Original Article

Comparison of flanged intrascleral intraocular lens fixation versus iris claw intraocular lens fixation: A retrospective study

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Purpose: To compare the visual outcome and complications of retropupillary fixated iris claw intraocular lens (IOL) and sutureless intrascleral IOL fixation using the flanged fixation technique at 1 year. **Methods:** In this retrospective study, eyes that underwent either iris claw or flanged SFIOL from January 2016 to July 2017 with a minimum of 1-year follow-up were enrolled. Improvement in visual acuity, intraocular pressure measurements, endothelial cell count, central macular thickness, and complications were compared between and within groups at 6 weeks, 3 months, and 1 year postoperatively. **Results:** Data from 150 eyes were analyzed (n = 90 in the iris claw group and n = 60 in the flanged SFIOL group). Posterior capsular rent was the most common indication for IOL implantation (n = 51, 34%). The iris claw and SFIOL groups were comparable in terms of demographics and baseline characteristics. There was significant improvement in uncorrected distance visual acuity (UCDVA) at 6 weeks in both groups (P = 0.77), and at 1 year, the UCDVA was comparable between groups (0.36 ± 0.32 in the iris claw group and 0.30 ± 0.28 in the SFIOL, P = 0.75). Transient elevation of intraocular pressure was seen slightly more in eyes with SFIOL (17%), while ovalization of the pupil was the main sequelae seen in the iris claw group (20%). **Conclusion:** Both iris claw IOL fixation and SFIOL using flange are viable options for surgical correction of aphakia. Visual outcomes are excellent at 6 weeks and are maintained till 1-year follow-up, and complication rates are acceptably low, although ovalization of pupil is common with iris claw IOLs.

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Phacoemulsification with intraocular lens (IOL) implantation has become the standard of care for cataract surgery globally.[1] However, successful outcomes are mainly dependent on implantation of the IOL in the capsular bag which ensures centration of the lens and good visual outcomes. Damage to the capsular bag during surgery, reported to occur in approximately 1%–3% cases,[2,3] leads to difficulties in placement of the IOL in the bag. Occasionally, rupture of the posterior lens capsule and vitreous loss during surgery do not allow implantation of the IOL in the residual capsular bag or ciliary sulcus leading the surgeon to explore alternative techniques of IOL placement. These techniques are also required in cases with subluxated and dislocated lenses previously placed with IOLs due to various causes such as trauma, pseudoexfoliation, and other causes of zonular damage.

Alternative techniques for placement of IOLs in cases with inadequate capsular support include anterior chamber IOLs, iris-fixated IOLs which can be placed either in front or behind the pupil, and scleral-fixated IOLs.[4-6] Scleral-fixated IOLs (SFIOLs) are probably the most commonly used in this scenario and the technique has evolved tremendously over the past decade. Most surgeons have shifted from sutured SFIOLs to using sutureless techniques which yield equally good results even on the long-term and have a shorter learning curve.[5] Although sutureless SFIOL was proposed by Gabor and Pavlidis a decade ago,[7] followed by glued IOL by Kumar and Agarwal,[8] the sutureless SFIOL technique with flange recently described by Yamane *et al.* has been widely adopted in clinical settings with excellent results.[9]

Retropupillary fixation of iris claw lenses has also been used in surgical management of aphakia with good results.[10-12] Recently, Madhivanan *et al.* reported good outcomes using this technique compared to Gabor's technique of sutureless SFIOL placement over the long-term.[13] There are not many studies that directly compare outcomes of retropupillary iris claw IOL fixation with sutureless SFIOL techniques. Given the widespread use of Yamane's technique for SFIOL placement, it is imperative that we compare the outcomes of this technique with retropupillary iris claw IOL placement in the same setting. In this study, we compare the indications and outcomes of these two techniques of IOL placement in the surgical correction of aphakia.

Methods

This retrospective study was approved by the local Institutional Ethics Committee and adhered to the tenets of

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the Declaration of Helsinki. Informed consent was obtained from all patients before any surgical procedure. Patients who underwent iris claw IOL implantation and SFIOL using the Yamane's flanged technique either as a primary or secondary procedure from January 2016 to July 2017 with a minimum of 1-year follow-up were included in the study after retrieving their medical case records. Baseline demographic data such as age, sex, and operated eye were noted. Preoperative characteristics such as cause of aphakia (post cataract or post trauma), previous surgical procedure if any, and lens status at first presentation to the clinic (namely, aphakia, subluxated or dislocated cataract, subluxated or dislocated IOL) were recorded. Preexisting ocular pathology, the technique of IOL implantation, and postoperative complications were also noted.

