

Surgical Outcomes and Complications of Sutureless, Glueless, Flapless Scleral Fixated Posterior Chamber Intraocular Lens (SFIOL)

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Conflict of interest: Nil

Abstract:

Introduction: Secondary intraocular lens implantation refers to intraocular lens insertion at a time remote from the initial cataract extraction (or less commonly, from the trauma that led to the loss of the lens). There are a variety of cataract extraction methods, including phacoemulsification, extracapsular cataract extraction and intracapsular cataract extraction. An IOL can be placed in the anterior chamber between the cornea and iris, as in iris-fixated and closed- or open-loop anterior chamber IOLs (AC IOLs), or it can be implanted in the posterior chamber within the ciliary sulcus posterior to the iris, as in sutured iris-fixated and sclera fixated posterior chamber IOLs (PC IOLs).

Aims and Objectives: To evaluate surgical outcomes and complications in patients undergoing intrascleral fixated posterior chamber intraocular lens surgery.

Purpose: To evaluate the surgical outcomes and complication of sutureless, glueless, flapless scleral fixated posterior chamber intraocular lens (SFIOL) of patients presented at a tertiary care hospital in Gujarat.

Methods: This prospective clinical study was conducted on 36 patients in department of Ophthalmology, GMERS Medical College, Gandhinagar, Gujarat.

Result: 36 patients were included who presented to Department of Ophthalmology. These patients were followed up for a period of 4 weeks postoperatively and BCVA with Snellen's distance visual acuity chart was noted. 7 cases (19.44%) had BCVA 6/9 and above after 4 weeks post operatively. 3 cases (8.33%) had a BCVA 6/36 or less. Post operatively complications like striate keratopathy was seen in 9 Cases (25%). 2 patients (5.55%) had high IOP. 1 patient (2.77%) developed hyphema. 1 patient (2.77%) had IOL decentration on 1st postoperative day.

Conclusion: The proportion of males was higher than females. Maximum number of patients was found in the age group of 61-70 years followed by 51-60 years. Total 9 (25%) patients had history of trauma. Scleral fixated intraocular lens implantation in the posterior chamber is safe and effective method for correcting aphakia with a better visual outcome. It avoids the disadvantages associated with spectacles and contact lens usage like aniseikonia, relative spectacle magnification (RSM), spherical aberrations, heavy lenses (glasses), visual field limitation. Scleral fixated intraocular lens implantation in the posterior chamber has less chances of complications like bullous keratopathy, UGH syndrome, iritis, CME etc, which were commonly seen in ACIOLs and iris fixated IOLs.

Keywords: Scleral Fixated Posterior Chamber Intraocular Lens (SFIOL).

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Introduction

Secondary intraocular lens implantation refers to intraocular lens insertion at a time remote from the initial cataract extraction (or less commonly, from the trauma that led to the loss of the lens). [1]

Cataract is the commonest age-related disease in most countries worldwide. There are approximately 45 million blind people in the world. At least 80% of these people live in developing countries and more than half are blind as a result of cataract. [2] It is estimated that in India alone, more than 5.1 million patients undergo cataract surgery in a year. [3]

There are a variety of cataract extraction methods, including phacoemulsification, extracapsular cataract extraction and intracapsular cataract extraction. [4] The intracapsular method of cataract extraction was the preferred technique for nearly 50 years. However, the momentum shift towards ECCE probably began in 1967. [5] In intracapsular cataract extraction (ICCE), the lens is removed along with the capsule and in Extracapsular cataract extraction (ECCE), posterior capsule is spared. [6] Since 1970, phacoemulsification and extracapsular cataract surgery have replaced intracapsular cataract, except for rare instances, such as subluxated lenses or eyes in which a question of patient sensitivity to lens material exists. [7] However placement of a posterior chamber intraocular lens may not be possible in all eyes that undergo this procedure, due to unforeseen complications that may occur intraoperatively. [3]

Modern cataract surgery involves phacoemulsification of the opacified crystalline lens and the implant of an intraocular lens (IOL) in the capsular bag. In some conditions this is not possible due to the type of cataract (e.g., traumatic cataracts with lens subluxation, cataracts in pseudo-exfoliative syndrome with zonular/capsular dehiscence) or to systemic and congenital disorders characterized by weakness of zonules/capsule (e.g., familial or idiopathic ectopia lentis, Marfan syndrome, etc.) or to intraoperative complications (e.g., large breaks of the posterior capsule, accidental aspiration of the capsular bag, etc.) leaving the patient aphakic. [8] Aphakia can be corrected by either spectacle lens, contact lens or intraocular lens. The insertion of an intraocular lens within the aphakic eye overcomes the optical disadvantages of aphakic spectacles and the handling and wearing difficulties encountered with contact lens. [9,10] An IOL can be placed in the anterior chamber between the cornea and iris, as in iris-fixated and closed- or open-loop anterior chamber IOLs (AC IOLs), or it can be implanted in the posterior chamber within the ciliary sulcus posterior to the iris, as in sutured iris-fixated and

sclera fixated posterior chamber IOLs (PC IOLs). [11] The preferred lens for aphakic rehabilitation is a posterior chamber lens. Major advantages of a posterior chamber IOL over anterior chamber IOL are

1. A PCIOL is closer to the focal point of the eye reducing the image magnification.
2. Its position away from delicate anterior chamber structures especially the corneal endothelium and anterior chamber angle.
3. The risk of CME, glaucoma and corneal oedema is lower with PCIOLs [12,13]

This study was done to Evaluate surgical outcomes and complications of suture-less, glue-less, flapless scleral fixated posterior chamber intraocular lens implantation.

