Comparison Of Scleral-Fixated Posterior Chamber Intraocular Lens Implantation And Posterior Iris-Claw Intraocular Lens Implantation In The Treatment Of Aphakia With Insufficient Capsular Support

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Abstract

Aim : To compare the outcome of scleral-fixated posterior chamber intraocular lens (PCIOL) with retro-pupillary fixation of iris-claw intraocular lens (IOL) in the treatment of aphakic eyes with insufficient capsular support as regard to the safety, complications and visual outcomes of the procedure. **Methods :** A total of 40 patients were divided into 2 equal groups : 20 eyes were implanted with scleral fixated PCIOL and 20 eyes were implanted with iris-claw IOL. Postoperative corrected distance visual acuity (CDVA), intraocular pressure (IOP) & postoperative complications were compared between the 2 groups during the followup period on day 1, 7 days, 14 days,1 month and after 3 months. **Results:** On the first postoperative day, the CDVA ranged from 0.06 to 0.32 in the iris-claw group, with a mean of 0.26 ± 0.108 and it ranged from 0.06 to 0.18 in the scleral- fixated group with a mean of 0.12±0.044; there was a statistically significant difference between the groups. After the 3 months post-operatively, the CDVA ranged from 0.25 to 0.8 in the iris-claw group with a mean of 0.56±0.25 and it ranged from 0.15 to 0.6 in the scleral-fixated group with a mean of 0.46±0.16; there was no statistically significant difference between the 2 groups. On the day 1 postoperatively the mean intraocular pressure in the iris-claw group was 15.46±2.48 mmHg whereas in scleral fixating IOL group it was 19.24±3.86 mmHg with a statistical difference between 2 groups. Iris claw groups showed higher rates of pupillary distortion, anterior chamber reaction and cystoid macular oedema-postoperatively. Whereas corneal oedema, vitreous haemorrhage and retinal detachment were higher in the scleral fixation group. **Conclusion:** Iris claw IOL implantation can give a significant improvement in vision with fewer complications than SFPCIOL in patients with insufficient capsular support. **Keywords :** Iris-Claw intraocular lens, Scleral-fixated posterior chamber intraocular lens, Visual acuity, Aphakia.

Introduction : Modern day cataract surgery requires an intact posterior capsule to implant an IOL "In-the-bag". It maximizes the chances of optimal surgical and refractive outcomes. The IOL is positioned within the lens capsule, well-centered to the pupillary axis, and the IOL-capsular complex is adequately supported by lens zonules.

The crystalline lens capsule is an elastic basement membrane which contains the lens substance. The thinnest part of the capsule is located at the posterior pole.[1] In the absence of adequate posterior capsular support due to lack of integrity of posterior capsule or zonules, such as during complicated cataract surgery when the posterior capsule is ruptured, an IOL is placed in the ciliary sulcus to maintain excellent visual outcomes.[2]

The best method of aphakia correction is in the bag implantation of PCIOL. When this ideal procedure is not possible the other alternatives are broadly categorized into two: extraocular and intraocular. The former includes contact lenses and aphakic glasses, the latter ones are further divided into anterior and posterior chamber IOL implantation. Anterior Chamber Intraocular Lenses (ACIOL) can be with or without iris claw and the posterior chamber, fixation of the lenses can be with glue or sutures.

Spectacles are rarely used for visual rehabilitation of aphakia, because those types of glasses are also associated with complications like pincushion distortions, reduced visual field and jack-in-the-box phenomenon apart from being heavy to wear.[3]

Contact lenses (CLs) are considered the most common

treatment, as they are widely available and effective to treat aphakia. Complications in wearing CLs[4]are generally caused by poor maintenance, overextended wearing, and wearing in a polluted environment. Several corneal and conjunctival complications are also common and are mostly due to corneal hypoxia. The complications include conjunctivitis, especially giant papillary conjunctivitis, corneal vascularization, corneal edema, corneal abrasions, chronic endothelial dysfunction, and the dreaded acanthamoeba conjunctivitis.

