



VISUAL OUTCOMES AND COMPLICATIONS OF SFIOL IN APHAKIC PATIENTS- AN OBSERVATIONAL STUDY.

Dr. Chitra Pande*

MS, Sr. Oculoplasty Consultant, Mahatme Eye Bank Eye Hospital, Run By SMM Eye Welfare Charitable Trust, Nagpur. *Corresponding Author

Dr. Milind L Sonone

MBBS, MS, DOMS, Mahatme Eye Bank Eye Hospital, Run By SMM Eye Welfare Charitable Trust, Nagpur.

Dr. Ketaki Ingle

MBBS, DNB. Mahatme Eye Bank Eye Hospital, Run By SMM Eye Welfare Charitable Trust, Nagpur.

ABSTRACT

PURPOSE: To study the Visual outcomes and complications in patients with secondary scleral fixated intraocular lens implantation. **METHODS:** It is a prospective, hospital-based observational study from July 2018 to May 2019. 37 Patients who undergone scleral fixated intraocular lens were included after informed consent & statistical analysis was done with the help of JASP 0.8 and MICROSOFT-Excel 2013. **RESULTS:** Out of 37 cases, 70% were male and 30 % were female. Mean Pre-operative BCVA (LogMAR) (within range of 0.6 to 1) was 0.89 ± 0.14 . On first post-operative day the mean BCVA logMAR 0.70 ± 0.19 which was statistically significant ($P < 0.001$). Similarly at the end of 1 week, 4 weeks, 3 months and 6 months, the post-operative mean BCVA improved to logMAR 0.65 ± 0.18 , 0.53 ± 0.13 , 0.36 ± 0.13 and 0.30 ± 0.16 respectively. 32.43% patients had post-operative astigmatism of 1.75. The mean astigmatism was 1.63 ± 0.34 which was statistically significant ($P < 0.001$). **CONCLUSION:** Scleral fixated posterior chamber intraocular lens implantation technique is safe and effective method.

KEYWORDS : Sfiol, Vitrectomy, Intraocular Lens, Aphakia, Cataract

INTRODUCTION

Surgery for cataract has undergone drastic refinements over the last century. Pioneers in the field continue to introduce and propagate newer technique of cataract surgery and intra ocular lens implantation. Ideally, surgical extraction of lenticular material and intraocular lens (IOL) placement in a bag, with good centration is done as a single procedure, even in difficult situations like traumatic cataract and subluxated cataract with insufficient capsular and zonular support as well as in cases with accidental posterior capsular rupture. But in certain situations, despite of all efforts primary implantation cannot be possible. In such aphakic cases because of following perceptual and refractive problems there is need for secondary implantation.¹

Aphakic spectacles give a limited field of vision with a roving ring scotoma & image enlargement. Contact lens intolerance in cases of persons with physical disabilities like elderly individuals, people with tremors and other physical disabilities which make handling and use of contact lens difficult.

There are several ways to proceed with secondary IOL implantation, such cases are anterior chamber intra ocular lens implantation, Iris claw intra ocular lens implantation and Scleral fixated intraocular lens implantation.

Implantation of an IOL into the anterior chamber (ACIOL) is associated with complications such as corneal decompensation, iris ischemia, hyphema, iritis, secondary glaucoma or cystoid macular edema.¹

Implantation of both anterior and retropupillary iris claw lens are associated with complications, like secondary glaucoma, corneal edema, shallow AC, hyphema, dislocation, pupil distortion, vitreous haemorrhage, IOL decentralization and endophthalmitis.² SFIOL is an attracting alternative to patients with contraindications to ACIOL and iris or angle abnormality. They offer good visual outcome and good anatomical results with relatively low complication rate.