Aims and Objectives:

1. To evaluate surgical outcomes in patients undergoing intrascleral fixated posterior chamber intraocular lens surgery.
2. To evaluate complications in patients undergoing intrascleral fixated posterior chamber intraocular lens surgery.

Materials and Methods:

Type of Study Design: Prospective clinical study.

Sample Size: 36

Around 20 patients undergo Scleral fixated posterior chamber intraocular lenses (SFIOL) every year.

Study Area: Department of Ophthalmology, GMERS Medical College and Civil Hospital, Gandhinagar, Gujarat.

Study Population: Patients presenting in Department of ophthalmology, GMERS Medical College and Civil Hospital, Gandhinagar, who fulfil inclusion criteria and give consent.

Study Duration: 2 years starting from November 2020 to November 2022.

Inclusion Criteria:

- Male and Female Patients of 18-90 years age group.
- Aphakia (may be post-operative or traumatic)
- Post-operative dislocated PCIOL.

Exclusion Criteria:

- Patients with central corneal opacity, glaucoma, uveitis.
- Any fundus abnormality affecting visual function like macular degeneration, chorioretinal atrophy etc.

Pre-Operative Preparation

- Detailed Medical History
- Anterior Segment Examination
- Posterior Segment Examination
- Iol Power Calculation (PMMA Three Piece Intraocular Lens)

Systemic Examination

Mydriasis: Preoperatively pupils were dilated using 0.5% tropicamide, 10% phenyl- ephrine and flurbiprofen. These drops were instilled every 15 minutes one hour before surgery. Preoperatively antibiotic eye drops were instilled one hour before surgery.

Akinesia and Anaesthesia:

Akinesia and Anaesthesia of the eye was achieved by peribulbar injection of 5ml of 0.75% bupivacaine, 5 ml of 2% lignocaine with 75 units of hyaluronidase and 1:200000 adrenalin. This was given with 24G needle. Peribulbar block was given at the junction of outer one third and inner two thirds of the lower orbital rim. The needle was directed away from the eye and towards the floor of the orbit with eye in primary gaze. In the superior orbital margin injection was given at the junction of medial one- third and lateral two third towards the roof of the orbit.

Lowering of IOP: The IOP was reduced by giving tab. Acetazolamide 250mg one hour before the surgery. Ocular hypotony was also achieved by ocular compression after peribulbar block using steady digital pressure on globe for 20 seconds periods separated by 10 seconds interval.

Cleaning of Skin and Conjunctiva:

Preparation included use of 5% povidone iodine to clean the surrounding skin. Skin area that extended from midline to beyond lateral canthus and from above the eyebrows to well down onto the cheek was cleaned. 5% iodine solution was applied into conjunctival cul-de sac with subsequent saline wash to cleanse the conjunctiva.

Surgical Technique:

Sutureless, Glueless, Flapless Intrasceral Pciol (Posterior Chamber Intra Ocular Lens) [17].

Superior 270-degree conjunctival peritomy is followed by light scleral cautery to achieve adequate haemostasis. Two partial-thickness scleral pockets are then made, with the help of 20 Gauge (G) microvitreoretinal (MVR) trocar blade, for permanent incarceration of the IOL haptics.

Pockets are created 180-degree apart, parallel to the limbus, and 1.5–2 mm away from the limbus. A scleral tunnel is made superiorly with the help of a crescent blade. Next, three standard 25G pars plana vitrectomy (PPV) sclerostomy ports are constructed

at 2, 10, and 4'o clock. two ciliary sulcus-based sclerotomies are created close to the scleral pockets for 22 externalization of IOL haptics, using a 24G needle. First, lensectomy and anterior vitrectomy are performed. Entry into the anterior chamber is then made through the scleral tunnel with the help of a keratome blade. A standard three-piece non foldable PMMA IOL is implanted. With the tailing haptic fixated at the scleral incision, the leading haptic is grasped at the tip with a 25-gauge end gripping forceps and pulled out through the sclerotomy. Haptic is then tucked into the scleral pocket. The tailing haptic is inserted into the posterior chamber. IOL that does not fall as one haptic is already incarcerated in the scleral pocket. Second haptic is visualized with the help of a binocular indirect ophthalmoscope (BIOM), grasped, and pulled out through the second sclerotomy.

Tailing haptic is also tucked into the limbus-parallel scleral pocket. Finally, centralization of the IOL is done by adjusting the amount of haptic in each pocket. Vitrectomy ports, the scleral tunnel, and the conjunctiva are finally sutured. All the sites were inspected for wound leakage. Postoperative pad and patch done after giving subconjunctival gentamycin and dexamethasone injection. In case IOL subluxation is seen in the postoperative period, it can be centralized easily by performing a localized peritomy over the 2 scleral pockets and adjusting the length of haptic stuck in the scleral pocket.

Post-Operative Management

Postoperatively patients were treated with topical antibiotic-steroid drops for a period of 4 weeks which was gradually tapered. 23 Patients was followed up for a period of 4 weeks. Postoperative day 1 Patient was examined

- Slit lamp biomicroscope
 1. Wound approximation
 2. Corneal status
 3. Anterior chamber depth and reaction
 4. IOL centration
- BCVA with Snellen's distance visual acuity chart
- IOP by Goldman's applanation tonometry.

