



## COMPREHENSIVE, PROSPECTIVE VIEW ON THE IMPLANTATION OF A SCLERAL FIXED INTRAOCULAR LENS AND ITS MORBIDITY.

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### ABSTRACT

When an intraocular lens is put in the PC, complications such as BK, ACAD, PBG, iris chafe, hyphema, uveitis and pseudophakodonesis may be avoided. TS were used to secure a PCIL in two surgical techniques. Here, inside & outside technique are used. As a consequence, we made the decision to look into the outcomes and complications of SFIOL surgery. SFIOL was shown to be a good and best therapy for improving visual rehabilitation and minimizing long-term issues in individuals with weak posterior capsular support after surgery or trauma.

**Keywords:** SFIOL, Outcomes Complications Intraocular Lens Inside & Outside Technique.

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### INTRODUCTION

Studies conclude that potential complications associated with the use of anterior chamber intraocular lenses (ACIOLs) comprise anterior angle glaucoma damage, pupillary block glaucoma and pseudophakodonesis. The proximity of ACIOLs to the cornea and ACA has the potential to exacerbate conditions such as BK, glaucoma, and PAS.<sup>1</sup> Scleral-fixated intraocular lenses (SFIOLs) have gained significant attention in the last ten years due to their independence from capsular support. Moreover, a SFIOL is a viable alternative for patients who encounter postoperative complications following the implantation of an ACIOL. Additionally, SFIOL is a feasible option for patients who are ineligible for ACIOL due to an abnormality in their iris or angle. In 1986, Malbran et al., were the first to investigate TS fixation of PCL as a treatment option for aphakic patients.<sup>2</sup>

Placement of an IL in the PC has been shown to prevent various complications such as BK, ACAD, PBG, IC, hyphema, uveitis, and pseudophakodonesis.<sup>3</sup> 2 surgical techniques have been described for TS to secure a PCIL.<sup>4</sup> Thus, we in our study we evaluate & examined postoperative outcomes & complications of SFIOL.

### AIM

To investigate and determine the results and complications of SFIOLs

### INCLUSION CRITERIA

1. Patients who underwent SFIOL implant in our hospital.

2. Patient of less than 25 years & more than 76 years.
3. Both male & female genders were included.

#### **EXCLUSION CRITERIA**

1. All ASP like CCO, glaucoma, uveities etc. affecting VO.
2. All PSP affecting visual function like MD, chorioretinal atrophy & complications.
3. Patients with systemic diseases affecting postoperatively.
4. Patients who get absent in any stage of investigation.

#### **MATERIALS & METHOD**

We have conducted our study in KIMS, Karad starting from October 2018 ending to May 2020 over a period of 18 months .

**STUDY TYPE-** Our study was prospective, interventional hospital based type of study.

#### **METHODOLOGY**

The study included patients with a h/o of OT resulting in CBR or difficult cataract surgery which results in aphakia & those who complete follow-up of 3 months. These include the patient's name, age, gender, address, duration of aphakia, h/o of trauma, any previous surgery & its specifics, any systemic diseases like DM, hypertension, BA, tuberculosis & epilepsy & test like CBC, RBS & BP. Further, all included patients were taken up for surgery after their systemic diseases had been controlled.

#### **PRE-OPERATIVE EVALUATION INCLUDES:-**

1. "Visual Acuity" using Snellen's distance was done for all patients.
2. **Slit Lamp(SL) Biomicroscopic Examination-** AS examination was done with SL. The presence of aphakia and status of capsular remnants and integrity of the posterior capsule was noted. Presence of any vitreous strands in pupillary area, anterior chamber or vitreous incarceration in scleral wound was noted. Pupillary abnormalities and posterior synechiae if present, was noted.
3. Measurement of IOP in all patients preoperatively.
4. **Fundus Examination-** Fundus examination with direct ophthalmoscope and indirect ophthalmoscope using +20 D lens was done to assess the peripheral retina.
5. **IOL POWER CALCULATION-** Keratometry was performed with Bausch and Lomb keratometer. Preoperative and postoperative Kh and Kv readings were taken. Axial length of the eye was taken with the help of „A“ scan. IOL power calculation was done using SRK-T formula.
6. Patients underwent for B scan and OCT whenever required.

