

Safety and Efficacy of Artisan Aphakia Iris-Claw Intraocular Lens in Tertiary Hospital in Indonesia

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Abstract

Introduction: Iris-claw Intraocular Lens (IOL) is one of the alternatives to correct aphakia without sufficient capsular support. This technique is preferred because it has a simple procedure. Iris-claw IOL was originally designed to be fixated on the anterior chamber. The use of retropupillary fixation is increasing because the location is more physiologic and it shows less risk to corneal endothelial damage. **Purpose:** To describe safety and efficacy of iris-claw Artisan IOL in correcting aphakia without sufficient capsular support. **Methods:** This is a descriptive retrospective study of patients with aphakic iris-claw Artisan IOL implantation in National Eye Center Cicendo Eye Hospital, Indonesia from July 2017-July 2019. Patients were divided into prepupillary and retropupillary group. The Uncorrected Visual Acuity (UCVA), Best-Corrected Visual Acuity (BCVA), Safety Index (SI), Efficacy Index (EI), and complications were recorded. The procedure is safe if SI value ≥ 1.0 and effective if EI value ≥ 1.0 . **Results:** There were 54 eyes in the retropupillary group and 17 eyes in the prepupillary group. In the prepupillary group, there were 94.11% eyes with SI ≥ 1.0 , the mean SI was 1.79 ± 1.02 , 50% of eyes with EI ≥ 1.0 , and the mean EI was 0.77 ± 0.20 . In the retropupillary group, there were 96.29% eyes with SI ≥ 1.0 , the mean SI was 2.49 ± 2.23 , 74.07% of eyes with EI ≥ 1.0 , and the mean EI was 1.75 ± 1.64 . Postoperative UCVA and BCVA were improved significantly compared to preoperative visual acuity in both groups ($p < 0.05$). **Conclusion:** Prepupillary and retropupillary iris-claw IOL implantation are safe. Retropupillary fixation technique is more effective in improving visual acuity.

Keywords

Iris-Claw, Aphakia, Safety Index, Efficacy Index

1. Introduction

The ideal condition to correct aphakia is the implantation of an Intraocular Lens (IOL) in the bag [1]. Inadequate capsular support will prevent IOL implantation in the bag or sulcus and may be caused by capsular rupture, zonulysis, zonular weakness, pseudoexfoliation syndrome, pathologic myopia, ocular trauma, or Marfan syndrome [1] [2]. In such cases, alternative procedures are angle fixated, scleral fixated, iris sutured, or iris-claw IOL implantation [3] [4] [5]. Surgeon's experience, as well as eye conditions, determines the procedure of choice [3].

Implantation of angle-fixated anterior chamber IOL (AC IOL) seems easy but has some limitations and disadvantages. The main constraint is sizing. Insufficient size of IOL could damage corneal endothelium and anterior chamber angle due to rotation and/or dislocation. Excessive size of IOL gives too much pressure to the root of iris leading to damage of anterior chamber angle, the formation of peripheral anterior synechiae, an increase in intraocular pressure, and glaucoma. Angle-fixated AC IOL is also associated with chronic inflammation, corneal decompensation, cystoid macular edema, and hyphema [2] [4] [5] [6].

The scleral-fixated lens is implanted in a more physiologic location far from corneal endothelium and anterior chamber angle, but suturing technique is difficult. It requires excessive intraocular manipulation and longer surgical time. Possible complications are suture erosion, chronic inflammation, retinal detachment, vitreous and suprachoroidal hemorrhage. Suture exposure may also increase the risk of endophthalmitis [7] [8] [9].

The disadvantages of iris-sutured IOL comprise longer surgical time and the high difficulty level of technique. It also increases the risk of hypotony and intraoperative bleeding during needle passage as well as iris architecture disruption. The resulting iris damage leads to peripheral anterior synechiae, dyscoria, and limitation to dilatation [5] [10] [11] [12].