Post-operative Day 7/ Day 30 patient was examined for

- BCVA with Snellen's distance visual acuity chart
- Slit lamp biomicroscope
 1. Corneal status
 2. Anterior chamber depth and reaction
 3. IOL centration
- IOP by Goldman applanation tonometer

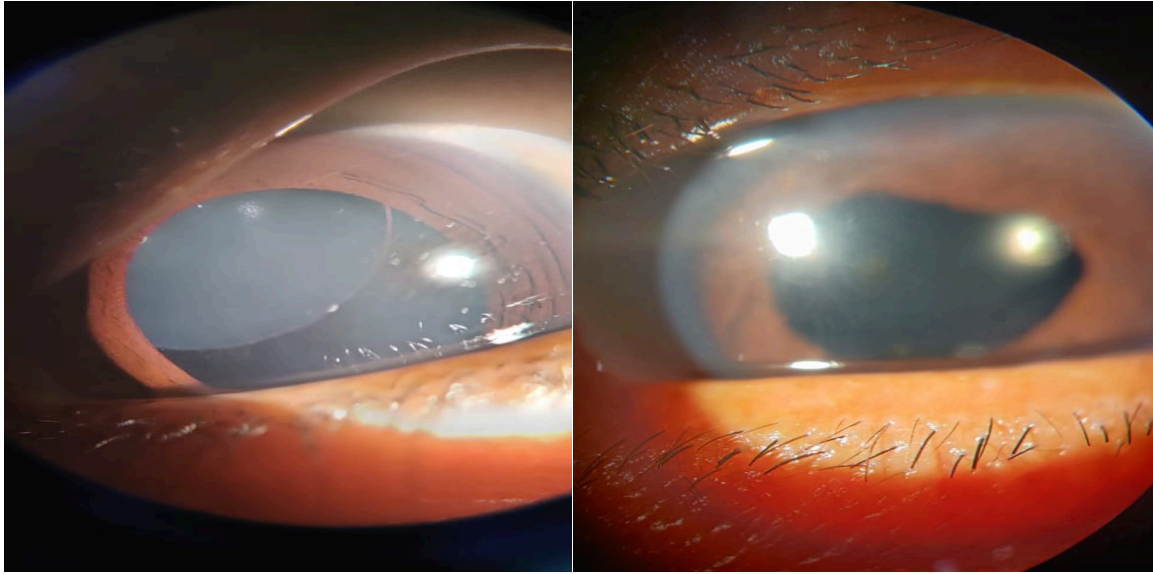


Figure 1: Superotemporal Subluxation of Lens Post-Operative

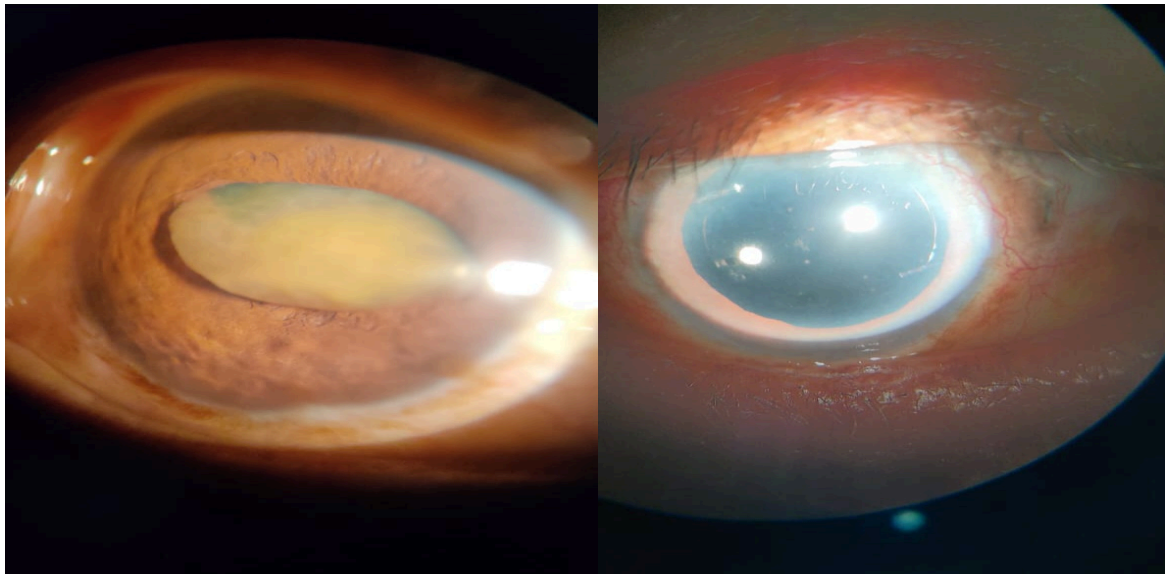


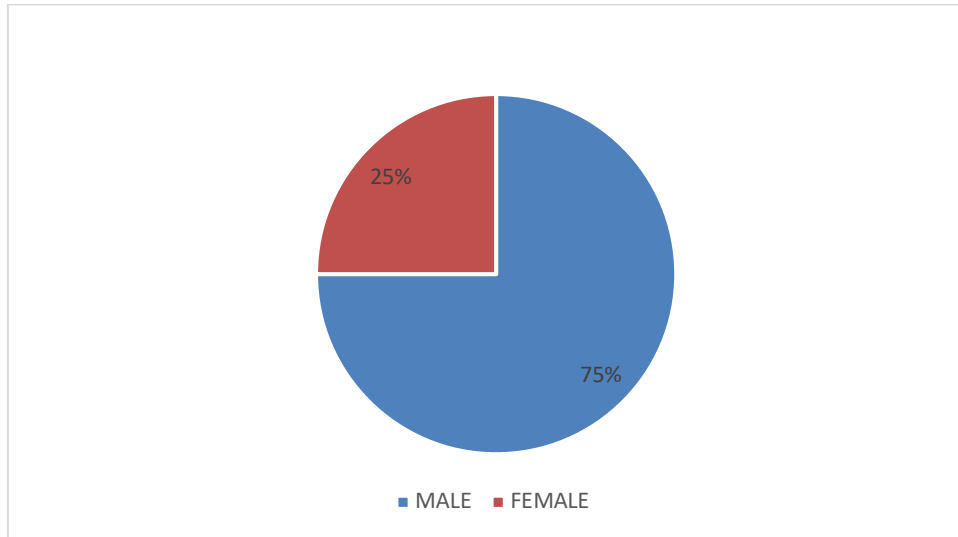
Figure 2: Traumatic Dislocated Lens Post-Operative



