

Original Research Article

VISUAL OUTCOME PROFILE IN SUTURED SCLERAL FIXATED INTRA OCULAR IMPLANTATION

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Received : 18/06/2023
Received in revised form : 17/07/2023
Accepted : 30/07/2023

Keywords:
SFIOL, Ab-Externo, Aphakia, BCVA.

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DOI: 10.47009/jamp.2023.5.4.223

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5 (4); 1107-1111



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Abstract

Background: Aphakia means absence of lens. The condition was previously managed with high convex lenses or contact lenses. To evaluate long term outcomes and complications of sutured scleral-fixated foldable intraocular lens (IOL) implantation. **Materials and Methods:** It was a Retrospective study conducted in Department of Ophthalmology at Rajah Muthiah Medical College and Hospital, Annamalai University. Medical records of those consecutive 50 patients who were operated during the period of September 2019 to august 2022 were collected from medical record department of the institution and visual outcome was analysed. Patient's demographic data (age, gender, address, occupation) and history were all collected. SPSS was used for analysis. **Result:** Out of 50 cases most of the patients came under the age group 46-75 years (62%). The study has male preponderance. Pre operatively only 56% had BCVA of 6/12 or better whereas post operatively 84% had 6/12 or better. Of the 50 eyes 24 patients has normal other eye. Therefore majority of the patients seeking surgery were patients with monocular aphakia with good correctable vision. Fourteen patients with inadequate BCVA at 6 weeks improved to adequate BCVA at 6 months which may be due to resolving of chronic uveitis and vitreous hemorrhage and this was statistically significant. **Conclusion:** The technique of Ab-externo SFIOL implantation showed good visual outcome in the absence of serious complications.

INTRODUCTION

Aphakia means absence of lens (natural crystalline lens or artificial intra ocular lens). The condition was previously managed with high convex lenses or contact lenses. But those management has several limitations. Ahakic glasses are heavy and also the have many optical aberrations like spherical and chromatic aberrations, limited field of vision, prismatic effect like roving ring scotoma also it cannot be used for unilateral aphakia. Similarly contact lens has its own limitations like cumbersome usage, infections due to unhygiene and ignorance, allergy, high maintenance.^[1,2]

So in current era, after the advancement in secondary IOL implantation we can go for that option instead of burdening the patients. Current choices include implantation of an anterior chamber (AC) IOL, iris-fixed intraocular lens (IOL) (pre- or retropupillary),

sutureless intrascleral posterior chamber IOL fixation, and scleral-fixated IOL with sutures. Each technique offers unique advantages and disadvantages regarding surgical complexity, operative duration, and potential complications, and there is still no clear consensus on the optimal approach.^[3] But this scleral fixated IOL has more advantage of retaining the anatomical location as posterior chamber intra ocular lens we give more consideration for this procedure than other methods.^[4]

In order to reduce suture-related complications, some studies embedded the haptics of three-piece IOL into the scleral tunnel, but there are still some risks of postoperative hypotony, IOL slippage and lens deviation, Scleral tunnel rupture, insufficient haptic fixation power, and haptics distortion after surgery.^[5,6] Recently this method and propose a new named flanged IOL fixation technology which will greatly reduce the shortcomings of previous scleral

tunnel technology %.^[7] But in our study we have analysed the visual outcome and complications of Ab. Externo 2 point fixation of sutured scleral fixated intra ocular lens implantation.