Implantation technique of iris-claw IOL is easier than iris sutured or scleral fixated lens. Haptic is fixated to midperipheral iris where the iris was less vascularized and less reactive. This location is far from corneal endothelium and iridocorneal angle, so it avoids the problem associated with IOL sizing, damage to the iris root, and anterior chamber angle. Iris-claw IOL was originally designed to be fixated on the anterior pupil (prepupillary). Retropupillary fixation later developed due to more physiologic location, far from corneal endothelium, and easier to implant than prepupillary procedure. The major disadvantage is that iris-claw IOL implantation required a 5.5 mm incision thus increased the risk of surgically induced astigmatism. This could be minimized using a scleral tunnel incision [4] [7] [11].

As previous studies of Indonesian aphakic iris-claw IOL have not been reported, this study aims to describe the safety and efficacy of iris-claw Artisan IOL implantations in correcting aphakic patients without adequate capsular support.

2. Subject and Methods

This is a descriptive retrospective study in National Eye Center Cicendo Eye Hospital, Bandung, Indonesia. Medical records from July 2017 until July 2019 were evaluated. The study adhered to the Declaration of Helsinki and was approved by the Institutional Review Board (IRB) of Padjadjaran University. Patients' informed consent was not required by the IRB because the data were collected retrospectively. Patients' data were de-identified to protect privacy. All aphakic patients with age > 18 years old, minimum 1 month follow-up, complete medical records, and implanted iris-claw IOL by ophthalmologist staff of Cicendo Eye Hospital are included. Exclusion criteria are an eye with a poor prognosis such as optic disc atrophy or retinal abnormalities. The intraocular lens used was aphakic iris-claw Artisan IOL (Ophtec BV, Groningen, The Netherlands) with 8.5 mm length, maximum tall 1.04 mm, and optic zone-wide is 5.4 mm. Patients were divided into retropupillary and prepupillary groups.

Indications, corneal endothelium cell count, UCVA, BCVA, safety index, efficacy index and complication were all evaluated. Primary procedure was conducted, if lens extraction and IOL implantation were done within the same time. Secondary procedure was carried out, if implantation were done at different times after lens extraction. Visual acuity was measured using the Snellen chart. Uncorrected visual acuity was examined before surgery and after surgery (1 day, 1 week, and 1 month). Best-corrected visual acuity was examined before and 1 month after surgery. Finger counting and hand movement were calculated as decimal values. Increased or decreased visual acuity was recorded if there was ≥ 2 lines difference of the Snellen chart.

Safety index (SI) is the ratio between BCVA after and before surgery. Refractive surgery is safe if SI value ≥ 1.0 . Efficacy index (EI) is the ratio between UCVA after surgery and BCVA before surgery. Refractive surgery is effective if EI value ≥ 1.0 . [13] [14].

Objective spheris was measured using an auto refractometer RM-8900 (Topcon). Corneal endothelial cell count was measured using specular microscope SP-3000P (Topcon). A-constant used were 115 for prepupillary and 117 for retropupillary implantation. Biometry was measured using optical biometry IOL Master V.5 or ultrasound biometry TomeyBio Meter AL-100. The implantation procedure was carried out by 6 ophthalmologists while the implantation technique was chosen based on operator preference.

Statistical analysis was performed using SPSS 22.0. Data distribution in prepupillary group was tested using the Saphiro-Wilk test while in retropupillary group tested using the Kolmogorov Smirnov test. The differences of UCVA between the time of follow-up was tested using the Friedman test. The comparison between preoperative UCVA and after 1 month one was tested using the Wilcoxon test. The comparison between preoperative BCVA and after 1 month one was tested using the Wilcoxon test. Significant results were shown if p value < 0.05.