Hence IOL implantation is the most appropriate treatment for visual rehabilitation and correction of aphakia. Options[5] for intraocular lens (IOL) implantation in the absence of capsular support include ACIOLs, iris-fixated IOLs, and scleral-fixated IOLs. Choice of IOL and implantation technique depends greatly on patient age, comorbid ocular conditions, and the patient's ocular anatomy.

Iris claw IOLs were first introduced in 1986 by Fechner and Worst to correct myopia, but were later used to correct aphakia.[6] The new generation of IC-ACIOLs have good visual outcomes and are associated with fewer complications in the treatment of aphakia.

Malbran and colleagues were the first to described sutured SFIOLs[7] for the management of aphakia following intracapsular cataract extraction in the 1980s which was followed by sutureless technique described by Scharioth and coworkers.[8] Nowadays Dr. Agarwal's[9] technique of sutureless SFIOL with Fibrin glue is widely used.

SF-PCIOL implantation is technically difficult; it requires considerable operative time and is associated with complications such as IOL tilt, decentration, displacement into the vitreous cavity, choroidal hemorrhage, retinal detachment, CME, and conjunctival erosion secondary to use of trans-scleral sutures.[10] The iris claw lens was fixated to the mid-peripheral iris, where the iris is less vascularized and less reactive.[11] This feature makes the implantation easy to process. However, non foldable lens and large incision are the major disadvantages of the lens.The new generation of iris-claw IOLs have good visual outcomes and are associated with fewer complications in the treatment of aphakia.

Our aim is to compare the outcome of scleral-fixated posterior chamber IOL with retro-pupillary fixation of iris-claw IOL in the treatment of aphakic eyes with insufficient capsular support as regard to the safety, complications and visual outcomes of the procedure in the same surgical setting.

Material and Methods : In this prospective experimental study 40 patients with surgical aphakia with poor capsular support were included from our tertiary care center as well as the referred patients from September 2016 to January 2018. The Ethical Committee approval was taken before beginning the study. The study protocol and informed consent forms were obtained from all the participants and followed the tenets of the Declaration of Helsinki.

Inclusion criteria :

1) Monocular surgical aphakia with poor capsular support
2) No evidence of iris atrophy
3) Undilated pupil $\leqslant$ 5 mm in diameter, and corrected visual acuity (VA) $\geqslant$ 0.1

Exclusion criteria :

1) Aphakia due to cause other than cataract surgery
2) Significant irregular astigmatism (>2 D corneal astigmatism)
3) Posterior segment pathologies such as cystoid macular edema, choroidal neovascular membrane
4) Iridoschisis >2 o'clock
5) Corrected VA <0.1

Study sample :

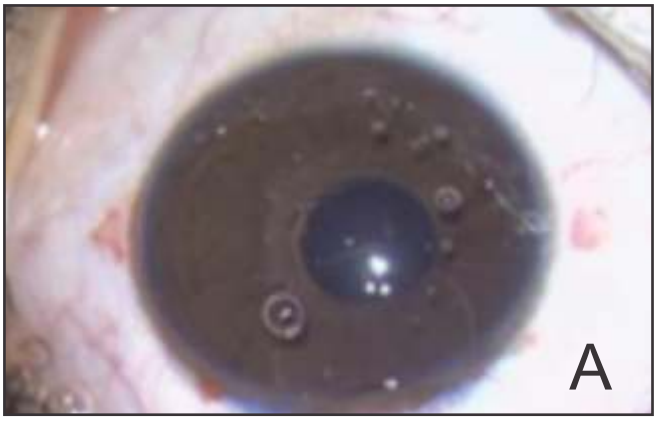
A total of 40 patients were divided randomly into two equal groups : Group A included 20 eyes in which the iris-claw lens was used, which is an iris-claw, biconvex, polymethylmethacrylate (PMMA) IOL with an 8.5-mm length, 0.95-mm maximum height, and 5.0-mm optical zone. It had an A-constant of 115. Group B included 20 eyes in which a 3 piece IOL was sclerally fixed. The IOL was a 6 mm optic, with 12.75 mm overall diameter. It had an A-constant of 118.5.