#### **SURGICAL TECHNIQUE**

Two milliliters of xylocaine 2% and bupivacaine 0.75 percent hyaluronidase formed a peribulbar block (PB). Painting the eye area with the same solution after topical PI 5% drops After preparing the patient, a superior conjunctival peritomy was performed from 4 to 10 o'clock. A 3.2-mm triangular sclera flap filled the area after a 4.7-mm CS wound and complete anterior vitrectomy. Thick, rubbery AC and RPS. A straight 10-0 polypropylene suture was passed through one end of the sclera bed, 1 mm posterior to the surgical limbus,

parallel to the iris, and visible through the pupil. A 28-gauge hollow needle was passed through the 4-o'clock sclera bed to extract the straight needle from its barrel. Sinsky hooks removed the CS wound suture loops. The IOL's upper and lower eyelets were tied to the suture loop before trimming. A suture held the IOL in place. The scleral bed got a second 10-0 polypropylene suture before the first. The suture keeping the lens in place is tied to the other end of the polypropylene suture. The opposite end of the scleral bed experienced the same. A conjunctival peritomy and sclera flap were sutured.

Postoperatively treatment was given with topical Moxifloxacin 0.5 % + Dexamethasone 0.1 % eye drops (2 hourly) & followed up done for period of 3 months.

### POST-OPERATIVE EVALUATION

After 1 week, 1 month & 3 months all patients were re-examined. Patients were examined for best corrected VA using Snellen's distance and near VA charts, SL examination for wound approximation, corneal status, ACD ,reactivity & IP measurement. The fundus was examined using a slit lamp equipped with a direct ophthalmoscope, an indirect ophthalmoscope, and a +90 D lens. Both pre & post-operative keratometry (Kh and Kv) measurements were taken. Postoperative complications like corneal edema, striate keratopathy, anterior uveitis, increased intraocular pressure, IOL decentering, cystoid macular edema, vitreous hemorrhage, and retinal detachment were reported.

### RESULT

#### AGE

Age	Number	Percentage
Less than 25 years	2	2.99
26-35 years	1	1.49
36 to 45 years	6	8.96
46 to 55 years	10	14.93
56 to 65 years	32	47.76
66 to 75 years	14	20.90
More than 76 years	2	2.99
<b>Total</b>	67	100.00
<b>Mean age</b>	57.39 ± 12.67 years	

**TABLE 1 : AGE DISTRIBUTION.**

In our study we have found that , majority of patients (47.76%) belonged to the age group of 56–65, followed by 66–75 years (20.90%) and 46–50 years (14.93%). The patients had a mean age of 57.39 years, or 12.67 years.

**GENDER**

Gender	Number	Percentage
Male	40	59.70
Female	27	40.30
Total	67	100.00
M:F ratio	1:0.69	

**TABLE 2 : GENDER DISTRIBUTION.**

In our study we have found that , majority of patients were males (58.21%), while 40.30% were females. The M: F ratio observed in our study was 1:0.69

**LATERALITY**

LATERALITY	Number of subjects	Percentage
RIGHT	35	52.24
LEFT	32	47.76
TOTAL	67	100.00

**TABLE 3: LATERALITY**

In our study we have found that, right side was affected more (52.24%) when compared with left side (47.76%).

**DIAGNOSIS**

DIAGNOSIS	Right Eye		Left Eye	
	Number	Percentage	Number	Percentage
SA	27	40.3	17	25.37
SL	6	8.96	7	10.45
TA	2	2.99	2	2.99
TSL	1	1.49	6	8.96

**TABLE 4 : DIAGNOSIS**

In our study we have found that , surgical aphakia(SA) was the commonest finding (40.3% right sided & 25.37% left sided), followed by subluxated lens (SL) (8.96% right sided &10.45% left sided), traumatic aphakia(TA) (2.99% each left & right sided) and traumatic dislocated lens (TDL) (1.49% right sided & 8.96 % left sided).