3. Results

There were 149 eyes with aphakic iris-claw IOL implantation from Juli 2017-Juli 2019. Eligible patient eyes based on inclusion and exclusion criteria were 71 eyes from 62 patients. Patients' ages ranged from 18 to 87 years old; the mean age from the prepupillary group was 56 ± 16.4 years old while from the retropupillary group was 52.7 ± 17.8 years old. Also, there were more male subjects compared to female subjects. Most of our cases had endothelial cell count ≥ 2000 cells/mm². One case from the retropupillary group had endothelial cell count of 827.5 cells/mm². The most common indication of primary procedure in both groups was zonular weakness (11.76% and 14.81%). These patients had zonular weakness but examination results excluded pseudoexfoliation syndrome, Marfan syndrome, trauma, or surgical complication as underlying causes. The most common indication for the secondary procedure in both groups was an aphakic eye with inadequate capsular support after complicated cataract surgery (52.94% and 27.77%). Clinical characteristics are shown in **Table 1**.

In prepupillary group, improvement of UCVA after surgery occurred in 94.11% (n = 16) eyes while it remained the same in 5.88% (n = 1) eyes. Improvement of BCVA after surgery occurred in 82.35% (n = 14) eyes, while it

Table 1. Clinical characteristics of the patients.

Clinical Characteristics	Prepupillary n (%) 17 eyes	Retropupillary n (%) 54 eyes
Age (mean \pm SD)	56 ± 16.4	52.7 ± 17.8
Sex		
Male	9 (52.94)	48 (88.89)
Female	8 (47.06)	6 (11.11)
Endothelial Cell Count (cells/mm²)		
≤ 1000	0 (0)	1 (1.85)
1000 - 2000	5 (33.33)	25 (46.30)
≥ 2000	12 (66.67)	28 (51.85)
Primary Procedure	4 (23.52)	24 (44.44)
Zonular weakness	2 (11.76)	8 (14.81)
Pseudoexfoliation Syndrome	0 (0)	5 (9.25)
Marfan syndrome	0 (0)	6 (11.11)
Trauma	1 (5.88)	3 (5.55)
Surgical complication	1 (5.88)	2 (3.70)
Secondary Procedure	13 (76.48)	30 (55.56)
Aphakia	9 (52.94)	15 (27.77)
IOL subluxation	3 (17.65)	10 (18.51)
IOL drop	1 (5.88)	5 (9.26)

IOL: Intraocular Lens.

remained the same in 11.76% (n = 2) eyes, and decreased in 5.88% (n = 1) eye. There were 94.11% (n = 16) eyes with SI \geq 1.0 and the mean SI was 1.79 ± 1.02 . There were 50% (n = 7) eyes with EI \geq 1.0 and the mean EI was 0.77 ± 0.20 . After surgery, 17.65% of eyes had UCVA \geq 0.5 and 82.35% of eyes had BCVA \geq 0.5. The comparison of UCVA before and after 1-month surgery showed a significant improvement with a p-value of 0.001. The differences of UCVA between follow-up time can be seen in **Table 2**. The median UCVA increased from 0.014 to 0.32 after one month (p-value < 0.001). The comparison of BCVA before and after 1-month surgery was significant with a p-value of 0.001 as depicted in **Table 3**.

In retropupillary group, UCVA after surgery improved in 98.15% (n = 53) eyes and decreased in 1.85% (n = 1) eye. BCVA improved in 74.07% (n = 40) eyes, remained the same in 22.22% (n = 12) eyes, and decreased in 3.70% (n = 2) eyes. There were 96.29% (n = 52) eyes with SI \geq 1.0, while the mean SI was 2.49 ± 2.22 . There were 74.07% (n = 40) eyes with EI \geq 1.0, while the mean EI was 1.75 ± 1.64 . After surgery, 57.41% (n = 31) eyes had UCVA \geq 0.5 and 79.63% (n = 43) eyes had BCVA \geq 0.5. Comparisons of UCVA before and after 1-month surgery showed a significant improvement with a p-value < 0.001. The differences of UCVA between follow-up time is shown in **Table 2**. The median UCVA increased from 0.014 to 0.45 after one month (p-value < 0.001). The comparison of BCVA before and after 1-month surgery was significant with a p-value < 0.001.