A study done by Malbran et al in 1986 in aphakic eyes showed transcleral sulcus fixation of posterior chamber IOLs after intracapsular cataract extraction (ICCE).³ PCIOL's made specifically for suturing to sclera have eyelets on haptic to aid fixation, and a large diameter optic (7mm) to compensate for possible decentration. Scleral fixation of PCIOL can be done by two techniques: Ab- Externo and Ab- Interno. Ab-Interno technique is associated with more complications and less favourable visual outcome compared to Ab- Externo technique.⁴ As there are few published randomised control trials on

scleral fixation techniques in aphakia, in this research work, we tried to study the safety, efficacy, postoperative visual outcome and complication rate in cases where scleral fixated posterior chamber intraocular lens implantation to be done in aphakic patients coming to tertiary eye centre in central India.

METHODS

It was a prospective, hospital based Observational clinical study conducted during July 2018 to May 2019 in Mahatme Eye Bank and Eye Hospital, Nagpur. We studied the secondary scleral fixated intra ocular lens implantation in 37 patients over a period of 6 months. Informed consent was obtained from the patient after explaining the necessity of the surgery, complication likely to occur and prognosis about the visual outcome.

Age group of 18-75 years of both sex, patients with surgical aphakia with inadequate capsular support due to posterior capsular rupture in small incision cataract surgery or Phacoemulsification surgery, Traumatic aphakia and subluxation of lens was the inclusion criteria.

Patient having no perception of light, patient with the only eye, surgical aphakia with decompensated corneas, aphakic patients with posterior segment pathologies like cystoid macular oedema, choroidal neovascular membrane, etc and age group < 18 years were excluded. Patients underwent scleral fixated intraocular lens implantation 4 weeks after the primary surgery. All patients were thoroughly investigated and underwent secondary scleral fixated lens implantation.

Pre-operative visual acuity, BCVA in logMAR, IOP by applanation tonometer, slit lamp examination, gonioscopy and B-scan were recorded. Recording of Post-operative best corrected visual acuity (BCVA), IOP, keratometry and complications encountered were noted at regular follow-up of 7 days, 6 weeks, 3 months & 6 months. All surgeries were performed by senior surgeon who had 5 or more years of experience.

Data analysis was done with the help of JASP 0.8 and MICROSOFT-Excel 2013. Quantitative data was presented with the help of mean, standard deviation and median. Wilcoxon Signed Rank test and other non-parametric tests were performed. Further data was plotted in histograms.

RESULTS

Maximum number of patients were in the age group of 61 to 75 years i.e. 40% patients belonged to this age group (Table 1). The mean age of

patients in our study was 55 ± 11 years.

Table 1: Age wise distribution of subjects

Age Grp (years)	No. of patients	Percentage (%)
18-30	01	2.7 %
31-45	07	18.9%
46-60	14	37.8%
61-75	15	40.5%
Total	37	100%

Out of 37 cases, 70% were males and 30 % were females. Thus in this study male dominated with Male: Female ratio of 2.36: 1.

Maximum numbers of cases among the male were found in 61-75 years age group (46.15%), whereas among female maximum cases were found in 46-60 years age group (45.45%). The minimum numbers of cases were found in 18-30 years age group in both male and female.

Scleral fixation of intra-ocular lenses was done. 56.75% patients were of accidental posterior capsule rupture during routine cataract surgery. 24.32% cases were of subluxated cataract followed by cases of traumatic cataract (18.91%).

Etiology of subluxated cataract includes, trauma (44.44%), hyper-mature shrunken cataract and morgagnian cataract (22.22%) each and remaining (11.11%) the cause was undetermined. Pre-operative uncorrected visual acuity (LogMAR) was 2.1 ± 0.27.

Table 2: Postoperative BCVA (in LogMAR) at various follow up times

Sr. No.		Preoperative BCVA	Postoperative BCVA	P Value*
1.	At postop Day 1	0.89± 0.14	0.7± 0.19	<0.001
2.	At postop week 1		0.65±0.18	<0.001
3.	At postop week 4		0.53±0.13	<0.001
4.	At postop Month 3		0.36±0.13	<0.001
5.	At postop Month 6		0.3±0.16	<0.001

*Wilcoxon Signed rank test

The Post-operative visual acuity was checked by Snellen chart and converted to logMAR. On first post-operative day, the mean BCVA logMAR was 0.70 ± 0.19, which was statistically significant (P<0.001) (Table 2).