Figure 3: Traumatic Subluxated Lens Post-Operative

Observation and Results:**Table 1: Sex Distribution**

Sex	No. of patients	Percentage
Male	27	75 %
Female	9	25 %

**Figure 4:****Table 2: Age Wise Distribution of Patients**

Age group (in years)	No. of patients	Percentage
21-30	1	2.78 %
31-40	0	0 %
41-50	5	13.89 %
51-60	11	30.56 %
61-70	13	36.11 %
71-80	4	11.11 %
81-90	2	5.56 %

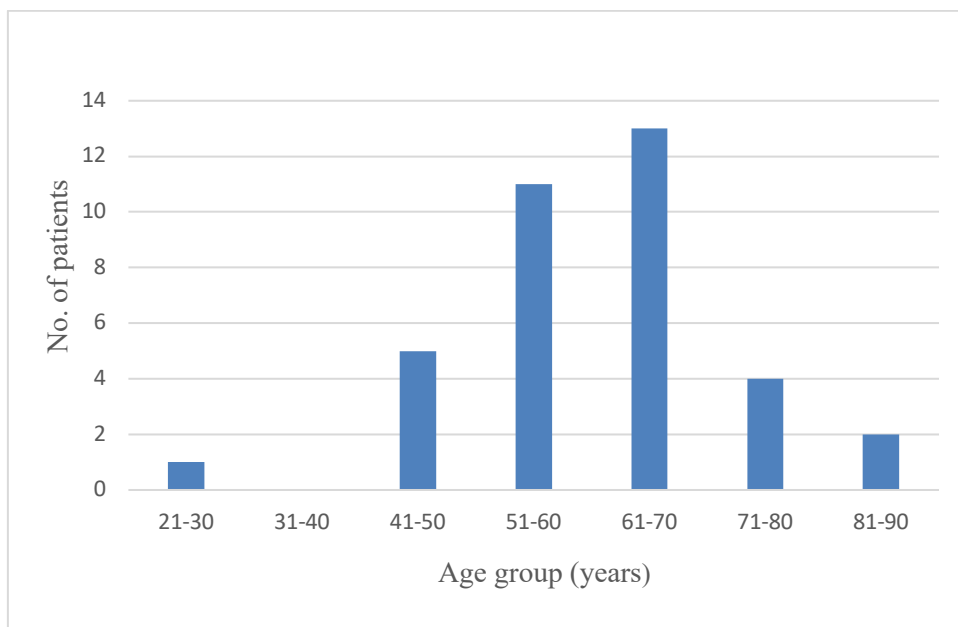
**Figure 5:**

Table 3: Pre-operative BCVA

Visual Acuity	No. of Patients	Percentage
6/6	2	5.55 %
6/9	2	5.55 %
6/12	4	11.11 %
6/18	2	5.55 %
6/24	3	8.33 %
6/36	3	8.33 %
6/60 or less	20	55.55 %

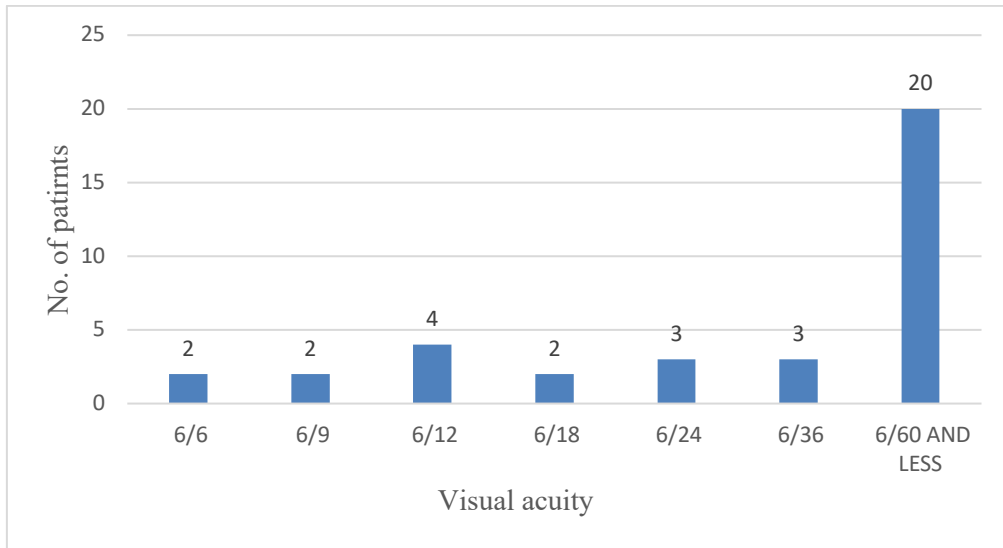


Figure 6:

Table 4: BCVA on Day 1 Post-operatively

Visual Acuity	No. of patients	Percentage (%)
6/6	0	0 (%)
6/9	0	0 (%)
6/12	1	2.77(%)
6/18	4	11.11(%)
6/24	9	25(%)
6/36	1	2.77(%)
6/60 or less	21	58.33(%)