In our study, UCVA was significantly improved between the time of follow-up in both groups. Using SI \geq 1.0, retropupillary implantation was slightly safer than prepupillary (96.29% vs 94.11%). The difference between the two groups could be seen using EI. Using EI \geq 1.0, retropupillary implantation gave better results than prepupillary implantation (74.07% vs 50%).

Table 4 indicates complications in this study. The most common complication in the retropupillary group was pupil ovalization. Secondary glaucoma occurred in one eye from both groups. Corneal decompensation occurred in 1.85% (n = 1) eye of the retropupillary group. One patient had haptic detachment but could be reattached successfully.

Table 2. Uncorrected visual acuity improvement between follow-up.

UCVA	Time				p-value*
	Pre-operative	After 1 day	After 1 week	After 1 month	
Prepupillary					
Mean (SD)	0.035 (0.070)	0.101 (0.087)	0.236 (0.170)	0.325 (0.176)	
Median	0.014	0.08	0.20	0.32	<0.001
Range	0.002 - 0.250	0.01 - 0.25	0.01 - 0.63	0.05 - 0.70	
Retropupillary					
Mean (SD)	0.040 (0.097)	0.179 (0.189)	0.354 (0.241)	0.467 (0.251)	
Median	0.014	0.125	0.32	0.45	<0.001
Range	0.003 - 0.500	0.00 - 0.63	0.01 - 1.00	0.05 - 1.00	

*Friedman test; UCVA: Uncorrected Visual Acuity.

Table 3. Best corrected visual acuity improvement after 1 month of follow-up.

BCVA	Prepupillary			Retropupillary		
	Before surgery	After surgery	p value*	Before surgery	After surgery	p value*
Mean (SD)	0.361 (0.277)	0.707 (0.258)		0.334 (0.305)	0.705 (0.288)	
Median	0.40	0.80	0.001	0.25	0.80	<0.001
Range	0.005 - 0.800	0.16 - 1.00		0.005 - 1.00	0.10 - 1.00	

*Wilcoxon test; BCVA: Best Corrected Visual Acuity.

Table 4. Complication after 1 month of follow-up.

Complication	Prepupillary n (%)	Retropupillary n (%)
Pupil ovalization	1 (5.88)	9 (16.67)
Secondary Glaucoma	0 (0)	1 (1.85)
Hypotony	0 (0)	1 (1.85)
Uveitis	0 (0)	1 (1.85)
Corneal Decompensation	0 (0)	1 (1.85)
Detached haptic	0 (0)	1 (1.85)
Hyphema	1 (5.88)	0 (0)

4. Discussion

Choosing surgical techniques to correct aphakic eyes with inadequate capsular support remains challenging [2]. The technique which offers the lowest complication rate combined with the best possible visual outcome should be chosen according to patient's condition and surgeon's experience. Iris-claw Artisan IOL is an effective choice for aphakia correction with several advantages like easy to implant, minimally invasive, has shorter surgical time, and has fewer complications compared to other techniques [3] [6] [7] [11] [12].

Previous studies reported that iris-claw Artisan IOL implantation in both locations is safe to corneal endothelium but prepupillary fixation still has a small risk of endothelial touch in the shallow anterior chamber. Peralba *et al.* reported a greater reduction in the prepupillary group (9.6% versus 8.7%) after 1 year [1]. Toro *et al.* also reported a greater reduction in the prepupillary group (11.6% versus 9.5%) after 5 years [15]. The difference was not significant in both studies. However, in our study retropupillary fixation in most cases is conducted to protect corneal endothelium and provide a more physiological IOL position. It is also easier to implant iris-claw Artisan IOL in retropupillary position in some cases where the procedure is combined with pars plana vitrectomy.

Some of our surgeons prefer to do prepupillary implantation with minimum corneal endothelial cell 1000 cells/mm². There is no consensus for minimal endothelial cell count for iris-claw IOL implantation. Toro *et al.* and Peralba *et al.* recommend doing retropupillary implantation if the endothelial cell count is less

than 1200 cells/mm² [1] [15]. Toro *et al.* reported good results of 2 patients with endothelial cell > 900 cells/mm² implanted by retropupillary iris-claw [15]. In our study, there was a patient in retropupillary group with endothelial cell count of 827.5 cells/mm². After surgery, BCVA in this patient was 1.0 with no corneal decompensation until the last follow-up.