MATERIALS AND METHODS

It was a Retrospective study conducted in Department of Ophthalmology at Rajah Muthiah Medical College and Hospital, Annamalai University, Chidambaram. Medical records of those consecutive 50 patients who were operated during the period of September 2019 to August 2022 were collected from medical record department of the institution and visual outcome was analysed. Patient's demographic data (age, gender, address, occupation) and history were all collected. SPSS was used for analysis.

and cases were selected on the basis of inclusion criteria and exclusion criteria of which inclusion criteria are 1. patients who had given written informed consent 2. post intracapsular cataract extraction aphakia complicated cataract surgery with posterior capsular dehiscence, 3. Subjects who have undergone lensectomy with posterior segment surgery 4. Traumatic subluxation / dislocation of crystalline / cataractous lens 5. Congenital conditions with subluxated / dislocated crystalline / cataractive lens 6. Subluxated / dislocated posterior chamber intraocular lens and exclusion criteria is 1. central corneal opacity, 2. glaucoma, 3. uveitis, 4. posterior segment diseases.

Methodology

Patient's demographic data (age, gender, address, occupation) and history were collected. Visual outcome at post operative day 1, day 7, 6th week and 6th month were noted and compared. Similarly intraoperative and post operative complications were all noted and analysed. Records of visual acuity, corneal clarity, IOP, best corrected visual acuity and complications noted from the record and those were analysed

Surgical Technique

The surgical procedure of transcleral sutured IOL fixation is performed under peribulbar block and facial block. Preoperative pupillary dilatation was achieved with 2% tropicamide with phenylephrine hydrochloride. The eye of the surrounding adnexa were cleaned with 5% povidone iodine solution. Wire speculum was used to separate eyelids. Superior rectus was sutured with bridle suture. Fornix based conjunctival flap was taken at 12'O' clock position. Partial thickness scleral tunnel created at 2mm above limbus. Ab externo approach will be done using straight needle Ethicon STC-6 or Alcon SC-5. After making partial thickness flap on 3 O clock position the straight needle is passed approximately 0.75 mm posterior to limbus through the tunnel. On other side at 9 O clock position hypodermic hollow needle of 25, 27 or 28 gauge should be passed. The straight needle is then negotiated through hollow hypodermic

needle. The hypodermic needle should be withdrawn with the straight needle inside it. Anterior chamber is entered and suture is taken out with hook, the suture is cut and end is tied to eyelet of the IOL haptics. IOL is inserted behind iris by pulling the sutures from either side. The polypropylene suture knot should be buried to avoid irritation and suture related endophthalmitis. Scleral flaps will be used to cover the knots. If possible the knot will be buried in the sclera. Conjunctival flap will be repositioned. The posterior chamber IOLs used for scleral fixation should be of large diameter optics (7mm) and haptics should have eyelets. Commonly available scleral sutured IOLs are Alcon C270BD, Pharmacia U1528, ORC C540MC

Statistical Analysis

Means and standard deviations (SDs) of the quantitative variables were calculated. A paired t-test was used to detect differences in quantitative variables when data obeyed normal distribution; otherwise, the Wilcoxon matched-pairs signed ranks sum test was used. Differences were considered statistically significant if the P value was <0.05. All calculations were performed using SPSS software (version 24, SPSS, Inc.).

RESULTS

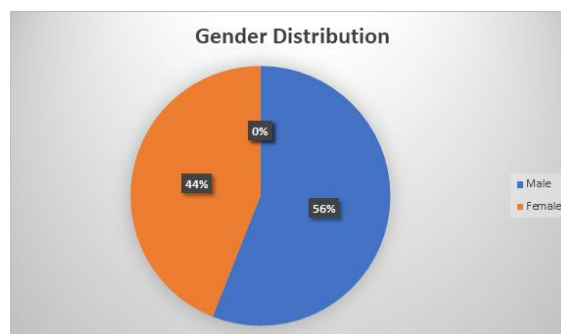


Figure 1: Gender wise distribution

As per [Figure 1] there is no gross difference in gender distribution. Male 56% female 44%