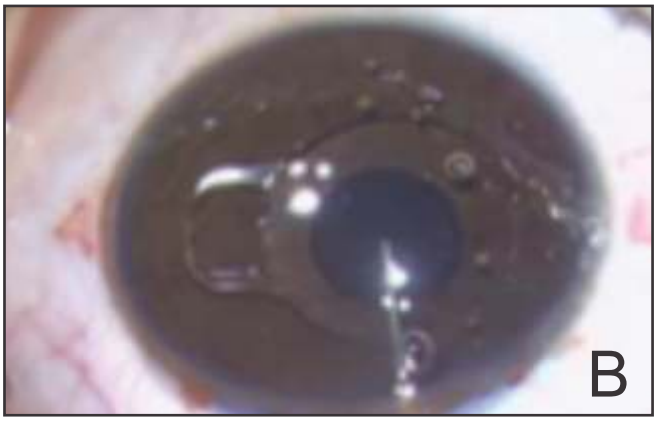
Pre-operative assessment : All patients underwent

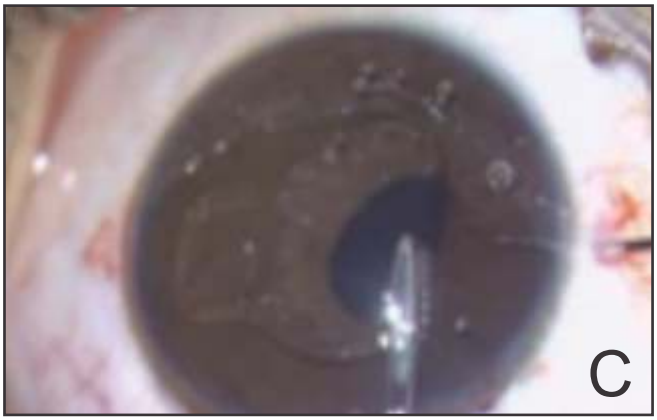
complete preoperative ophthalmologic evaluation including best corrected visual acuity (BCVA), and subjective refraction. The measurements taken were as follows: 1) slit-lamp examination with emphasis on position of previous surgical peripheral iridectomy and pupil 2) keratometry and A scan 3) A constant (117.0) and SRK/T formula used for IOL power calculation 4) Dilated fundus examination with 90 D and indirect ophthalmoscopy 5) Goldmann applanation tonometry. The lens in all cases was implanted either as a primary or secondary procedure along with Pars plana vitrectomy.

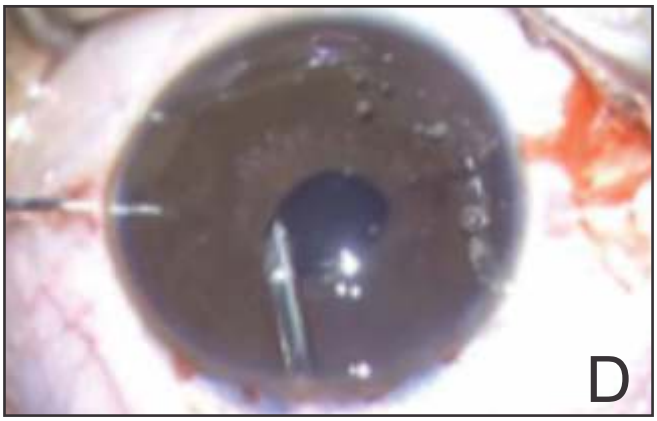
The Technique of surgery :

Group A (Iris claw lens) : Two side ports were made diagonally opposite - that is, at the 3 o'clock and 9 o'clock positions. If the vitreous was noted in the anterior chamber, anterior vitrectomy was performed. The conjunctiva was separated from adhesions, exposing the previous temporal scleral section, and the corneal tunnel was opened with iris repositor. The anterior chamber was formed with viscoelastic substance, and iris-claw IOL was introduced into the anterior chamber such that the haptics were in line with the side ports. Holding the optic of the lens with a lens forceps, one haptic was pushed under the iris with gentle manipulation. Simultaneously, a dialer was passed through the paracentesis on the same side and enclaving was performed. The endpoint was noting the dimple at the site of enclavation. Similarly, haptic enclavation in the other side was performed. Prophylactic Peripheral iridectomy done. The section was sutured with one interrupted 10-0 nylon and the conjunctiva with 8-0 vicryl. Postoperatively, topical antibiotics and cycloplegics for a week and topical steroids were administered in a tapering schedule over 6 weeks.