All patients underwent comprehensive ophthalmic evaluation including uncorrected distance visual acuity (UCDVA), best-corrected distance visual acuity, intraocular pressure (IOP) assessment using Goldman applanation tonometry, slit lamp examination, and fundus examination preoperatively and at 6 weeks, 3 months, and 1 year postoperatively [Figs. 1 and 2]. Noncontact specular microscopy (SP-1P; Topcon, Japan) was done at all visits to determine corneal endothelial cell counts. Optical coherence tomography (OCT) (DRI OCT 1; Topcon) for macular status was also done preoperatively in patients with clear media and in all patients postoperatively at 6 weeks and 1 year. Ovalization of the pupil was noted when the pupil appeared oval in shape along the axis of the placed IOL. Optical biometry was performed using the IOLMaster 500 apparatus (Carl Zeiss Meditec, USA), and SRK-T formula was used for IOL power calculations. Whenever IOLMaster readings were not obtained or unreliable, immersion biometry was used. The target refraction in all cases was − 0.50 diopters. Patients with visually significant coexistent pathology like corneal scars, retinal detachment, and glaucomatous optic atrophy were excluded. The choice of IOL placement was at the operating surgeons' discretion. Similarly, the choice of implanting the IOL at the time of the primary procedure (i.e., during cataract surgery or vitrectomy) or a secondary procedure at a later date was also decided by the operating surgeon.

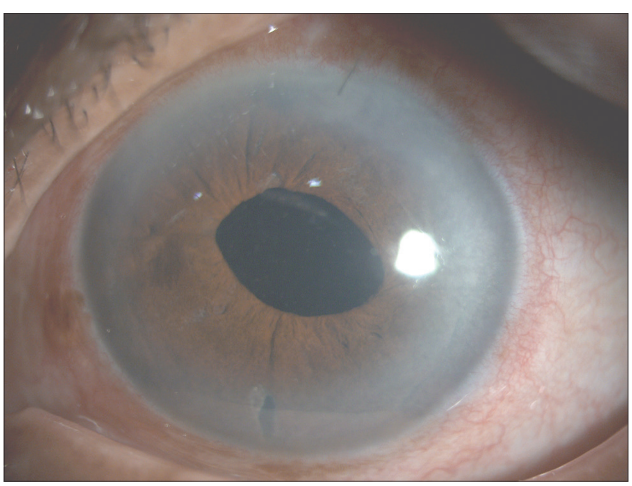

Figure 1: Six weeks postop photograph of retropupillary iris claw IOL fixation patient

Surgical technique

All cases were operated under peribulbar anesthesia by a single surgeon (ASK). All cases of phacoemulsification which were under topical anesthesia received peribulbar anesthesia when performing SFIOL or iris claw IOL fixation.

Retropupillary iris claw fixation technique was similar to that described previously[14] [Video Clip 1]. Briefly, a 5.2-mm sclera-corneal tunnel incision was made, centered at 12'o clock and two paracentesis incisions were made at 3'o clock and 9' o clock positions. In cases with posterior dislocation of lenticular matter or IOL, a 23-G complete pars plana vitrectomy was performed (CONSTELLATION; Alcon, USA). Following induction of posterior vitreous detachment, vitrectomy was completed followed by removal of the dislocated material using a phaco-fragmatome through a 20-G port which was sutured at the end of procedure. In other cases, only anterior vitrectomy was done. After adequate vitrectomy, intracameral pilocarpine 0.1 cc was injected to constrict the pupil followed by placement of the iris claw IOL (Excelens®; Excel Optics Pvt. Ltd., Chennai, India) into the anterior chamber. Holding the optic with a lens forceps, one haptic was tilted down and pushed under the iris with gentle manipulation. Simultaneously, a Sinsky hook was passed through the paracentesis on the same side and the iris was enclavated into the haptic claw with gentle push of the Sinsky hook. Then with similar maneuver, the other haptic enclavation was done. Viscoelastic material was aspirated; anterior chamber and scleral tunnel were secured with sutures if required.