**VISUAL ACUITY  
PRE-OPERATIVE BCVA**

BCVA	Preoperative	
	Number	Percentage
6/6	0	0.00
6/9	0	0.00
6/12	0	0.00
6 / 18	3	4.48
6 / 24	26	38.81
6 / 36	10	14.93
6 / 60 or less	28	41.79
<b>Total</b>	67	100.00

**TABLE 5 : PRE-OP BCVA**

In our study we have found that, majority of the patients was less than 6/60 (41.79%), followed by 6/24 (38.81%) patients, 6/36 (14.93%) patients & 6/18 (4.48%) patients.

**Kh& Kv VALUE**

KERATOMETRY	Preoperative		Post-operative		Significance
	Mean	SD	Mean	SD	
<b>Kh value</b>	43.12	1.58	44.40	1.93	t is 3.515422. <b>p is 0.0008.</b> p < .05.
<b>Kv value</b>	43.60	1.47	45.35	1.56	t is 6.462354. <b>p &lt; 0.00001.</b> p < .05.

**TABLE 6: Kh & Kv Value.**

In this study we have assessed preoperatively and postoperatively Kh and Kv values & found that kn value showed stastically insignificant result (Mean ±SD) & Kv showed stastically significant result (Mean±SD).

**CORNEAL ASTISMATISM (CA)WITH AXIS**

CA	Preoperative		Post-operative	
	Mean	SD	Mean	SD
A	1.29	1.47	1.76	1.50
AXIS	85.88	57.98	108.05	57.48
Significance	The value of t is 3.423012. The value of <b>p is 0.00107.</b>			

**TABLE 7: PRE-OP & POST-OP AA.**

In our study we have found that , mean pre-op A (1.29±1.47), while mean post-op A(1.76±1.50). We have analyzed levels with student t test showed stastically significant at p < 0.05.

**CA FROM KERATOMETRY(K) READINGS WITH AXIS**

ASTIGMATISM	Pre –operative		Post-operative	
	Number	Percentage	Number	Percentage
ATR	23	34.33	22	32.84
OBL	11	16.42	9	13.43
WTR	29	43.28	30	44.78
NIL	4	5.97	6	8.96
Total	67	100.00	67	100.00
Significance	The chi-square statistic is 0.6392. The p-value is 0.887409.			

**TABLE 8: CA READING WITH AXIS.**

In our study we have found that , MCA of the study participants was evaluated through the estimation of K values with the axis, allowing for the determination of the type of corneal astigmatism present. Preoperative astigmatism was observed in 29 cases exhibiting with-the-rule (WTR) , 23 cases displaying against-the-rule (ATR) & 11 cases manifesting oblique OBL. The results of the postoperative examination revealed the presence of 30 cases of WTR, 22 cases of ATR & 9 cases of OBL .Result showed non significany at p < .05

**POST-OPERATIVE BCVA ;DAY1**

BCVA	Post-operative Day 1	
	Number	Percentage
6/6	0	0.00
6/9	0	0.00
6/12	10	14.93
6 / 18	22	32.84
6 / 24	14	20.90
6 / 36	7	10.45
6 / 60 or less	14	20.90
<b>Total</b>	67.00	100.00

**TABLE 9 :POST-OP BCVA**

In our study we have found that, post-op BCVA was improved to 6/18 (32.84%), followed by 6/24 (20.90%) patients, 6/12 (14.93%) patients, less than 6/60 was observed (20.90%) patients.