Similarly at the end of 1 week, 4 weeks, 3months and 6 months, the post-operative mean BCVA improved to 0.65 ± 0.18, logMAR 0.53 ± 0.13 logMAR, 0.36 ± 0.13 logMAR and 0.30 ± 0.16 logMAR respectively. The difference between BCVA at these followup periods and preoperative BCVA was statistically significant (P<0.001 for all).

Mean preoperative BCVA was 0.89±0.14 while postoperative BCVA was 0.13 ± 0.16, which is statistically significant (P<0.001). The mean preoperative IOP was 17.3± 1.51 while postoperative IOP was 17.84± 2.28 which is statistically not significant. The mean preoperative astigmatism was 1.16 ± 0.32 while postoperative was 1.63± 0.34, which is statistically significant (P<0.001) (Wilcoxon Signed Rank test).

Table 3: Complications in study cohort

	Complications	Number of occurrences	%
Intraoperative	Vitreous Hemorrhage	0	0
	Vitreous Prolapse	0	0
Early Postoperative	Corneal Edema	9	24.3
	Raised IOP	12	32.4
	Shallow Anterior Chamber	3	8.1
	Hyphema	2	5.4
	Anterior Chamber Reaction	6	16.2
	Decentration of lens	4	10.8
	Dislocation of lens	0	0
	Hypotony	0	0
	Postoperative Vitreous Hemorrhage	2	5.4
	Endophthalmitis	0	0

Late Postoperative			
IOL Decentration	4		10.8
Optic capture	0		0
Sut.Granuloma	0		0
Pupillary Distortion	3		8.1
Vit. Hemorrhage	0		0
Persistent Uveitis	0		0
Retinal Detachment	0		0
Endophthalmitis	0		0
Cystoid Macular Edema	5		13.5
Secondary Glaucoma	3		8.1
Uveitis	0		0
IOL tilt	1		2.7
Sec. Glaucoma	3		8.1

In this study none of patient had intraoperative complications. In early post-operative complications, 32% patients had raised IOP which was control on short term anti glaucoma drug (Timolol E/D BD), 24% had corneal edema which subsides on subsequent follow up. 16% patients had anterior chamber reaction, 5% of patients had early post-operative vitreous haemorrhage which subsides.

In late post-operative complication, the 13.5% patients had cystoid macular edema which was responsible for low vision in that patients. 8.1% patients had pupil distortion and secondary glaucoma and 10.8% had IOL decentration (Table 3).

DISCUSSION

In our study secondary scleral fixation of posterior chamber SF-PC-IOL with vitrectomy, wherever indicated, was done. The technique used in the study was Ab-externo 2 point scleral fixation technique. All the patients were operated by the same surgeon, they were meticulously followed upto 6 months and the results were documented.

The mean age of patients in our study was 49.06 years. Maximum number of cases among the men (46.15%) were in the age group of 61to75 years, whereas among the women, 45.45% were in the age group of 46 to 60 years.

All eyes included in this study lacked the support of >270° of continuous lens capsule in which posterior chamber IOL implantation was not possible.

Of the total 37 patients, 15% of patients had posterior capsule rupture with intact hyaloid phase while 85% of patients had posterior capsule rupture with vitreous prolapse without entry of nuclear material into the vitreous. In later group we needed through anterior vitrectomy and in some cases pars plana vitrectomy to avoid vitreous incarceration into the wound and to prevent traction on the vitreous base. Vitrectomy was done with the help of Automated Vitrectomy probe.

Pre-operatively, the visual acuity was meticulously measured, so as to compare the post-operative BCVA after scleral fixated IOL implantation. Mean pre-operative BCVA logMAR was 0.89 ± 0.14.

