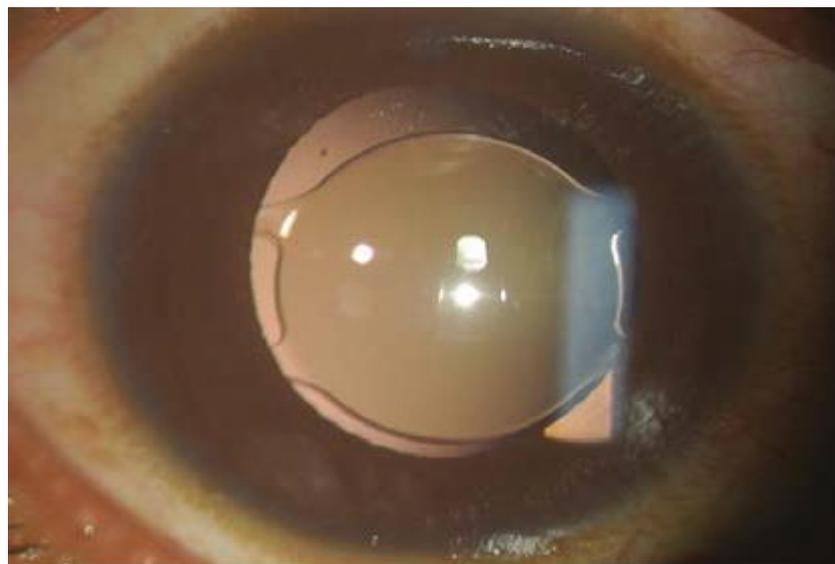


Fig [4] Box plot showing the change in the median of IOP between the two groups over the follow-up periods

**Table [3]:** Complications of the studied patients

		RP-IOL	FSFT
<b>Early Complications, n [%]</b>	No complications	9 [45%]	10 [50%]
	Increase intraocular pressure	3 [15%]	1 [5%]
	Hypotony	2 [10%]	1 [5%]
	Anterior chamber reaction	3 [15%]	2 [10%]
	Corneal oedema	2 [10%]	3 [15%]
	Pupil distortion	5 [25%]	1 [5%]
	Vitreous hemorrhage	1 [5%]	2 [10%]
	Wound leak	2 [10%]	0 [0%]
<b>Late Complications, n [%]</b>	Cystoid macular edema	1 [5%]	3 [15%]
	Decentration	1 [5%]	2 [10%]
	Tilt	0 [0%]	2 [10%]
	Retinal detachment	0 [0%]	1 [5%]
	Iris atrophy	6 [30%]	0 [0%]
	Disenclavtion or Dislocation of the IOL	2 [10%]	2 [10%]

**Figure [5]:** Pupil ovalization after RPIC IOL implantation**Figure [6]:** Tilted Scleral fixated IOL**Figure [7]:** Good well centered iris claw IOL

## DISCUSSION

Many methods and alternatives have been developed to address the issues associated with secondary IOL implantations because most ophthalmologists dread leaving patients aphakic.

Our goal in doing this research is to evaluate the two approaches to aphakia treatment that have been previously described by **Yamani et al.** one uses an iris claw IOL that is attached to the back of the eye, and the other uses a scleral fixed IOL.

We compared intraoperative and post-operative problems to determine safety, and visual acuity, refractive outcomes, and spherical equivalency to measure effectiveness. Forty eyes from forty patients were chosen, with twenty eyes from each procedure, based on inclusion criteria. There were two groups of patients in our study: one received RP-ICIOLs, and the other received 3-piece IOLs implanted using the flanged suture less SFIOL procedure [the FSFT group].

Fifteen ladies [RP-ICIOL 7-8] and twenty-five guys [RP-ICIOL 13 & FSFT group 12] were a part of our study. There are more men than women participating in this study. The fact that men are more likely to suffer from work-related injuries and are often the breadwinners in their families explains why they seek out visual rehabilitation services first.

Inadequate capsular support for intraocular lens [IOL] implantation was the result in 26 out of 68 eyes [65%] of these patients' cataract surgeries due to unintentional posterior capsular rent [PCR]. As a result of lens subluxation, seven eyes [17.5%] became aphakic following I.C.C.E. Two cases of intraocular lens subluxation occurred in 5% of cases, and five eyes [12.5%] had traumatic cataracts with posterior capsule tears that prevented primary implantation.