**POST-OPERATIVE COMPLICATION :DAY1**

POST-OPERTAIVE COMPLICATIONS	Day 1	
	Number of subjects	Percentage
C E	42	62.69
S K	8	11.94
A U	2	2.99
CME	1	1.49
R-IOP	1	1.49
ERM	0	0.00
RD	0	0.00
NIL	12	17.91

**TABLE 10: POST-OP : DAY 1**

In our study we have found that ,for day 1 postop,common complications were corneal edema (CE) (62.69%), striate keratopathy (SK) (11.94%), anterior uveitis(AU)2.99%, cystoid macular edema (CME) & raised (R) IOP(1.49%) patients.

**POST-OPERATIVE BCVA :1 WEEK**

BCVA	Post-operative	
	Number	Percentage
6/6	0	0.00
6/9	8	11.94
6/12	23	34.33
6 / 18	18	26.87
6 / 24	13	19.40
6 / 36	3	4.48
6 / 60 or less	2	2.99
<b>Total</b>	67	100.00

**TABLE 11 : POST-OP : WEEK 1.**

In our study we found that ,there was an improved for 6/12 (34.33%), followed by 6/18 (26.87%) patients, 6/24 (19.40%) patients & 6/9 (11.94%). Less than 6/60 was observed (2.99%) patients.

**POST-OPERATIVE COMPLICATION: 1 WEEK**

POST- OPERATIVE COMPLICATIONS	1 week	
	Number of subjects	Percentage
CE	24	35.82
R-IOP	4	5.97
SK	3	4.48
AU	2	2.99
CME	1	1.49
ERM	0	0.00
RD	0	0.00
NIL	31	46.27

**TABLE 12 : POST-OP : WEEK 1 (OUTCOME)**

In our study we have found that , commonest complications were CE (35.82%) cases, followed by R- IOP (5.97%) cases, SK (4.48%), AU (2.99%) cases and CME (1.49%) cases.



**POST-OPERATIVE BCVA : 3 WEEKS**

BCVA	Post-operative	
	Number of subjects	Percentage
6/6	0	0.00
6/9	22	32.84
6/12	25	37.31
6 / 18	12	17.91
6 / 24	4	5.97
6 / 36	2	2.99
6 / 60 or less	2	2.99
<b>Total</b>	67	100.00

**TABLE 13 : POST-OP :WEEK 3.**

In our study we have found that ,improvement seen in 6/12 (37.31%), followed by 6/9 (32.84%) patients, 6/18 (17.91%) . Less than 6/60 was observed (2.99%) patients.

**POST-OPERATIVE COMPLICATION : WEEK 3**

POST- OPERATIVE COMPLICATIONS	3 weeks	
	Number of subjects	Percentage
CE	6	8.96
R-IOP	6	8.96
CME	3	4.48
AU	2	2.99
SK	1	1.49
ERM	1	1.49
RD	0	0.00
NIL	46	68.66

**TABLE 14 : POST-OP :WEEK 3 ( OUTCOME).**

In our study we have found that , commonest complications were CE and R-IOP (8.96%), followed by CME (4.48%), AU (2.99%), SK & ERM (1.49%) patients.

**POST-OPERATIVE BCVA : 3 MONTH**

BCVA	Post-operative = 3 months	
	Number of subjects	Percentage
6/6	0	0.00
6/9	37	55.22
6/12	13	19.40
6 / 18	8	11.94
6 / 24	1	1.49
6 / 36	5	7.46
6 / 60 or less	3	4.48
<b>Total</b>	67	100.00

**TABLE 15 : POST-OP : 3 MONTHS.**

In our study we have found that, improvement seen at 6/9 (55.22%), followed by 6/12 (19.40%), 6/18 (11.94%) patients. Less than 6/60 was observed (4.448%) patients.

**POST-OPERATIVE COMPLICATION : 3 MONTHS**

POST- OPERATIVE COMPLICATIONS	3 months	
	Number of subjects	Percentage
CME	9	13.43
R-IOP	6	8.96
A U	2	2.99
RD	2	2.99
ERM	1	1.49
S K	0	0.00
C E	0	0.00
NIL	46	68.66

**TABLE 16: POST-OP : 3 MONTHS.**

In our study we have found that , commonest complications were CME (13.43%) R-IOP (8.96%), followed by A U & R D (2.99%) & ERM among (1.49%) patients.