Best Corrected Visual acuity was noted on the 1st post-operative day by Snellen chart. Similarly follow-up examinations were performed at 1 week, 6 weeks, 3 months & 6 month. At every consultation we measured BCVA and IOP, performed slit-lamp, bio-microscopy and fundus examination as well as at every examination centralization of IOL was also evaluated after full mydriasis.

In this study, BCVA on day one was logMAR 0.7 ± 0.19, which have p value <0.001. At the follow-up of 1 week, BCVA was 0.65±0.18 which was significant (p value < 0.001). At the subsequent follow up of 4 week BCVA was 0.53±0.13 having p value <0.001. At the follow up of 3 month BCVA was 0.36±0.13 and at 6 month the BCVA was 0.3±0.16 which was statistically significant (p value < 0.001).

Comparison of pre-operative and final post-operative BCVAs of these patients showed that BCVA improved post-operatively in all patients. Corneal edema, raised intra-ocular pressure and intra-ocular inflammation which were common in early post-operative period was responsible for reduced BCVA in initial follow-up. However on further follow-up, many of these patients improved as the corneal edema reduced and intra-ocular pressure & inflammation were controlled with medical management.

On further follow-up, some of our patients developed complications like Cystoid Macular edema (CME) & Secondary Glaucoma which were responsible for reduced vision at 3 months & 6 months post-operatively.

Our findings were compared with Chakrabarti A. et al.⁵ who reported post-operative BCVA of 6/6 to 6/12 in 75%, 6/18 to 6/60 in 12.5% & less than 6/60 in 12.5% of patients who underwent scleral fixation of PCIOL. The causes of poor vision were CME, Choroidal tear & Macular degeneration.

Pre-operatively 95% of our patients had astigmatism less than 1.0 D. On post-operative keratometric examination at 3 months, 82.5% of patients had astigmatism in the range of 1.0 D to 2.5 D. This was attributed to large section of 7 mm needed to insert SF-PCIOL having large optic size of about 6.5 mm. Monteiro M. et al.⁶ documented mean post-operative astigmatism of -2.42 D in fixation of rigid SF-PCIOL.

In our study all the patients had normal or controlled IOP before surgery. In the post-operative period all patients were put on prophylactic anti-glaucoma medications i.e. Tab. Acetazolamide 250 mg BD or TDS as required, along with Betaxolol eye drops for at least 15 days. In the early post-operative period, only 10% of our patients had transient rise of intra-ocular pressure. The anti-glaucoma drugs were probably the reason for less incidence of raised IOP in early post-operative period. Some of the Studies like Lee V.Y.W. et al., Chan C.C. et al. and Gondula B. et al. reported transient rise in IOP during early post-operative period in 38%, 17% and 30% cases respectively.^{7,8}

Lee V.Y.W. et al. found that there was a statistically significant higher complication rate in early post-operative period in the primary SF-PCIOL group. Study suggested that eyes undergoing primary SF-PCIOL implantation may have a greater risk of post-operative inflammation with associated complications like CME. They reported corneal edema in 76%, raised IOP in 38%, Hyphema & vitreous haemorrhage in 26% each.⁷ Similar, above said, difficulties were encountered in our study, and however our complication rate was much less and not comparable.

In our study the common late post-operative complications included Pupil distortion (8.1%), late secondary glaucoma (8.1%), cystoid macular oedema (CME) in 13.5%, IOL Tilt (2.7%) and IOL Decentration (10.8%). Post-operative Astigmatism in the range of 1.0 D to 2.5 D was observed in 82.5% cases undergoing secondary scleral fixation. Vision threatening complications like endophthalmitis & retinal detachment were not seen in any case.

CME was one of the complication affecting post-operative visual outcomes. CME occurs in eyes with ruptured anterior vitreous phase and vitreous prolapse into anterior chamber, requiring anterior vitrectomy during surgery.⁹ The peak incidence in CME occurs 6-10 weeks after surgery. However some authors have found that vitreous loss at cataract surgery predisposes to CME even after one year or more.⁹ Spontaneous resolution occurs in approximately 95% of uncomplicated cases, within 6 months. However sufficient vitreous cleaning during the surgery may help in reducing the chances of CME, thus giving favourable results.