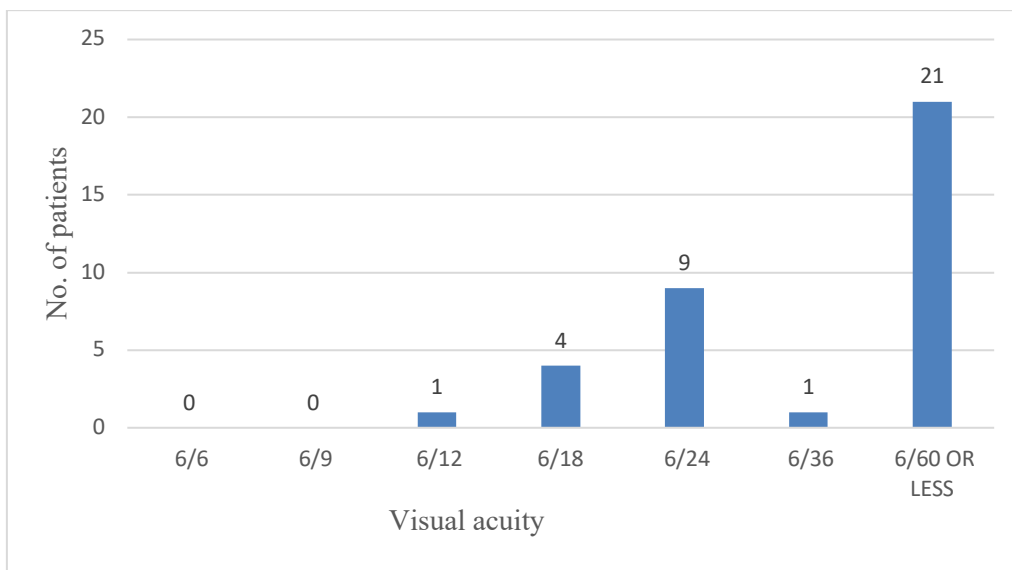


Figure 7:

Table 5: Complication profile on 1st Post-operative Day:-

Complication	No. of patients	Percentage (%)
Wound leak	0	0 (%)
Striate keratopathy	9	25(%)
Corneal Oedema	2	5.55(%)
Hyphema	1	2.77(%)
AC shallow	2	5.55(%)
SFIOL Decentration	1	2.77(%)
Glaucoma	2	5.55(%)
Vitreous Hemorrhage	0	0(%)
Endophthalmitis	0	0(%)

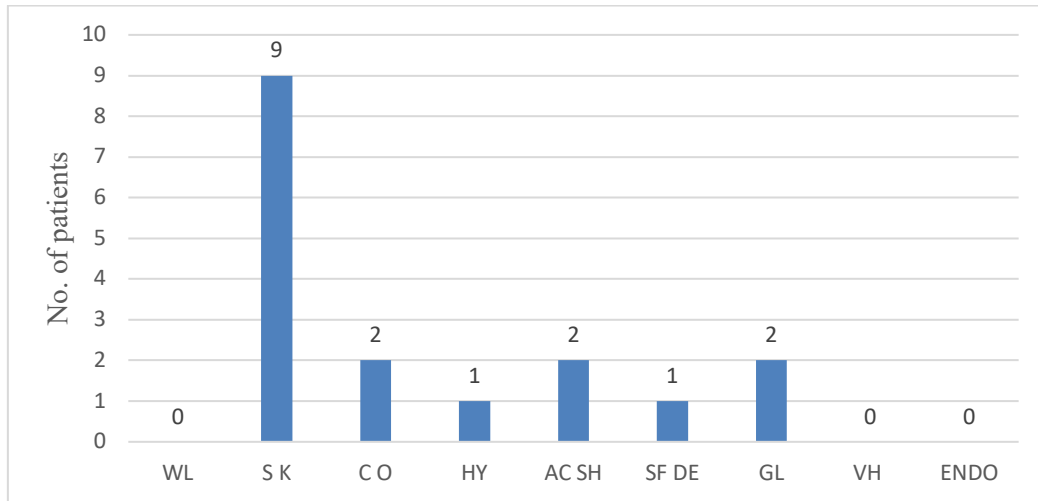


Figure 8:

Table 6: BCVA 1 week Post-operatively

Visual Acuity	No. of patients	Percentage (%)
6/6	0	0 (%)
6/9	1	2.77(%)
6/12	4	11.11(%)
6/18	5	13.88(%)
6/24	6	16.66(%)
6/36	12	33.33(%)
6/60 or less	8	22.22(%)

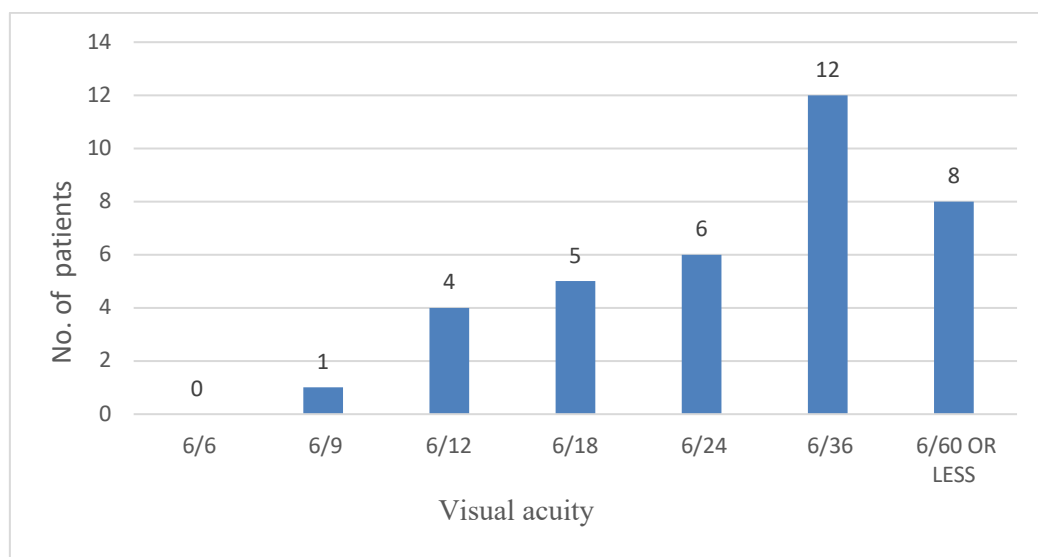


Figure 9:

Table 7: Complication profile 1 week Post-operatively

Complication	No. of patients	Percentage (%)
Striate keratopathy	3	8.33 (%)
Corneal Oedema	1	2.77 (%)
Hyphema	1	2.77(%)
AC shallow	0	0 (%)
SFIOL Decentration	0	0 (%)
Glaucoma	1	2.77 (%)
Vitreous Hemorrhage	0	0 (%)
Endophthalmitis	0	0 (%)

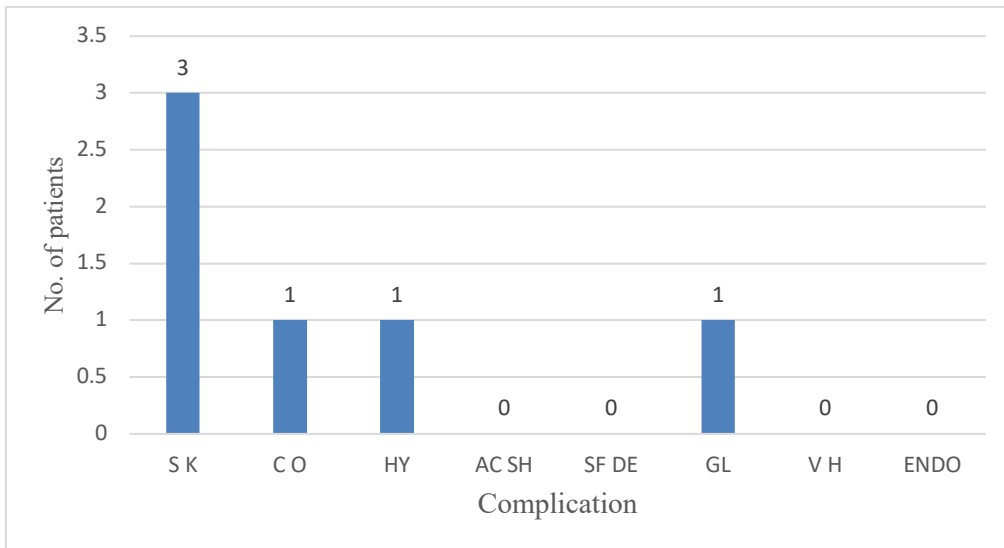


Figure 10:

Table 8: BCVA 4 weeks Post-operatively

Visual Acuity	No. of patients	Percentage (%)
6/6	0	0 (%)
6/9	7	19.44(%)
6/12	13	36.11(%)
6/18	11	30.55(%)
6/24	2	5.55(%)
6/36	1	2.77(%)
6/60 or less	2	5.55(%)

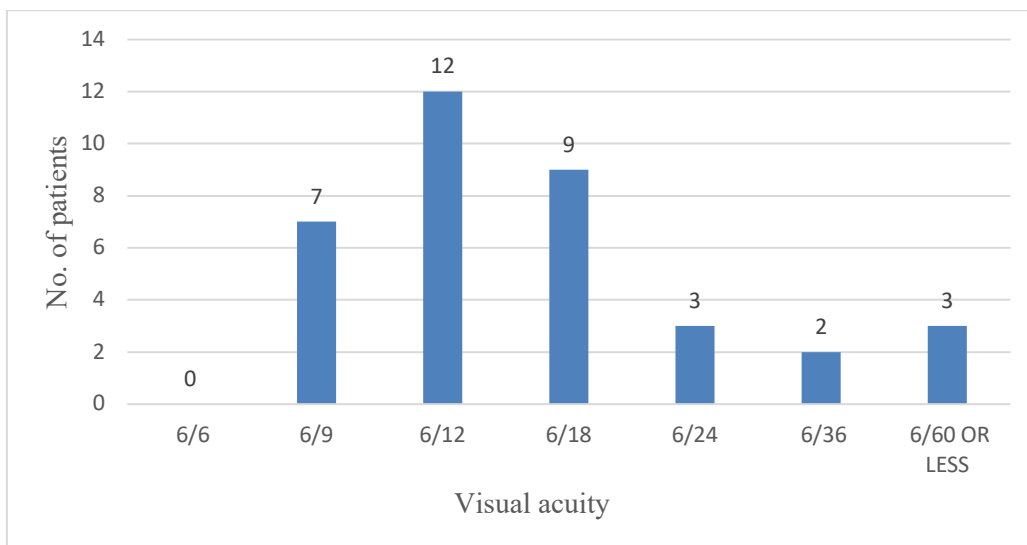
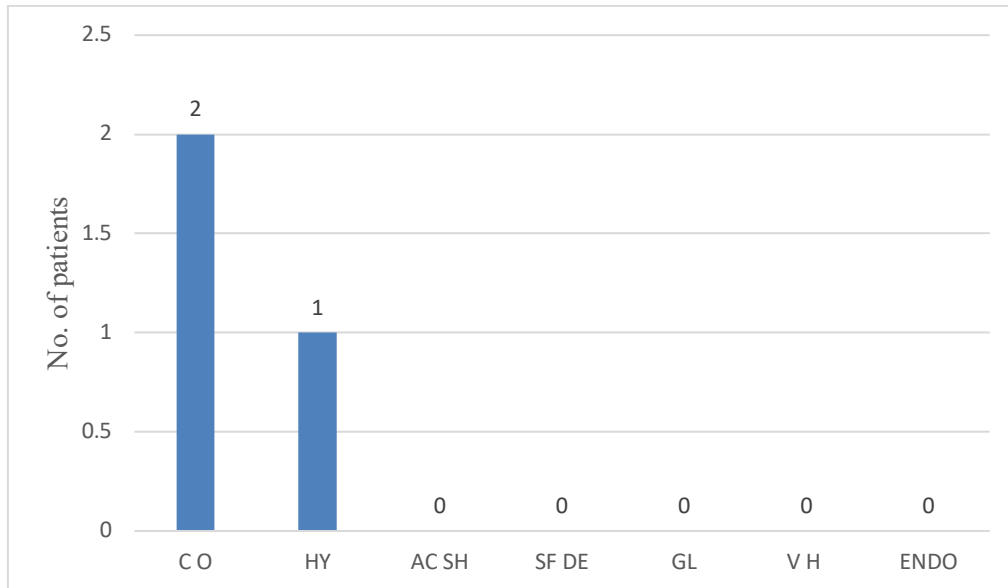