The flanged SFIOL technique used was as described by Yamane *et al*.[9] [Video Clip 2]. The conjunctival entry spots were marked 180° apart with a toric marker at 4'o clock and 10'o clock meridians, 2 mm from the limbus. Following adequate vitrectomy as mentioned above, a foldable three-piece IOL Tecnis ZA9003 (Abbott Medical Optics, Santa Ana, CA, USA) and Sensar AR40e (Abbott Medical Optics) were introduced initially in the anterior chamber through limbal or sclerocorneal tunnel. Using the previous marking, a 27-G needle was inserted 2 mm from the limbus keeping it tangential with the iris plane to avoid ciliary body injury. A 23-G end gripping forceps was introduced from a paracentesis to insert the tip of the leading haptic into the lumen of the 27-G needle. The haptic was externalized and the tip was heated with a thermal cautery to create a flange, which was then fixed intrasclerally as described by Yamane. The same technique was repeated at the 180° opposite meridian to fixate the trailing haptic. Viscoelastic material was aspirated and anterior chamber was formed

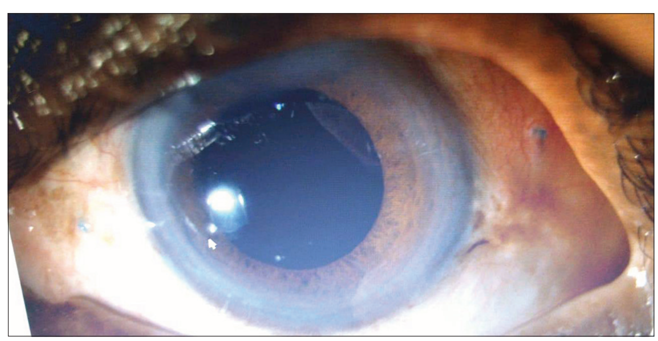

Figure 2: Six weeks postop photograph of intrascleral IOL fixation patient

with balanced salt solution. In both procedures, if pars plana vitrectomy was performed, the cannulas were removed at the end and integrity of the wound was ensured.

Following surgery, the patients' eye was padded for 6 h and topical nepafenac eyedrops were given three times a day for 2 weeks, topical moxifloxacin eye drops were given for 4 weeks, and topical prednisolone 1% eye drops were given in tapering dose for 6 weeks.

Statistical analysis

All continuous variables were expressed as mean with standard deviation, and group differences were analyzed using Student's *t*-test or Wilcoxon rank-sum test. Categorical variables were expressed as proportions (*n*, %) and group differences were analyzed using Chi-square or Fischer's exact test. All data were entered in Microsoft Excel and were analyzed using STATA 12.1 I/c (Stata Corp, Fort Worth, TX, USA) and P values < 0.05 were considered statistically significant.

Results

Data from 150 eyes of 150 patients that satisfied the inclusion criteria were analyzed and included 90 eyes with iris claw IOL and 60 eyes with flanged SFIOL implantation. Primary IOL fixation was carried out in 45 eyes (28%), while the remaining 115 eyes (72%) had secondary IOL implantation. Of primary implantation, 27 (61%) were carried out for subluxated cataracts and the remaining for dislocated cataracts combined with parsplana vitrectomy. Posterior capsular rent was the most common indication for secondary IOL implantation (n = 51, 51%), followed by subluxated IOL removal (n = 31 eyes, 27%), dislocated cataract (n = 19, 17%), and dislocated IOL (n = 14, 12%).

The iris claw and SFIOL groups were comparable in terms of demographics and baseline characteristics [Table 1]. At 6 weeks postoperative, the UCDVA was 0.46 ± 0.32 in the iris claw group and 0.40 ± 0.30 in the SFIOL group (P = 0.77), and at 3 months, there was again no difference in the UCDVA between groups (0.39 ± 0.30 in the iris claw group and 0.37 ± 0.28 in the SFIOL group, P = 0.79). Table 2 shows comparison between groups at 1-year follow-up. The vision, endothelial cell counts, and macular thickness were again comparable between the groups.

There was significant improvement in the UCDVA between preoperative and 6 weeks postoperative time points in both groups (P < 0.001), although there were no differences in this metric at other time points, including at 1-year follow-up. There was significant reduction in the corneal endothelial cell count at 1-year follow-up in both groups (P < 0.001), although there were no intergroup differences. There was no difference in mean macular thickness throughout the study period in both groups.