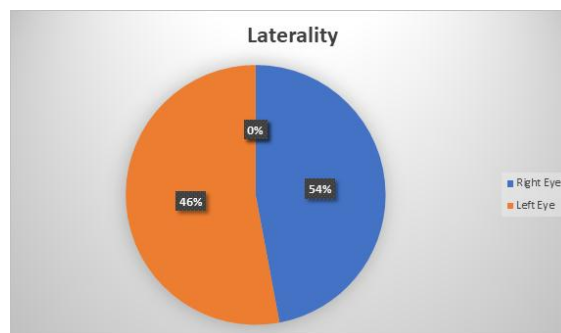


Figure 2: Laterality distribution

There is no significant difference in laterality also since both eyes are equally operated. Laterality Right eye 54% left eye 46%

Table 1: Age wise distribution of study participants

Age distribution in years	Number	Percentage
0-15	1	2
16-30	3	6
31-45	10	20
46-60	15	30
60-75	16	32
>75	5	10

As per [Table 1] out of 50 cases most of the patients come under the age group 46-75 years (62%). And least common age group was 0-30 years (8%).

Table 2: Visual Acuity Pre and Post BCVA

Visual acuity	Pre-Operative BCVA		Post Operative BCVA	
	No.	%	No.	%
6/6	1	2	1	2
6/9	7	14	22	44
6/12	19	38	19	38
6/18	23	46	2	4
6/24	-	-	4	8
<=6/60			2	4

Pre operatively only 56% had BCVA of 6/12 or better whereas post operatively 84% had 6/12 or better.

Table 3: Intraoperative and Post-Operative Complications

Serial No.	Intra-OP		Post-OP	
	Complications	No.	Complications.	No.
1.	Vitreous hemorrhage	3	Astigmatism	12
2.	Hyphaema	4	Uveitis	8
3.	-	-	CME	4
4.	-	-	IOL decentration	2
5.	-	-	Suture Erosion	2

As per [Table 3] intra operatively 3 patients had vitreous hemorrhage of which 1 patient had unresolved hemorrhage leading to inadequate visual recovery. Similarly post operatively cystoid macular edema hinders the visual recovery rest of the complications remains treatable. Most common post-op complication was Astigmatism.

Table 4: Pre and Post-Operative BCVA at 6months

Pre operative BCVA	Post operative BCVA at 6 months			P value
	Adequate	Inadequate	Total	
Adequate	28	0	28	0.02
	100%	0%	100%	
Inadequate	14	8	22	
	63.6%	36.4%	100%	
Total	42	8	50	
	84%	16%	100%	

14 patients with inadequate preoperative BCVA improved to adequate BCVA at 6 months and it was statistically significant.

Table 5: Comparison between 6 weeks and 6 months Post-Operative BCVA

Post operative BCVA at 6 weeks	Post operative BCVA at 6 months			P value
	Adequate	Inadequate	Total	
Adequate	28	0	14	0.02
	100%	0	100%	
Inadequate	14	8	22	
	63.6%	36.3%	100%	
Total	42	8	50	
	84%	16%	100%	

As per [Table 5] fourteen patients with inadequate BCVA at 6 weeks improved to adequate BCVA at 6 months which may be due to resolving of chronic uveitis and vitreous hemorrhage and this was statistically significant.

Table 6: Comparison between 1st Day and 6 weeks Post-Operative BCVA

1 st Post operative day BCVA	Post operative BCVA at 6 weeks			p-value
	Adequate	Inadequate	Total	
Adequate	12	0	12	0.01
	100%	0	100%	
Inadequate	16	22	38	
	42.1%	57.9%	100%	
Total	28	22	50	
	56%	44%	100%	

As per [Table 6] comparisons between 1st post-operative and 6 weeks post-Operative was significant. Around 56% patients were adequate and 44% were inadequate as per post-operative BCVA.