Figure 11:

Table 9: Complication profile 4 weeks Post-operatively

Complication	No. of patients	Percentage (%)
Corneal Oedema	2	5.55 (%)
Hyphema	0	0(%)
AC shallow	0	0 (%)
SFIOL Decentration	0	0 (%)
Glaucoma	0	0 (%)
Vitreous Hemorrhage	0	0 (%)
Endophthalmitis	0	0 (%)

**Figure 12:**

Discussion

In our study, total 36 patients taken for SFIOL implantation because of intolerance of contact lens and/or spectacle correction. Various designs and fixation sites have been introduced for the correction of aphakia, but the posterior chamber IOL has become clearly the treatment of choice nowadays.

In our study, 36 cases presented with monocular aphakia, traumatic subluxated or dislocated cataractous lens, subluxated or dislocated IOL. They were treated surgically with scleral fixated posterior chamber IOL(SFIOL) implantation.

In our study, the mean age of the patients is 61.63 years (range 21 to 90 years). Shweta Walia and Santosh Kashyap et al. describe Thirty eyes of 30 patients completed the study (mean age 54.20 years) with a mean follow-up of 3 months. [19] In Shin Yamane et al. study among 35 eyes of 34 patients completed the study (mean age 67.8 year) with mean follow up of 10 months. [20]

Jiannan Liu, Wenxue Fan et al. describe 68 eyes of 66 patients completed the study (mean age 61 year [range 25-82 years]) with mean follow up of 10 months. [21] Ole Kjecha et al. describe 91 eyes of

81 patients completed the study (mean age 62 years) with mean follow up of 36 months. [18]

In a study of 82 eyes by McAllister AS, Hirst LW, 2011 the mean age at surgery was 62 years (range 15 to 97 years). [15] Mazhri ZU and Qadri WM et al. describe 50 eyes of 48 patients completed the study with mean age of 51 years (range 17-76 years). [14]

In our study 36 eyes of 36 patients completed the study mean age 61.63 years (range 21 to 90 years) with mean follow up of 1 months.

In our study, 75% of the patients were male and 25% were female (male to female ratio of 3:1) with mean follow up of 1 months. Shweta Walia and Santosh Kashyap et al. describe 30 eyes of 30 patients completed the study which had 60% and 12 were female [40%] with a mean follow up of 3 months. [19]

In Shin Yamane et al. study among 35 eyes of 34 patients completed the study (23 were male [67.64] and 11 were female [32.35%]) with mean follow up of 10 months. [20] Ole Kjecha et al. describe 91 eyes of 81 patients completed the study (41 were male [50.6%] and 40 were female [49.4%]) with mean follow up of 36 months. [18]

Jiannan Liu, Wenxue Fan et al. describe 68 eyes of 66 patients completed the study (47 were male [71.21%] and 19 were female [28.78%] with mean follow up of 10 months. [21] Mazhri ZU and Qadri WM et al. describe 50 eyes of 48 patients completed the study (35 were male [70%] and 15 were female [70]) with mean follow up of 21.4 months. [14]

In our study, 7 cases (19.44%) achieved BCVA of 6/9 and above. 13 cases (36.11%) had BCVA of 6/12. 11 cases (30.55%) had BCVA of 6/18. 2 cases (5.55%) had 6/24. 1 case (2.77%) had BCVA of 6/36 and only 2 cases (5.55%) had BCVA of 6/60 or less. Ghaeseminejad AK and Ahmadieh H reported the outcomes of trans-scleral fixation of PCIOL in 18 patients by a retrospective study. Postoperatively 9 cases (50%) had BCVA of 6/12 and above while 9 cases (50%) had a BCVA of below 6/12. [16]

In our study, 20 cases (55.55%) had BCVA of 6/12. 2 cases (5.55%) had 6/24. 14 cases (33.33%) had BCVA between 6/18 to 6/36 and only 2 cases (5.55%) had BCVA of 6/60 or less. Mazhri ZU and Qadri WM et al. describe 50 eyes of 48 patients completed the study with 36 cases (72%) had BCVA of 6/12 and above, 8 cases (16%) had BCVA between 6/18 to 6/36 and 6 cases (12%) had BCVA of 6/60 or less. [14] In our study, 36 patients who underwent scleral fixated IOL. 86.11% of patients achieved BCVA of 6/18 and above postoperatively. Singh PG & Tripathy SK retrospectively studied 21 patients who underwent scleral fixation of IOL. 77% of patients achieved BCVA of 6/18 and above postoperatively.