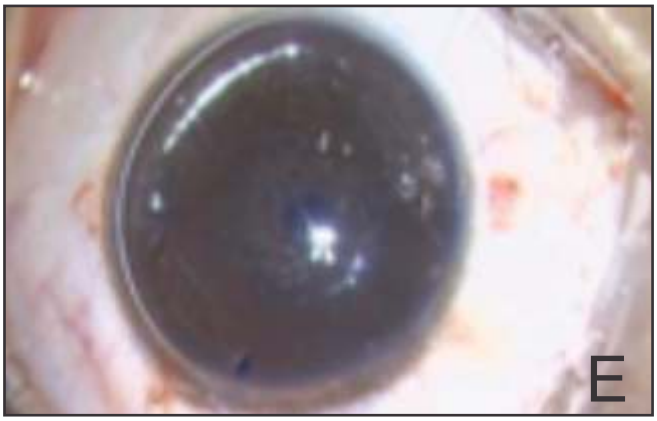
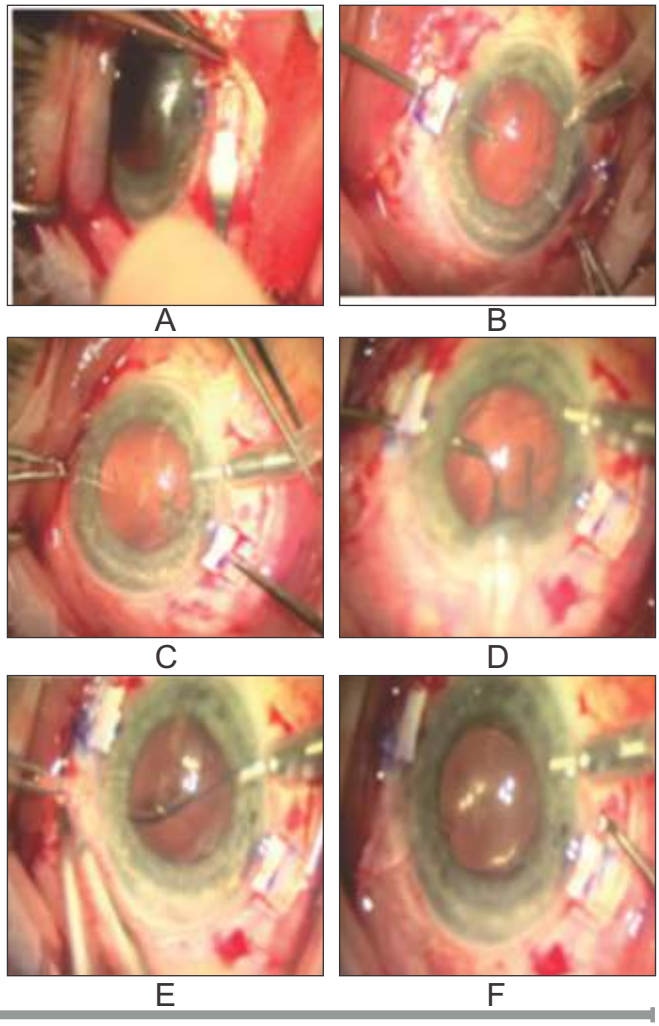


Figure 1: A) Insertion of Iris claw IOL B) IC-IOL in AC C) One haptic is placed behind the iris and enclaved D) Second haptic is fixated behind is iris by enclavation E) Prophylactic iridectomy and closure

Group B (Scleral fixating IOL) : Two partial-thickness scleral flaps were constructed 180 degrees opposite from each other. Anterior and core vitrectomy was performed in all cases before IOL implantation to clear the vitreous from the anterior chamber and around the lens. Sclerotomies are made within the flaps and, after an introduction of the IOL into the eye, the haptics are grasped through the sclerotomies with forceps and externalized. Next, fibrin glue is applied to the bed of the flap, and the outer portion of the scleral flap is folded over the haptic, sealing the scleral flap.