Table 3 shows comparison of postoperative complications between the groups during the study. Transient elevation of IOP was seen slightly more in eyes with SFIOL which was managed with topical antiglaucoma medications for 1 month. None of these patients required prolonged medications beyond the 6 weeks time point. Ovalization of the pupil was the main sequelae seen in the iris claw group. Retinal detachment (n = 1) and cystoid macular edema (n = 3) were rarely seen in our series. The retinal detachment patient underwent pars plana vitrectomy with endolaser with 1000cs silicon oil injection and subsequently underwent silicon oil removal after 6 months. The UCDVA at 3 months postoperative oil removal was 0.4 logMAR and the retina was well-attached. One patient in the SFIOL group developed persistent postoperative vitreous hemorrhage and underwent pars plana vitrectomy at 6 weeks with excellent visual recovery with UCDVA of 0.3 logMAR. There were no cases of pupillary block, uveal tissue inflammation, or endophthalmitis noted in our study.

Discussion

In this retrospective study with 1-year follow-up, we found no differences in visual outcomes in eyes undergoing implantation with either the iris claw IOL or the sutureless flanged SFIOL

Table 1: Comparison of demographics and preoperative parameters between iris claw and SFIOL

Parameter	Iris claw group (*n*=90)	Yamane's SFIOL (*n*=60)	*P*
Mean age (years)	62.0±23.0	57.06±16.9	0.12
Gender (% men)	55 (61%)	34 (57%)	0.73
Pre-op UCDVA (logMAR)	1.36±0.64	1.48±0.58	0.48
Mean preop endothelial cell count (cells/mm^2)	2329±828	2334±830	0.86
Mean preop central macular thickness (µm)	240±38	241±39	0.91
Mean preop intraocular pressure (mmHg)	16.40±3.25	15.95±4.05	0.77
% Primary surgery	25 (27%)	12 (20%)	0.32
% PCR	30 (33%)	21 (35%)	0.61

SFIOL: Sutureless intrascleral intraocular lens; UCDVA: Uncorrected distance visual acuity; PCR: Posterior capsular rupture

Table 2: Comparison of postoperative parameters at 1-year follow-up

Parameter	Iris claw group (*n*=90)	Yamane's SFIOL (*n*=60)	*P*
Mean postpop UCDVA (logMAR)	0.36±0.32	0.30±0.28	0.75
Mean postop endothelial cell count (cells/mm^2)	2154±786	2160±789	0.92
Mean postop central macular thickness (µm)	250±45	248±46	0.89
Mean postop intraocular pressure (mmHg)	14.40±4.25	16.25±3.95	0.13

SFIOL: Sutureless intrascleral intraocular lens; UCDVA: Uncorrected distance visual acuity

Table 3: Comparison of complications between iris claw and SFIOL groups

Complication	Iris claw group (*n*=90)	Yamane's SFIOL (*n*=60)	*P*
IOP elevation*	7 (7.79%)	10 (16.6%)	0.04
Retinal detachment	1 (1.11%)	Nil	0.41
Transient hypotony	5 (5.56%)	1 (2.5%)	0.65
Cystoid macular edema	2 (2.22%)	1 (2.5%)	0.81
Pupil ovalization	18 (20%)	Nil	**<0.001**
Vitreous hemorrhage	1 (1.11%)	1 (2.5%)	0.37

SFIOL: Sutureless intrascleral intraocular lens; IOL: Intraocular lens. *Immediate postop period; Bold: *P* value <0.05 is considered significant

fixation technique. Uncorrected vision improved in both groups at the 6 weeks time point and then remained stable till 1-year follow-up. There were minimal complications across both groups with the SFIOL group experiencing slightly more IOP elevation in the immediate postoperative period, although this was transient. Ovalization of the pupil was seen in 20% of eyes that received the iris claw IOL. None of the IOLs subluxated or dislocated either during surgery or at follow-up.