In the study conducted by **Kelkar et al.** [4], the most prevalent reason for secondary IOL implantation was posterior capsular rent [n = 51, 51% of the eyes], followed by subluxated IOL removal [n = 31 eyes, 27% of the eyes], displaced cataract [n = 19, 17% of the eyes], and dislocated IOL [n = 14, 12% of the eyes].

When comparing the RP-ICIOL group to the sutured scleral fixed IOL group, **Aalok** [6] found that the median surgical time was 28.5±8 minutes, ranging from 25 to 35 minutes, which is similar to the time it took for the majority of cases in the RP-ICIOL group.

The average amount of time it took to fix the scleral lens in this study was 40.5±5 minutes, which is longer than the 35.6 ± 14.0 minutes recorded in a study by **Muth et al.** [7] for patients with aphakia. On the other hand, **Park et al.** [8] reported a mean surgical time of 20 ± 4.6 minutes for flanged IOL fixation, which is shorter than our time. We speculate that this is because they used flanged IOL fixation in cases of dislocated IOLs following pars plana vitrectomy, eliminating the need for anterior vitrectomy.

In certain situations, the patient may already have a trifocal intraocular lens [IOL] implanted within the eye, eliminating the need for a fresh IOL injection. Additionally, they may be able to introduce the haptic of the IOL into the vitreous cavity through the lumen of the needle, making the externalization step much easier and taking less time. Iris claw fixation appears to be a more time efficient method than flanged scleral fixation, taking only 28 minutes as opposed to 40 minutes for the flanged scleral fixated IOL. However, no prior research has directly compared these two techniques' operating times.

Both methods considerably enhance both best-corrected and uncorrected visual acuities. There was a significant improvement in UCVA from 1.0 Log Mar preoperative to 0.40 Log Mar postoperative in the RP-ICIOL group [p value < 0.001] and in BCVA from 0.55 Log Mar preoperative to 0.33, 0.30 Log Mar at 1, and 6 months postoperative [p value < 0.003]. We observed that this matched the results reported in the literature for RP-ICIOL implantation. The final mean CDVA improved from 1.36 ± 0.64 logMAR preoperatively to 0.36 ± 0.32 at 1 year follow up, according to a study by **Kelkar et al.** [9], which examined 104 eyes of 102 patients undergoing primary retrofixation of iris claw IOL with IVTA.

In aphakia or when a dislocated IOL is removed in conjunction with secondary iris claw IOL implantation, **Forlini *et al.*** <sup>[10]</sup> also discovered that the mean postoperative LogMAR was 0.3.

**Mansoori *et al.*** <sup>[11]</sup> conducted a large retrospective study with 122 participants, and they found that the final mean CDVA improved dramatically from  $1.36 \pm 0.52$  log MAR before surgery to  $0.5 \pm 0.42$  at the last follow-up visit after surgery. Statistical significance was not discovered between the two groups, despite the fact that our results were superior than the aforementioned research.

The FSFT group showed an improvement in UCVA, going from 0.9 LogMar before surgery to 0.42 LogMar after [p value < 0.001].

The results of UCVA improving from  $1.23 \pm 0.63$  to  $0.50 \pm 0.45$  logMAR were initially reported by **Yamane *et al.*** <sup>[5]</sup> in a large-scale study [n=100] following FISF. The results of a different study conducted by **Abd-Elhafez *et al.*** <sup>[12]</sup> were comparable; the average UCVA decimal before surgery increased significantly from  $0.101 \pm 0.06$  to  $0.237 \pm 0.10$  after surgery, and the difference between the two was statistically significant.

Over the course of the follow-up period, our BCVA similarly demonstrated improvement, going from 0.56 LogMar before surgery to 0.32 and 0.21 Log Mar at 1 and 6 months post-operatively [p values < 0.004 and 0.008, respectively].

**Yamane *et al.*** <sup>[5]</sup> found an improvement in their huge study, going from  $0.25 \pm 0.49$  to  $0.04 \pm 0.25$ . Their final BCVA might be better than ours because of his extensive expertise with these techniques, and his initial BCVA was better than ours as well.