The corneal section was closed, and the conjunctiva was reposited with fibrin glue. Postoperatively, topical antibiotics and cycloplegics for a week and topical steroids were administered in a tapering schedule over 6 weeks.



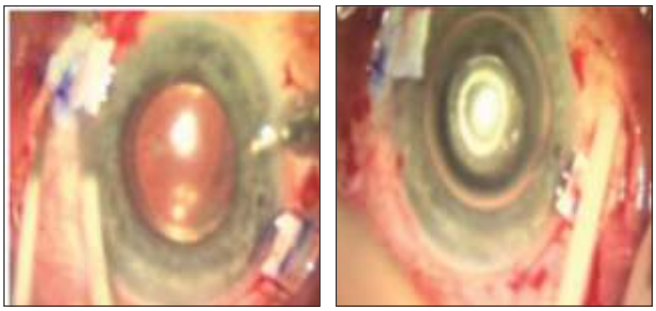


Figure 2: A) Scleral-flaps are made at 180^0 **B**) Anterior and core vitrectomy done **C)** Sclerotomies are made within flaps **D)** 3 piece IOL implanted in AC and optics are gasped with intraocular forceps **E)** One haptic externalized **F)** Second haptic externalized **G)** Haptics are secured within flaps **H)** Fibrin glue applied

Results :

Patients were subdivided into two groups
The iris-claw group (group A) : This group included 20 eyes of 20 patients, of whom 9 were male and 11 patients were female. The mean age was 54.64 ± 11.2 years. The mean preoperative corrected distance visual acuity (CDVA) was 0.36 ± 0.21. Among 20 patients with surgical Aphakia 12 eyes had inadequate capsular support after phacoemulsification or ECCE surgery and 8 eyes were aphakic after small incision cataract surgery (SICS)

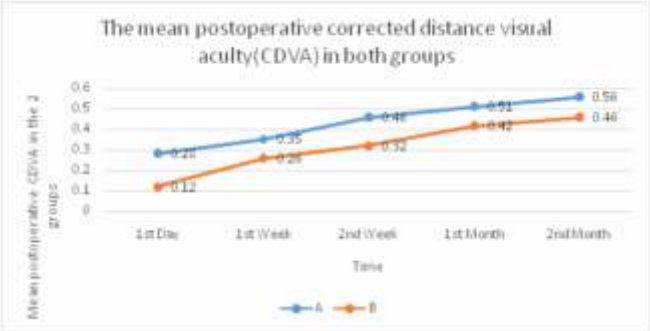
The scleral fixation group (group B) : This group included 20 eyes of 20 patients, of whom 14 were male and 6 patients were female. The mean age was 56.1 ± 12.2 years. The mean preoperative CDVA was 0.37 ± 0.196. Among 20 patients with surgical aphakia 15 eyes had inadequate capsular support after phacoemulsification or ECCE surgery and 5 eyes were aphakic after SICS.

Operative data Duration of surgeries In group A, the duration ranged from 15 to 30 min, with a mean of 22.5 ± 4.6min, and in group B it ranged from 45 to 80 min, with a mean of 62.5 ± 7.8 min. The P value was less than 0.00001. Intraoperative difficulties Minor intraoperative complications occurred in both groups. Subconjunctival hemorrhage occurred in five cases in scleral-fixating group and small intraoperative hyphema occurred in 2 iris-claw cases during enclavation.