In our study, Decentration of IOL was noted in 1 Case (2.77%). Other complication like anterior uveitis, Retinal detachment or vitreous haemorrhage was not seen. Ghaeseminejad AK and Ahmadieh H reported the outcomes of transscleral fixation of PCIOL in 18 patients by a retrospective study. Early postoperative complications like uveitis were seen in 3 cases (16.7%) which improved with steroid treatment. Decentration of IOL was seen in 2 cases (11.1%). Retinal detachment developed in 1 patient (5.6%). 1 case (5.6%) had significant IOL tilting were seen in 3 cases (16.7%) which improved with steroid treatment. Vitreous haemorrhage was seen in 2 cases (11.1%) which resolved spontaneously. [16]

In our study, Early post-operative complications like transient corneal oedema were seen in 2 cases (5.55%). IOL decentration in 1 case (2.77%). 1 case (2.77%) had hyphema. Late postoperative complications were seen in 2 patients (5.55%) corneal oedema. No suture exposure or optic capture detected after 4 week follow up. Singh PG & Tripathy SK retrospectively studied 21 patients who underwent scleral fixation of IOL. 1 case

(4.5%) had intra operative vitreous haemorrhage. Early post-operative complications like transient corneal oedema were seen in 13 cases (59%). IOL decentration in 3 (13.6%). 1 case (4.5%) was seen to have hyphema and fibrinous reaction is seen in 2 cases (9%). Corneal oedema in 2 eyes (9%) and optic capture in 1 eye (4.5%). In our study, the main cause of reduced vision was corneal pathologies. Complications included striate keratopathy in 9 cases (25%), corneal oedema in 2 cases (5.55%), glaucoma in 2 cases (5.55%) and SFIOL decentration in 1 case (2.22%).

In case series published in ophthalmology 2008 by American academy of ophthalmologists, among the 25 eyes studied, best-corrected visual acuity (BCVA) improved postoperatively in 48% cases by 1 Snellen line. The main cause of reduced vision was corneal and retinal pathologies and amblyopia. Complications included transient intraocular haemorrhage in 13 eyes (52%), transient choroidal effusion in 2 eyes (8%), late endophthalmitis in 1 eye (4%), retinal detachment in 1 eye (4%), and late IOL dislocation due to breakage of polypropylene sutures after 7 to 10 years in 6 eyes (24%).

In our study, most serious complication was glaucoma which was occur in 1 case (2.22%), in which no prior history of glaucoma was present. In a retrospective analysis carried out by Kjekka, O. et al (2008), among the 91 eyes studied, the most serious complication was suprachoroidal haemorrhage, which occurred in two eyes. They concluded that secondary implantation of posterior chamber intraocular lenses with transscleral fixation is a reasonably safe procedure in adults, with relatively few serious complications. Even in patients with long term follow-up, suture breakage was not seen. [18]

In our study, hyphema was seen in 1 case (2.22%). Vitreous haemorrhage was not seen in any case. Vitreous haemorrhage (16%) and hyphema (10%) was the most common complication in Mazhri ZU and Qadri WM study. This was slightly higher compared to other studies. After modification of the technique by Basti et al, incidence was decreased from 20% to 13.3%. [14]

In our study, most common postoperative complication was striate keratopathy 9 cases (25%), followed by corneal oedema 2 cases (5.55%), AC shallow 2 cases (5.55%), glaucoma 2 cases (5.55%). In a case series carried out by Andrew S McAllister et al. among 82 eyes, most common postoperative complication was ocular hypertension (25 eyes [30.5%]). Suture breakage occurred in 5 eyes (6%) after mean of 4.9 years. [15] In our study, among 36 eyes of 36 patients, SFIOL decentration was noted in 1 case (2.77%). No other complication like iris capture of IOL,

ocular hypertension and cystoid macular oedema were detected. In Shin Yamane et al. study among 35 eyes of 34 patient postoperative complications included iris capture of the IOL in 3 eyes (8.6%), transient ocular hypertension in 2 eyes (5.7%) and cystoid macular oedema in 1 eye (2.9%). No other complications, namely retinal detachment, endophthalmitis, IOL dislocation, or vitreous haemorrhage, were detected during the follow up period. [20]

In our study, among 36 eyes of 36 patients, corneal oedema was noted in 2 cases (5.55%), during follow up of 1 month which were resolved on subsequent follow up. Jian nan Liu, Wenxue Fan et al. describe 68 eyes of 66 patient postoperative complications included transient IOP rise (4.5%), hyphema (3%), vitreous hemorrhage (1.5%), macular edema (1.5%), hepatic exposure (3%), and pupillary capture (8.8%) detected during follow up of 3 months. [21]

Conclusion

In our study, scleral fixated intraocular lens implantation in the posterior chamber was found to have the following outcome:

- The proportion of males was higher than females.
- Maximum number of patients is found in the age group of 61-70 years followed by 51-60 years.
- Total 9 (25%) patients had history of trauma.
- One young patient (30 years) who had Marfan syndrome with supero-temporal subluxation of lens was operated with good surgical outcome.
- Scleral fixated intraocular lens implantation in the posterior chamber was a safe and effective method for correcting aphakia with a better visual outcome.
- It avoids the disadvantages associated with spectacles and contact lens usage like anisokonia, relative spectacle magnification (RSM), spherical aberrations, heavy lenses (glasses), visual field limitation.
- Scleral fixated intraocular lens implantation in the posterior chamber has less chances of complications like bullous keratopathy, UGH syndrome, iritis, CME etc, which were commonly seen in ACIOLs and iris fixated IOLs.

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