We got Clinically Significant CME in 13.5% of our cases. When compared to other studies we found that CME was the leading cause of reduced BCVA in many of the studies. Nikica Gabric et al. documented CME in 16% cases,¹⁰ Lanzetta P. et al.¹¹ found CME in 30% cases while Chakrabarti A. et al.⁵ reported CME in 12% cases. On the other hand other authors like Lee V.Y.W. et al.⁷ reported CME in only 7% cases out of 30 cases of primary scleral fixation. Our results were comparable with those of Chakrabarti A. et al.⁵ & Lee V.Y.W. et al.⁷

Late secondary glaucoma was one of the significant complications in our study. It was noted in 3 eyes (7.5%) of our cases. Medical management was sufficient for control of raised intraocular pressure in all the 3 patients and none of them required any secondary surgery of glaucoma.

Lee V.Y.W. et al.⁷ documented late secondary glaucoma in 16% cases of SF-PCIOL implantation while Chan C.C. et al.⁴ reported this complication in 7% cases. Our results were comparable with Chan C.C. et al.⁴

In our study Pupil distortion was found in 8% of cases. Similarly Lee V.Y.W. et al.⁷ reported pupil distortion in 8% cases respectively. This complication was commonly associated with trauma.

Clinically significant IOL tilt is rare after trans-scleral IOL implantation. We could diagnose only one case of IOL tilt that was identified by bio-microscopic evaluation. We also got 4 cases of IOL decentration which was most probably because of laxity of suture tension. However this was not visually significant. Equal and adequate tension maintained at the suture help to prevent the IOL tilting.¹²

Hayashi K. et al.¹³ found that both IOL tilt and decentration were more common with the scleral-fixed IOL than with the "In-the bag" or "Out-of-bag" fixated IOLs. Holladay J.T.¹⁴ found that decentration greater than 1.0 mm causes radial astigmatism and tilt greater than 15 degrees cause common aberration that cannot be fully corrected with spectacles. Sharpe M.R. et al.¹⁵ documented one case each of IOL tilt & decentration (28%) in a study of 7 cases of SF-PCIOL implantation. Similarly Lee V.Y.W. et al.⁷ reported one case (3.3%) in his study.

It is acceptable to apply SRK II formula with a correction by 1.6 D to guarantee the postoperative emmetropia.¹⁶ Suto C et al.¹⁷ reported that power of the IOL should be decreased by 1.0 D if it is intended to be implanted into the sulcus or fixated trans-sclerally. In the present study, we have decreased the power of the IOL by 1D as the BCVAs improved postoperatively and the refractive error. When compared to other studies we found that CME was the leading cause of reduced BCVA in many of the studies. Nikica Gabric et al.¹⁰ documented CME in 16% cases, Lanzetta P. et al.¹¹ found CME in 30% cases while Chakrabarti A. et al.⁵ reported CME in 12% cases. On the other hand other authors like Lee V.Y.W. et al.⁷ reported CME in only 7% cases out of 30 cases of primary scleral fixation. Our results were comparable with those of Chakrabarti A. et al.⁵ & Lee V.Y.W. et al.⁷

Although there were no cases of suture exposure or erosion in our study at the follow-up of 6 months. Thus it was observed that Scleral fixated posterior chamber intra-ocular lenses provided acceptable visual acuity in most of patients. Intra-operative complications are rare, most of the early post-operative complications are transient & late post-operative complications are mostly responsible for deterioration of vision and need to be minimized. However the vision threatening complications are rare. We suggest, longer follow-up is necessary to document the long term outcome in such cases.

CONCLUSION

Scleral fixation intraocular lens implantation gives good visual outcome in patient of cataract with inadequate capsular support. Technique is difficult to master, but is generally safe and effective on short term follow up.