Postoperative data :

Postoperative corrected distance visual acuity

Graph 1 :

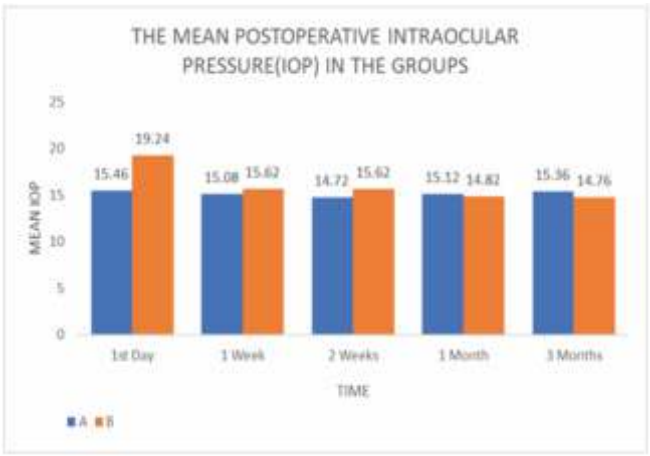


On the first postoperative day, the CDVA ranged from 0.06 to 0.32 in group A, with a mean of 0.26 ± 0.108. It ranged from 0.06 to 0.18 in group B, with a mean of 0.12 ± 0.044. There was a statistically difference between the groups. After the first postoperative week, the CDVA ranged from 0.08 to 0.43 in group A, with a mean of 0.35 ± 0.19. It ranged from 0.15 to 0.4 in group B, with a mean of 0.26 ± 0.06. There was no statistical difference between the groups.

After the first postoperative month, the CDVA ranged from 0.15 to 0.6 in group A, with a mean of 0.46 ± 0.28. It ranged from 0.15 to 0.47 in group B, with a mean of 0.32 ± 0.18. There was no statistical significant difference between the groups (P = 0.150).

After the first 3 months postoperatively, the CDVA ranged from 0.25 to 0.8 in group A, with a mean of 0.56 ± 0.25. It ranged from 0.15 to 0.6 in group B, with a mean of 0.46 ± 0.16. There was no statistical significant difference between the groups.

Graph 2:



On the first postoperative day, the IOP in group A ranged from 12 to 21, with a mean of 15.46 ± 2.48 mmHg, and in group B it ranged from 14 to 28, with a mean of 19.24 ± 3.86 mmHg. There was a statistical significant difference between the groups (P = 0.00038).

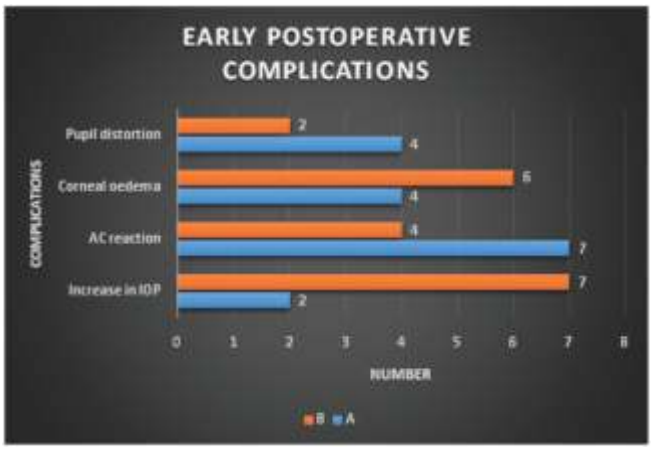
This rise in IOP was attributed to postoperative iridocyclitis. All cases received topical steroid and topical hypotensive medications.

After the first postoperative week, the IOP in group A ranged from 12 to 18, with a mean of 15.08 ± 2 mmHg, and in group B it ranged from 13 to 20, with a mean of 15.62 ± 2 mmHg, with no statistical significant difference between the groups (P = 0.361).

After the first postoperative month, the IOP in group A ranged from 12 to 19, with a mean of 14.72 ± 1.75 mmHg, and in group B it ranged from 12 to 18, with a mean of 14.82 ± 2 mmHg. There was no statistical significant difference between the groups (P = 0.478).

After the first 3 months postoperatively, the IOP in group A ranged from 13 to 20, with a mean of 15.36 ± 2 mmHg, and in group B it ranged from 12 to 18, with a mean of 14.76 ± 1.65 mmHg. There was no statistical significant difference between the groups (P = 0.019).