## DISCUSSION

Various studies have proved that , secondary implantation of IL in PC has been considered as safe & effective technique for patients with ICS following CS , S or ADL following trauma, CVD or pseudo exfoliation.

### AGE

In our study all 67 patients were selected for SFIOL implantation . So, the mean age we obtained was  $57.39 \pm 12.67$  years. Another similar study showed the mean age group of patient as 76.7 years.<sup>5</sup>

### GENDER

In our study, 39 patients were males & 27 were females .

### LATERALITY

We found that, both eyes were equally affected.

### DIAGNOSIS

Aphakia (65.67%) followed by SL (19.41 %), TSL (10.45%) & TA (5.98%).Furthermore, patients undergone secondary procedure & traumatic patients undergone for primary procedure. A study done by lee et al there were total of 30 patients (54.5%)in primary group & 25 patient (45.5%) in secondary SFIOL group .<sup>6</sup>

### VISUAL ACUITY

39 patients pre-operative VA showed between 6/36 to 6/18 & 28 patients showed VA 6/60 & less.

### CA FROM KERATOMETRY(K) READINGS WITH AXIS

The preop (A) mean was  $1.29 \pm 1.47$ , whereas the postop(A) mean was  $1.76 \pm 1.50$ . The difference between pre & post-operative MCA was statistically significant ( $p = 0.00107$ ). WTR accounted for 43.28 percent of cases preoperatively, followed by ATR (34.33%) and OBL (16.42%). Following surgery, we discovered that (44.78%) patients had WTR, (32.84%) had ATR & (13.43%) had OBL.

### Postoperative BCVA

Despite signs of a change from one type of (A) to another, the overall distribution of CA has remained quite steady. Postoperative BCVA improved to 6/9–6/12 (46.27%) patient, followed by 6/18–6/36 (50.75%) & 6/60 in (20.99%). There were 74.62 patients with 6/9–6/12 VA at 12 weeks, 20.89% with 6/18–6/36 & 4.48% with less than 6/60.

### POST-OP VISUAL ACUITY

After 12 weeks of follow-up, the removal of secondary problems leads to improved VA. In 17.91% of cases, the postoperative period was uneventful. The most prevalent postoperative complications were CE (62.69%), SK (11.94%), AU (2.99%), CME (1.49%), and raised IOP (1.49%).

### COMPLICATION (>3 months)

The frequency of complications has decreased since the early postoperative period. After 12 weeks, 68.66% of patients showed no signs of post-operative complications; however, 13.43% of patients experienced CME and 1.49% experienced ERM, both of which were treated medically. The initial event that led to capsular support failure and the subsequent SF were both linked to vitreous loss in all cases. Six patients (8.96%) had an elevation in IOP for one week; these cases were successfully treated with antiglaucoma medications. In two cases

(92.9 percent), transient AU in SFIOL was treated with steroids and topical cycloplegics. Two cases (2.99%) underwent RD 3 months after surgery as a result of posterior SF implantation and subsequent RD surgery. In any of the patients, there were no severe complications such as endothelial decompensation, vitreous or suprachoroidal hemorrhage, IOL displacement, IOL tilt, or endophthalmitis.

## **COMPARISON WITH PREVIOUS STUDIES**

### **VISUAL ACUITY**

We found that, post-operative outcomes can be corrected by VA after placement of SFIOL i.e. 6/12 in 50 (74.62%) patients. Another similar study, which we can use as comparative study to that of our study reported best corrected VA of 6/12 or better in 19 (76%) out of 25 patients.<sup>6</sup> Ghanem and colleagues reported postoperative BCVA of 6/9 or better in 10 (71.43%) out of 14 eyes undergoing scleral fixation of IOL.<sup>7</sup> Similarly, another study reported the improvement of postoperative BCVA 6/12 or better in 14 eyes (93.3%) undergoing SF of IOL.<sup>8</sup>