At the three-month follow-up, **Ishikawa *et al.*** <sup>[13]</sup> found an improvement from  $0.51 \pm 0.69$  to  $0.16 \pm 0.28$  log Mar. The RP-ICIOL group had a lower BCVA than the FISF group at 1 day postoperatively [0.5 vs. 0.43 log Mar], but this started to recover at 1 week after 1 month [0.35 vs. 0.40], and there were no differences at the last follow-up.

The correction of surgically caused astigmatism, which is a consequence of suturing a big wound, begins with the removal of the stitch, which typically takes place between one week and one month after surgery. Iritis may also play a role in this delay.

In terms of refractive result, both the RP-ICIOL and FSFT methods of IOL fixation for aphakia treatment are beneficial; patients' visual acuity is significantly improved in both groups, with around 75% and 70% of the respective groups reaching 0.3 log Mar or better.

The median intraocular pressure [IOP] was higher one day after surgery and initially lower with slit greater elevation on FSFT [18 vs. 14 preoperatively and 16 vs. 15 for the RP-ICIOL group, respectively].

In their first study using the **Yamane *et al.***'s approach, **Kelkar *et al.*** <sup>[14]</sup> found that the average intraoperative intraocular pressure was  $17.6 \pm 7.1$  mmHg before the procedure. At one week, it increased to  $21.2 \pm 9.1$  mm Hg [P = 0.06], but it reverted to normal levels at six weeks' follow-up [ $14.9 \pm 4.2$ , P = 0.16].

Comparing FSFT with RP-ICIOL, another study by **Kelkar *et al.*** <sup>[4]</sup> found similar results. Eyes using SFIOL, which were treated with topical antiglaucoma drugs for one month, showed a slightly higher transitory rise of intraocular pressure [IOP]. At the end of the six weeks, not a single one of these individuals needed any more medication. Three eyes [15%] in the RP-ICIOL group and one eye [5%] in the FSFT group] developed ocular hypertension among our research subjects.

Conservative treatment, including topical  $\beta$ -blockers and carbonic anhydrase inhibitors, alleviated the transitory elevation of intraocular pressure [IOP] within a month. Hypotony is observed in three cases in our investigation. 2 [10%] in the RP-ICIOL group and 1 5% in the FSFT group; one patient in the RP-ICIOL group had to have further surgery to repair a leaking wound.

According to **Mansoori *et al.*** <sup>[11]</sup>, nine eyes [7.4% of the total] experienced transitory

postoperative hypotony whereas two eyes [1.6%] experienced chronic hypotony caused by choroidal separation and needed oral steroids. According to **Yamane *et al.*** [5], two eyes experienced hypotony [ $<6$  mmHg] on the first day after surgery due to drainage from the sclerocorneal incision used to remove the intraocular lens [IOL] or the sclerotomy used for vitrectomy. In these eyes, the intraocular pressure [IOP] returned to normal devoid of any form of therapy.

Two patients [10%] in the iris claw group experienced wound leaks in the early postoperative period; one of these patients required resuturing, so no complications were found in the FSFT group. All instances respond well to topical steroids after 1 week with no major complications; however, 3 eyes [15.0%] in the iris claw group and 2 eyes [10.0%] in the scleral fixation group experienced a mild anterior chamber reaction, which may have been caused by excessive manipulation during the procedure.

Iritis, a condition where the iris-claw lens becomes stuck in the eye, might develop in the time after surgery. Although this complexity has been found at varying frequency in most investigations, it is as low as 0% in one, 3% in another, and 6% in the most recent [15, 16].

In their study, **Sumitha *et al.*** [17] after first treatment with topical antibacterial steroids, 23 out of 36 eyes [63.9% of the total] had a marked anterior chamber reaction that resolved with further follow-up visits. This discrepancy in reported AC reactions is due to the fact that studies identify AC reactions at varying grades; some use +2 and others use +3.

**Abd-Elhafez *et al.*** [12] also described one incidence of AC reaction. Two patients in the RP-ICIOL group [10%] and three patients in the FSFT group [15%] experience corneal edema on the first postoperative day. This disparity may be attributable to the comparatively lengthy operating time and numerous intraocular manipulations performed on the FSFT group.