Previous studies reported that aphakia iris-claw Artisan IOL implantation significantly improves visual acuity after surgery. Helvaci *et al.* reported that all two groups obtained a significant improvement in BCVA ($p < 0.05$) [3]. Mora *et al.* also reported that the groups showed comparable improvements in BCDVA after surgery (final BCVA: 0.34 ± 0.45 vs. 0.37 ± 0.50 logMAR in the anterior and retropupillary placement groups, respectively) [16]. Toro *et al.* reported CDVA improved significantly in both groups ($p < 0.001$, ANOVA), from the first week and during the entire follow-up ($p < 0.001$, Tukey HSD) [15]. In our study, there were also significant improvement of UCVA between follow-up time after surgery ($p < 0.05$) and improvement of BCVA after 1-month follow-up ($p < 0.05$).

Safety and efficacy are two important parameters to evaluate refractive surgery results. Based on the visual acuity of the same eye before and after surgery, we can retrospectively define the safety and effectiveness of the surgery. If postoperative BCVA is the same or more than preoperative BCVA ($SI \geq 1.0$), the procedure is safe. Same BCVA is considered safe because the patient did not lose their visual potential [13] [14]. In this study, patient in retropupillary group with $SI \geq 1.0$ is slightly higher than prepupillary group (96.29% vs 94.11%). The mean SI in the prepupillary group was 1.79 ± 1.02 while in the retropupillary group was 2.49 ± 2.23 . Other studies also reported slightly better results in retropupillary group but the differences are not significant. Peralba *et al.* reported postoperative BCVA equal or increased in 64.7% of patients from prepupillary group and 71.4% of patients from retropupillary group [1]. Toro *et al.* explained that there was no difference in BCVA between the two groups after 1 month-surgery. After 5 years of follow-up, BCVA remained the same or improved in 93% of patients in the retropupillary group and 92.5% in the prepupillary group [15].

In our study, SI value in both locations was high. The mean SI in the prepupillary group was 1.79 ± 1.02 while in the retropupillary group was 2.49 ± 2.23 . Ganesh *et al.* reported a Safety Index of 1.73 in retropupillary implantation using OV lens (Care Group, India) which may have different characteristics than Artisan IOL [17]. Correction of vision with aphakic glasses causes spherical aberrations, visual field reduction, and image size magnification. Aphakic glasses also result in disparity of image in unilateral aphakia. After IOL implantation, all of these problems were resolved, better BCVA could be achieved, resulting in a high SI value in both positions [1].

Even though both positions are safe, retropupillary implantation was more effective in our study. If the postoperative UCVA equals and even exceeds the preoperative BCVA ($EI \geq 1.0$), the procedure is effective [13]. This result represents an uncorrected vision after surgery at least as good as a correction with a patient's glasses or contact lens before surgery [14]. Efficacy Index ≥ 1.0

occurred in 50% of eyes from the prepupillary group and in 74.07% of eyes from the retropupillary group. The mean EI in the prepupillary group was 0.77 ± 0.2 while in the retropupillary group was 1.83 ± 1.66 . Eyes with low EI may still reach better BCVA after surgery. Better results in the retropupillary group might be due to more physiologic implantation location, being close to the eye's nodal point, resulting in more predictable refraction, and the procedure is less manipulative. Another possibility is in this study the number of patients is higher in the retropupillary group.

In the prepupillary group, reduced BCVA occurred in one eye. This is an aphakic eye after previous complicated cataract surgery. No retinal abnormalities in this eye but the other eye had an old retinal detachment. This eye had implanted iris-claw Artisan IOL through scleral tunnel incision near the cornea. This patient had two sutures that were too tight after surgery. Decreased BCVA was more likely due to surgical induced astigmatism. This patient only came to follow-up until 1 month. The visual acuity could be improved by releasing the sutures.