### **COMPLICATIONS**

In our study, early post-op complications were CE (62.69%), SK (11.94%) with persistence of CE in 6 Patients (8.96%) after 3 weeks. No IOL decentration or hyphema noted. Furthermore, according to Lin et al., transient CE occurred due to high or low IP, VL, fluid stream during AV, or postoperative AU.<sup>9</sup>

In our study, increase in IOP for 6 patients (8.96%) at 1 week with no h/o of glaucoma. In McAllister AS et al., incidence of post-op OH was 30.5%, 44% patients showed h/o of glaucoma.<sup>10</sup> In our study, CME was 13.43% end of (12 weeks) which was treated with topical NSAIDs & steroids. Another similar study which compared ciliary sulcus and pars plana locations for PCIOLs, here, CME was seen in 29% ciliary sulcus PCIOL group & 6.8% in pars plana PCIOL group and total incidence in both the groups were 5.1%.<sup>11</sup> In our study, 2 patients (2.99%) showed RD in 3 months postop which was managed surgically.

### **LIMITATION OF STUDY**

Our study does not analyze visual outcomes & complications of primary & secondary separately. Further to assess the best achievable results further long term follow ups are required.

### **CONCLUSION**

We conclude that, SFIOL has been a good and effective method for improving VR.

### **REFERENCE**

1. Lorente R, de Rojas V, de Parga PV, Moreno C, Landaluce ML, Domínguez R, Lorente B. Management of late spontaneous in-the-bag intraocular lens dislocation: retrospective analysis of 45 cases. *Journal of Cataract & Refractive Surgery*. 2010 Aug 1;36(8):1270-82.

2. Malbran ES, Malbran Jr E, Negri I. Lens guide suture for transport and fixation in secondary IOL implantation after intracapsular extraction. *International ophthalmology*. 1986 May;9(2-3):151-60.
3. Shrestha C, Shrestha S, Manoranjan A. Visual outcome following scleral fixated intraocular lens implantation. *Medical Journal of Shree Birendra Hospital*. 2017 Dec 23;16(2):63-8.
4. Can E, Başaran MR, Gül A. Scleral fixation of a single-piece multifocal intraocular lens. *European journal of ophthalmology*. 2013 Mar;23(2):249-51.
5. Kwong YY, Yuen HK, Lam RF, Lee VY, Rao SK, Lam DS. Comparison of outcomes of primary scleral-fixated versus primary anterior chamber intraocular lens implantation in complicated cataract surgeries. *Ophthalmology*. 2007 Jan 1;114(1):80-5.
6. Lee VY, Yuen HK, Kwok AK. Comparison of outcomes of primary and secondary implantation of scleral fixated posterior chamber intraocular lens. *British journal of ophthalmology*. 2003 Dec 1;87(12):1459-62.
7. Ghanem VC, Ghanem EA, Ghanem RC, Arieta CE. Monoscleral fixation of IOL after extracapsular extraction of subluxated lenses in patients with Marfan syndrome. *Arquivos Brasileiros de Oftalmologia*. 2004;67:763-7.
8. Ozdek S, Sari A, Bilgihan K, Akata F, Hasanreisoglu B. Surgical treatment of hereditary lens subluxations. *Ophthalmic Surgery, Lasers and Imaging Retina*. 2002 Jul 1;33(4):309-13.
9. Lin CP, Tseng HY. Suture fixation technique for posterior chamber intraocular lenses. *Journal of Cataract & Refractive Surgery*. 2004 Jul 1;30(7):1401-4.
10. McAllister AS, Hirst LW. Visual outcomes and complications of scleral-fixated posterior chamber intraocular lenses. *Journal of Cataract & Refractive Surgery*. 2011 Jul 1;37(7):1263-9.
11. Ma DJ, Choi HJ, Kim MK, Wee WR. Clinical comparison of ciliary sulcus and pars plana locations for posterior chamber intraocular lens transscleral fixation. *Journal of Cataract & Refractive Surgery*. 2011 Aug 1;37(8):1439-46.