Seven eyes [19.4%] experienced corneal stromal edema on the first day after surgery, according to **Sumitha *et al.*** [17]. In their study, **Yamane *et al.*** [5] detail a single instance of

temporary ocular edema. The incidence of ovalization of the pupil ranges from 2% to 25%, as documented in practically all studies on iris claw IOLs [18]. This was observed in one eye of the FSFT group [5% of the time] and five eyes of the RP-ICIOL group [25%] in our study.

Twenty percent of eyes that had the iris claw IOL had ovalized pupils, which is similar to the findings described by **Kelkar *et al.*** [4]. Still, they see pupillary ovalization often, which they attribute to entrapment of the iris stroma in the claw of the IOL haptic, which causes localized tissue atrophy and disfigurement of the pupil, even though they've been implanting iris claw IOLs for five years and have avoided excessive enclavation of the iris tissue into the IOL haptic. Additionally, the FSFT group does not record any cases.

Following retropupillary implantation, this problem was observed in 32.0 percent of patients by **Schallenberg *et al.*** [18]. On the other hand, for most cases of pupillary distortion, no intervention is necessary. A round pupil using ICIOLs may surely be achievable with surgical knowledge and ability.

Two eyes [10.0% of the total] in the scleral fixation group experienced postoperative vitreous hemorrhage, compared to one occurrence [5% of the total] in the iris claw group. Within a month, the minor vitreous hemorrhage had healed entirely. In their study of FSFT, **Abd-Elhafez *et al.*** [12] found 2 cases of vitreous hemorrhage [10.0%], whereas **Yamane *et al.*** [5] found 5 cases of vitreous hemorrhage [5%]. **Kelkar *et al.*** [4] found that one patient in the iris claw group experienced vitreous hemorrhage, while one patient in the SFIOL group had persistent postoperative vitreous hemorrhage. Both groups underwent pars plana vitrectomy at 6 weeks after surgery, and the patient in the former group had a remarkable visual recovery with a UCDVA of 0.3 log MAR.

After cataract surgery, CME is one of the main reasons why CDVA drops. One patient [5.0%] undergoing iris claw surgery and three patients [15.0%] undergoing scleral fixation had CME in this study. In the course of the procedure, these individuals had substantial anterior vitrectomy. Optical coherence tomography

[OCT macula] confirmed the issue, and after an initial recovery, they saw a gradual worsening of their vision. Topical treatment with steroidal and non-steroidal anti-inflammatory eye drops, as well as oral Diamox, was effective in managing the condition.

According to **Kim et al.** <sup>[20]</sup>, one eye [4% of the RP-IOL group] and two eyes [16%] in the FSFT group experienced CME. An injection of posterior sub tenon triamcinolone acetonide helped one patient in the FSFT group, and topical non-steroidal anti-inflammatory medications helped the majority of the CME.

Cystoid macular edema [n = 3] was described in the series by **Kelkar et al.** <sup>[4]</sup>. 2.22 percent of the cases involved the iris claw, while 2.5 percent involved FSFT.

In the study by **Yamane et al.** <sup>[5]</sup>, one patient [1% of the total] had cystoid macular edema at 6 months and was treated with non-steroidal anti-inflammatory eye drops, while three cases of CME were reported by **Abd-Elhafez et al.** <sup>[12]</sup>; two cases [10.0% of the total] in the scleral fixation group and one case [5.0%] in the retropupillary iris claw group experienced intraocular lens decentration and tilt.

Nevertheless, decentration was minor to moderate in most instances and does not impact the visual result. It has been observed that decomposition of ICIOL occurs occasionally, with a frequency of up to 7%. Nevertheless, as long as the optic covers the visual axis, no intervention is necessary.

The disenclavation of one haptic of the iris-claw lens necessitated retucking of the intraocular lens [IOL] in two patients [or 10% of the total], which could have happened as a result of trauma, insufficient iris tissue gripping by the lens haptic, or unsuccessful enclavation.

Very much like our outcome, **Choi et al.** <sup>[21]</sup>, during the 2-year follow-up period, 9.7% of the eyes needed further surgeries to repair partially disenclavated RP-IOLs. Despite this, it is not possible to directly compare this report to others due to certain restrictions.