Reduction of BCVA in the retropupillary group occurred in 2 eyes. One with corneal decompensation and the other with the possibility of SIA. In an eye with corneal decompensation, endothelial cell count before surgery is 1513.6 cell/mm^2 with hexagonality 0%. Visual acuity in the fellow eye is no light perception thus we still decided to implant iris-claw IOL in retropupillary position because this eye was a last hope for vision. This patient had multiple surgeries before Artisan aphakic IOL implantation. He underwent cataract extraction as a first surgery then IOL reposition eight years later as second surgery. Five years later, he underwent IOL exchange to AC IOL as third surgery. By the time, the AC IOL decentered again. Instability of decentered IOL with endothelial touch, improper AC-IOL, and multiple surgical procedures and manipulation could reduce the number of endothelial cells, lead to persistent corneal edema [18] [19] [20].

In an eye with the possibility of SIA, previous surgery done was complicated phacoemulsification converted to extracapsular cataract extraction using temporal corneal incision. This eye was left in aphakic condition and had 4 sutures after surgery. After two months, iris-claw Artisan IOL was implanted in this eye with the addition of three sutures. In this eye, BCVA after 1-month surgery decreased to 4 lines of the Snellen chart. Corneal incision induced greater SIA compared with scleral tunnel incision. Martinez *et al.* reported Surgically Induced Astigmatism (SIA) in the scleral tunnel incision group (0.73 ± 0.62 diopter) was significantly lower than in the corneal incision group (2.49 ± 1.36 diopter) ($p < 0.001$) [11] [12] [21].

The most common complication in this study is pupil ovalization. It did not influence postoperative BCVA. Ovalization may occur because of the tightness or asymmetric enclavation in midperipheral iris stroma. This condition tends to normalize over time, usually within 1 week but sometimes longer [7] [15] [22]. In this study, pupil ovalization occurred in 5.88% ($n = 1$) eyes from the prepupillary group and 16.67% ($n = 9$) eyes from the retropupillary group after 1

month follow-up. Martinez *et al.* reported pupil ovalization occurred in 11.8% of eyes but reversed within 6 month follow-up [11]. Gonnermann *et al.* reported pupil ovalization in 24.8% of eyes within first week after retropupillary implantation but persistent in only 13.9% eyes [5]. Persistent ovalization could be caused by misplaced IOL centration during enclavation resulting in the claw does not pinch midperipher iris but instead pinches the sphincter muscle of the iris. This study only follows up patients until 1-month post-surgery. Further study with a longer follow-up time is needed.

Secondary glaucoma occurred in 1.85% (n = 1) of eye from the retropupillary group after 1-month follow-up with a history of Pseudoexfoliation syndrome. Increased IOP is due to preexisting condition. Guell *et al.* reported significant IOP changes only in patients with pigment dispersion or pseudoexfoliation [23]. Toro *et al.* reported increased IOP in one patient from each group after 3 years of follow-up but they had a family history of primary open-angle glaucoma [15]. In our study, high IOP could be controlled by medication. Hypotony occurred in one eye with history of pars plana vitrectomy. The IOP was normalized after one week follow up without any intervention. Anterior uveitis occurred in one eye but the inflammation could be controlled by medication. Haptic detachment occurred in one eye but after reposition of the detached haptic the result is good.

5. Conclusion

In conclusion, iris-claw IOL implantation in both positions is safe but retropupillary implantation is more effective in increasing visual acuity. This is a preliminary study that used previously recorded data. This study has several limitations such as this is a retrospective study thus we only have limited complete medical records. Most of our patients only follow up for 1 month after surgery. In this study, implantation was performed by six surgeons. There are some variations in implantation technique and location preference between different surgeons. The subgroup sample is also small and unevenly distributed between prepupillary and retropupillary groups, so the results between the two groups are not statistically comparable. Further prospective studies with more homogenous samples and longer follow-up time could be done to give more accurate results.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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