Graph 3:



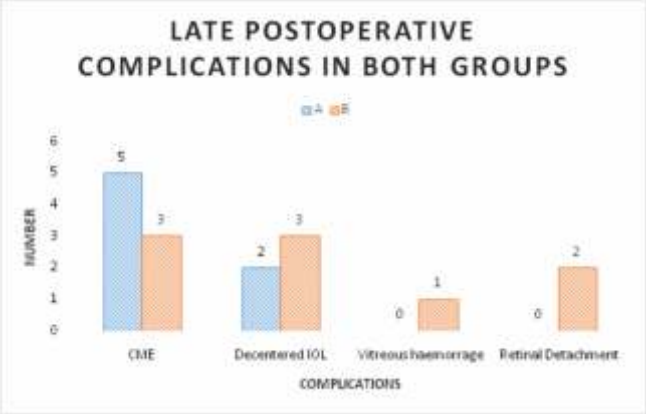
1) Elevated IOP (>20 mmHg): Elevated IOP occurred in two (10%) cases in group A and in Seven(35%) cases in group B. These cases were managed with topical steroid and topical IOP lowering medications.

2) Anterior chamber reaction: Seven(35%) cases in group A and four (20%) cases in group B showed anterior chamber reaction. The cases responded to topical steroids.

3) Corneal edema: Four (20%) cases in group A and Six (30%) cases in group B showed corneal edema; the cases responded to topical antiglaucoma and topical hypertonic agents.

4) Pupillary distortion: Four (20%) cases in group A and Two (10%) cases in group B showed pupillary distortion.

Graph 4:



1) CME was detected on OCT in cases with unexplained visual deterioration in Five (25%) cases of group A and in Three (15%) cases of group B.

2) IOL decentration was observed in two(10%) cases in group A and in Three (15%) cases in group B.

3) Vitreous haemorrahage was noted only in One (5%)case in Group B while there was no vitreous haemorrahge in any patients.

4) Retinal detachment was noted in 2 (10%) patients in Group B while none in Group A.

Discussion : Implantations of IC-IOL and SF-PCIOL are important operative modalities in visual rehabilitation to treat aphakia without sufficient capsular support. Although there are several previous studies and reviews focusing on the surgical procedure and outcomes between IC-IOL and SF-PCIOL implantations,[12] the conclusions are controversial, and no systematic review has compared IC-IOL and SF-PCIOL implantations in treating aphakia without sufficient capsular support. Since each operation has advantages and specific complications, it is difficult to determine which is more suitable for the management of patients without sufficient capsular support. Thus, we conducted a comparative study to determine efficacy, safety, and complexity between IC-IOL and SF-PCIOL implantations in correcting aphakia without adequate capsular support.

The mean surgical time in the Iris- claw IOL group (22.5 ± 4.6min) was significantly shorter than that in the scleral fixation group (62.5 ± 7.8 min). This difference can be due to the fact that, in the scleral fixation group, surgeons often struggle when searching for adequate fixation positions for the haptics. Scleral flaps are constructed to hide the knots, and proper vitrectomy is performed to avoid undesirable retinal detachment and ciliary choroidal hemorrhage. Because surgeons can omit these procedures in the retro-pupillary fixation of the Iris-claw IOL, surgical time could be shortened in comparison with scleral fixation.

Hara et al. (2011)[13] stated similar results. They stated that the mean surgical time in the Verisyse IOL group (20.0 ± 8.9 min) was significantly shorter than that in the scleral fixation group (49.7 ± 18.9 min) ($P < 0.0001$). This co-rrelates with our study.

In our study, no statistical significant differences were noted between the two groups in mean CDVA after surgery except CDVA of Iris claw IOL group was significantly better than the Scleral fixation IOL group 1 day after surgery. The retro-pupillary fixation of the Iris-claw IOL showed earlier visual recovery and fewer complications compared with SF-PCIOL.

Farrahi and colleagues (2012)[14] performed their study on anterior iris-claw IOL and scleral-fixed IOL. They found that the iris claw anterior chamber IOL (IC-ACIOL) group showed better results compared with the SF-PCIOL group in terms of postoperative BCVA at final follow-up, which was logMAR 0.24 ± 0.17 (decimal 0.58 ± 0.68) versus 0.41 ± 0.22 (decimal 0.39 ± 0.60), respectively ($P = 0.041$); BCVA of 20/40 or greater was present in nine (75%) IC-ACIOL patients versus five (38%) SF-PCIOL patients ($P = 0.027$), this also goes in favour with our study.