No iris atrophy was observed in the FSFT group during our study. However, six cases [30.0%] in the RP-ICIOL group had varying degrees of iris atrophy at the enclavation site. Fortunately, none of these cases affected the final visual outcome because the patients in this group did not experience any related uncomfortable symptoms like photophobia, glare, or multiplopia. Ischemic damage or mechanical strain on the iris sphincter muscles around the enclavation site could be the cause of iris atrophy.

In terms of how long atrophy can last; after a long-term follow-up period of seven years, **Forlini et al.** <sup>[10]</sup> found that iris atrophy occurred in only 5.0% of patients. Iris atrophy was noted in 59% of disenclavation cases, and disenclavation happened after face washing in 23% of cases.

In a study comparing iris claw with flanged scleral fixated IOL, **Kim et al.** <sup>[20]</sup> found that three eyes [13% of the total] experienced iris atrophy when the IOLs were dislocated. In a prior study, he found that nine percent of 225 eyes [9.8% of the total] experienced a single haptic dislocation at 90 days after the operation. disenclavation seems to be more common in patients with iris atrophy.

One eye in ten cases with FSFT presents with an IOL dislocation; this eye requires PPV and re-fixation of the IOL; the other eye presents with an IOL that has slipped from the scleral and requires re-fixation; both cases may be the result of insufficient flange size. Dislocation rates reported in published outcome data for FISHF of secondary IOLs range from 0% <sup>[5]</sup> to 29% <sup>[22]</sup> in a series of procedures performed in diabetic patients; however, all of these cases occurred in a subgroup using a 27G needle, and no cases were reported in a 30 gauge [G] ultrathin wall needle group, similar to **Yamane et al.** <sup>[5]</sup>'s findings. The fact that diabetes can change the orientation of collagen fibers and the rigidity of the scleral sacs could explain this high figure.

Just like us, even though 30 gauge [G] ultrathin wall needles are not accessible in our country, **Abdel Hafez et al.** <sup>[12]</sup> reported 2 cases [10.0%] of spontaneous IOL dislocation using a 27G needle. On the other hand, **Kelkar et al.**

<sup>[4]</sup> found no incidences of IOL dislocation when they used a 27G needle.

The RP-ICIOIOL group did not experience any cases of retinal detachment; however, the FSFT group had one case of RD one month after surgery; the patient was referred to the vitreoretinal unit, where they underwent vitrectomy with silicon oil injection and achieved good visual acuity by the end of the follow-up period.

One case of retinal detachment in the iris claw group following pars plana vitrectomy with endolaser and 1000 cs silicon oil injection was reported by **Kelkar et al.** <sup>[4]</sup>. FSFT group did not have any recorded incidences of RD, but no group in the study by **Kim et al.** <sup>[20]</sup> did either. After retropupillary, the incidence of retinal detachment has been recorded as low as 0% and as high as 3% <sup>[18]</sup>. Although **Yamane et al.** <sup>[5]</sup> and **Abdel Hafez et al.** <sup>[12]</sup> did not record any cases of RD in their research, **Iglicki et al.** <sup>[22]</sup> reported one incidence of RD in cases operated with the 27G technique. However, they note that this case may not have been related to the surgery or the surgeon's learning curve. So, it could just be a coincidence.

In sum: Our study's results suggest that both sutureless SFIOL employing flange and iris claw IOL fixation are good surgical solutions for aphakia correction. At one month, the results are visible, and they continue to be so until the six-month follow-up. We think that the retropupillary iris-claw IOL is a great surgical option for patients with aphakia and inadequate capsular support because it is cost-effective, offers good visual rehabilitation, has a short learning curve, and requires less surgical time. The complication rates are acceptable, but a significant proportion of eyes that receive these IOLs experience ovalization of the pupil. While FSFT has the benefits of not requiring sutures and not costing more than traditional scleral fixation. One disadvantage of scleral-fixed IOLs is the difficulty in learning the double-needle technique for implantation, especially the part about inserting the haptic into the needle's lumen. Another problem is the restricted variety of IOLs that are available. It is related with greater safety in the early

postoperative period and, once learned, can lead to improved visual outcomes.

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