Conflict of Interest-No

REFERENCES

1. Evereklioglu C, Er H, Bekir NA, Borazan M, Zorlu F. Comparison of secondary implantation of flexible open-loop anterior chamber and scleral-fixed posterior chamber intraocular lenses. *Journal of Cataract & Refractive Surgery*. 2003 Feb 1;29(2):301-8.
2. Jayamadhury G, Potti S, Kumar KV, Kumar RM, Divyansh Mishra KC, Nambula SR. Retropupillary fixation of iris-claw lens in visual rehabilitation of aphakic eyes. *Indian J Ophthalmol*. 2016 Oct;64(10):743-6.
3. Malbran E.S, Malbran E.Jr, Negri I. Lens guide suture for transport and fixation in secondary IOL implantation after intracapsular extraction. *Int Ophthalmol*. 1986;151-60.
4. Chan CC, Crandall AS, Ahmed IK. Ab externo scleral suture loop fixation for posterior chamber intraocular lens decentration: clinical results. *J Cataract Refract Surg*. 2006 Jan;32(1):121-8.
5. Chakrabarti A, Gandhi RK, Chakrabarti M. Ab externo 4-point scleral fixation of posterior chamber intraocular lenses. *J Cataract Refract Surg*. 1999 Mar;25(3):420-6.
6. Monteiro M, Marinho A, Salgado-Borges J, Ribeiro L, Castro-Correia J. Evaluation of a new scleral fixation foldable IOL in the absence of capsule support. *J Fr Ophtalmol*. 2007 Oct;30(8):791-7.
7. Lee VY, Yuen HK, Kwok AK. Comparison of outcomes of primary and secondary implantation of scleral fixated posterior chamber intraocular lenses. *British journal of ophthalmology*. 2003 Dec 1;87(12):1459-62.
8. Bading G, Hillenkamp J, Sachs HG, Gabel VP, Framme C. Long-term safety and functional outcome of combined pars plana vitrectomy and scleral-fixed sutured posterior chamber lens implantation. *American journal of ophthalmology*. 2007 Sep 1;144(3):371-7.
9. Evans T, Wu L. Pearls in Cataract Complications; Vitrectomy In The Management Of Posterior Capsule Rupture. In: *Highlights of ophthalmology*. 2007. p. 11-2. (3592).
10. Gabric N, Henc-petrinoric L, Dekaris I. Complications following two methods of posterior chamber intraocular lens suturing. *Documenta ophthalmologica*. 1996 Jun 1;92(2):107-16.
11. Lanzetta P, Bandello FM, Virgili G, Crovato S, Menchini U. Is scleral fixation a safe procedure for intraocular lens implantation?. In *Macular Edema 2000* (pp. 113-120).

Springer, Dordrecht.

12. Nair. Make it simple with the W1713 suture. *Indian J Ophthalmol.* 2001 Dec 1;49(4):277.
13. Hayashi K, Hayashi H, Nakao F, Hayashi F. Intraocular lens tilt and decentration, anterior chamber depth, and refractive error after trans-scleral suture fixation surgery. *Ophthalmology.* 1999 May;106(5):878–82.
14. Holladay JT. Evaluating the intraocular lens optic. *Surv Ophthalmol.* 1986 Jun;30(6):385–90.
15. R Sharpe M, Biglan A, C Gerontis C. Scleral fixation of posterior chamber intraocular lenses in children. *Ophthalmic Surg Lasers.* 1996 Jun 1;27:337–41.
16. Lipatov DV. Assessment of the efficiency of different formulae applied to calculating the optic power of an intraocular lens in trans-scleral fixation. *Vestnik ofthalmologii.* 2003;119(6):33-5.
17. Suto C, Hori S, Fukuyama E, Akura J. Adjusting intraocular lens power for sulcus fixation. *J Cataract Refract Surg.* 2003 Oct;29(10):1913–7.