On the first postoperative day, the IOP in group A ranged

from 12 to 21, with a mean of 15.46 ± 2.48mmHg, and in group B it ranged from 14 to 28, with a mean of 19.24 ± 3.86 mmHg. There was a statistically significant difference between the groups (P = 0.00038). This rise in IOP was attributed to postoperative iridocyclitis. All cases received topical steroid and topical hypotensive medications.

Hazar and colleagues (2013) stated that the mean IOP was not significantly different at baseline between the two groups. Although the mean IOP was significantly higher in the SF-PCIOL group than in the RP-IFIOL group (P = 0.042) at postoperative 1 week, there was no difference in IOP between the groups at other follow-up visits.[15] This also co-rrelates with our study.

Postoperative complications In our study, anterior chamber reaction occurred in seven(35%) eyes in the iris-claw group and in four (20%) eyes in the scleral fixation group. Visual acuity was markedly affected and deteriorated by this but with the application of intensive course of postoperative systemic and topical steroids and anti-inflammatory drugs, a dramatic improvement was achieved in all of the cases without a long-lasting effect on the visual acuity.[14]

These results are comparable to the results obtained by Hazar and colleagues (2013), who reported five (20.8%) cases after retro-pupillary iris-fixed IOL and three (9.6%) cases after scleral-fixed IOL implantation. No significant difference was found between the groups in terms of incidence of anterior chamber reaction.[15] In our study, corneal edema occurred into four (20%) cases in group A and in six(30%) cases in group B. Hazar and colleagues (2013) [15] reported a lower rate of corneal edema, one (4.1%) in the retropupillary iris-claw group and three (9.6%) in the scleral fixation group.[15] This co-relates with our study.

In this study, no postoperative vitreous hemorrhage occurred in the iris-claw group, whereas vitreous hemorrhage was seen in one (5%) eye in the scleral fixation group.

Vote et al [16] and Bading et al [17]found a rate of 6.3%-8.2% for RD and 3.2% for choroidal haemorrhage in their cases after the implantation of a trans-sclerally sutured PCIOL. In our study, 1 case (7.69%) of RD was found 3 months postoperatively. Transient hyphema and vitreous haemorrhage was observed in 2 cases (15.38%). No choroidal haemorrhage was found in our study, the reasons might be the combination of pars plana vitrectomy perfusion which effectively maintains the dynamic balance of intraocular pressure.

Hazar et al. (2013)[15] reported one (4.1%) case of hemorrhage in retro-pupillary iris-claw cases, whereas they reported two (6.4%) eyes with vitreous hemorrhage in scleral fixation cases.

CME has been the leading cause of the poor visual outcome in all series of PC lenses. This is always attributed to the initial pathology, which is present in the eye before fixation. In our work, CME was found in five patients (25%) of the retro-pupillary iris-claw group and into three patients (15%) of the scleral fixation group.

Hazar et al. (2013)[15] reported two (8.3%) cases of CME in the retro-pupillary iris-claw group, whereas they reported one (3.2%) eyes with CME in the scleral fixation group.

In this work, decentration was observed in two (10%) cases of the retro-pupillary iris-claw group and in three (15%) cases of the scleral fixation group.

Comparable results were achieved by Menezo and colleagues (1996)[18] who reported two (4.8%) cases of IOL decentration in the iris fixated Worst claw group, whereas they reported two (15.3%) cases in the sutured sulcus-fixated PC lens group.

Conclusion : This study shows that Iris claw IOL implantation is associated with good visual outcomes with a low complication rate compared to SFIOL implantation in patients with aphakia and insufficient capsular support. The retro-pupillary iris-claw lens implantation technique is simple and has low intraoperative and postoperative complications. So now we can say that it is a better option than a scleral-fixated IOL for an early and stable post-operative outcome.

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