In a recent study comparing iris claw (*n* = 48) with sutureless SFIOL fixated using the Gabor technique (*n* = 56) with a minimum 1-year follow-up, Madhivanan *et al.* showed that iris claw IOLs have delayed visual recovery at 1 month.[13] They attributed this to delayed wound healing in the iris claw group in which IOL implantation was performed as a primary procedure, that is, at the time of complicated cataract surgery itself. However, there were no differences at 1-year follow-up. We found no differences at 6 weeks follow-up. Madhivanan *et al.* also report that eyes with iris claw IOLs had more corneal and retinal pathology which could have also contributed to delayed visual improvements. In our series, most eyes underwent IOL implantation as a secondary planned procedure and none of the eyes had preexistent corneal or retinal pathology. Forlini *et al.* have reported the longest follow-up in eyes with iris claw IOLs.[11] In their series, visual recovery was excellent at 1 month and was sustained at 5 years without any significant IOL-related complications. We also reported our results from a series of 104 eyes with iris claw IOLs with early visual recovery, similar to most other authors.[4,12,14]

Ovalization of the pupil has been reported in nearly every study on iris claw IOLs with incidence ranging between 2% and 25%.[4,14,15] In our series, we found this in 20% eyes. Despite having significant experience in implanting iris claw IOLs over the past 5 years and avoiding excessive enclavation of iris tissue into the IOL haptic, we still observe pupillary ovalization frequently. In our opinion, entrapment of the iris stroma in the claw of the IOL haptic leads to localized tissue atrophy with disfigurement of the pupil. However, prospective longitudinal studies with serial anterior segment (AS) OCT scans are required to document iris changes in response to retropupillary iris claw IOL fixation. Despite an oval shape, the pupil does not resist pharmacological mydriasis, and a complete retinal evaluation is possible in eyes with iris claw IOLs.

The flanged technique of sutureless intrascleral fixation of the IOL haptic of a three-piece IOL, as described by Yamane *et al.*, has many advantages over the other techniques of sutureless SFIOL described previously. In our initial experience with a modified Yamane's technique, we found this to be easier to learn, without need for specialized instruments to exteriorize haptics and glue to fixate the haptics.[16] In addition, the lack of need for conjunctival dissection makes this technique truly sutureless. We also use a more readily available 27-G needle instead of a long 30-G needle for the surgical procedure which enables use of routinely available three-piece IOLs. Recently, Stem *et al.* have shown that using a 27-G intrascleral fixation of haptics with flange creates a more stable SFIOL compared with the traditional unflanged technique based on a cadaveric human eye study.[17] Despite being popular, not many authors have reported their outcomes using Yamane's technique.

Despite being comfortable with the use of iris claw IOLs, we now prefer using the modified Yamane's technique with flanges since this enables use of foldable IOLs through a 2.8-mm incision along with its inherent advantages as opposed to the iris claw IOL which requires a much larger incision. We also believe that the SFIOL lies in a more physiological location closer to the ciliary sulcus without causing any obvious tissue damage unlike the iris claw IOL which is adherent to the iris with the potential of persistent or recurrent inflammation, cystoid macular edema, and pigment dispersion with its sequelae. We prefer iris claw IOLs still in eyes which have poorly dilating pupils when placing SFIOL becomes more difficult and iris claw IOLs are much easier to place. We also believe that the choice of IOL should depend on individual surgeon's experience so that optimal results can be achieved.

We found an acceptably low rate of complications in our series with very few vision-threatening complications such as retinal detachment, cystoid macular edema, and persistent raised IOP. IOL positioning was also found to be stable without any tilt, decentration, or subluxation/dislocation during follow-up. Once the iris claw IOL is fixated intraoperatively, there is no disenclavation and IOL drop in the postoperative period. Similarly, once adequate flanges are created and buried intrasclerally, the IOL position remains stable without much change over 1 year at least.

The strength of the study is the relatively good sample size in each group and follow-up at 1-year time point which provides a fair idea of intermediate term results. To the best of our knowledge, this is the first study comparing complications and outcomes between iris claw and sutureless SFIOL using Yamane's flange technique. The drawbacks of the study are its retrospective nature and lack of AS OCT documentation related to the iris changes and exact IOL positioning as well as scleral changes due to persistent exposure to the IOL haptic.

Conclusion

In conclusion, both iris claw IOL fixation and sutureless SFIOL using flange are viable options for surgical correction of aphakia. Visual outcomes are excellent at 6 weeks and are maintained till 1-year follow-up. Complication rates are acceptably low, but ovalization of the pupil occurs in a significant proportion of eyes that receive the iris claw IOLs. Further prospective studies with longer term follow-up are required to be performed in a larger cohort of eyes, along with serial AS OCT, to determine the superiority of one technique over the other.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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