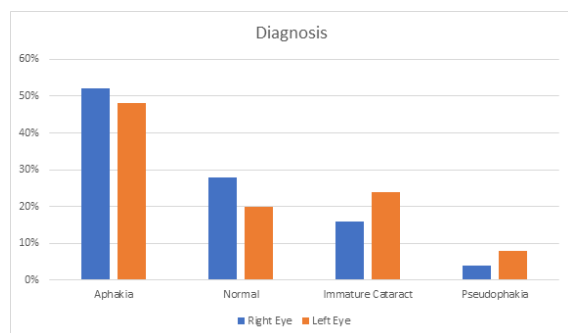


Figure 3: Diagnostic distribution in patients

As per [Figure 3] of the 50 eyes 24 patients has normal other eye. Therefore majority of the patients seeking surgery were patients with monocular aphakia with good correctable vision.

DISCUSSION

Average age at the time of surgery was 48 (range 13-83) yrs.

Han Zhao et al conducted a retrospective study from 2010 to 2018 in which they had early post operative complications of transient elevated intraocular pressure (IOP) in one eye (1.4%), and hypotony in three eyes (4.3%) and the Late postoperative complications included persistent elevated IOP in five eyes (7.2%), epiretinal membrane formation in three eyes (4.3%),^[4] and cystoid macular edema noted in one eye (1.4%) whereas in our study vitreous hemorrhage 3(6%), hyphaema 4 [8%] was noted as intra operative complications and astigmatism 12[24%], uveitis 8[16%], cystoid macular edema 4[8%], IOL decentration 2[4%] and suture erosion 2[4%] was noted. The present study didn't have any record of late complications like epiretinal membrane which might be due to non availability of any records after 6 months followup.

Retrospective study conducted by Kokame et al had the mean best-corrected visual acuity (BCVA) improvement from 0.83 ± 0.69 logarithm of the minimum angle of resolution (logMAR) at baseline to 0.50 ± 0.45 log MAR at the last follow-up visit. There was improved or unchanged BCVA in 44 eyes (84.62%) and reduced BCVA in 8 eyes (15.38%).^[5] Chakrabarti A conducted a prospective study in 82 eyes in which they have compared the visual outcome in ACIOL(41) and SFIOL(41) in which SFIOL group had visual outcome of BCVA of 6/6- 6/9 in 6(15%) patients, BCVA of 6/12- 6/18 in 21(51.2%) patients and 6/60 or worse in 14(34%) patients whereas our study has quite good visual outcome in comparing to above study.^[3]

Narain S et al conducted a retrospective study in 69 patients with SFIOL implantation following ocular trauma the results in BCVA preoperatively seem to

be 0.79 ± 0.86 log of the minimum angle of resolution (logMAR), which improved 0.20 ± 0.26 log MAR postoperatively ($P = 0.01$). BCVA improved or remained unchanged in 64 eyes (92.8%), VA decreased two lines in five eyes (7.2%).^[7] This results are quite similar to our study result also.

Ghanem VC et al conducted a study in which Twenty-eight patients were included with mean age of 42 years (Range 10-70). At the end of 3 months, majority of the patients, 18(60%), had visual acuities of 6/12 or better with astigmatism as most common complication, vitreous haemorrhage was seen in 4 (13.2%) eyes, IOP surge was noted in 6 (20%) eyes and Corneal decompensation in 1 eye (3%).^[8] This results is quite similar with our result in terms of age and complications especially vitreous hemorrhage and astigmatism but we have better visual outcome than their study.

Study conducted by Sasahara M et al had Best corrected pre-operative BCVA in the range of 6/24 to 6/18 (53.33%), 6/12 to 6/9 (16.66%), 6/60 to 6/36 (30%). In our study 6/6 to 6/9 in 20%, 6/12 to 6/18 in 80%. At final follow-up of 6 months, their results were, 63.33% in range of 6/12 to 6/9, 26.66% in 6/24 to 6/18 and 10% in 6/60 to 6/36.⁹ In our study the 6 month post operative BCVA was 6/6 - 6/9 in 48% of patients and 6/12 - 6/18 in 40% of patients and 12% of patients has visual acuity of 6/24 or less.

In a prospective study conducted by Shresta C et al found to have Best corrected visual acuity were 6/6 - 6/18 in 86.9% (n=20), 6/24 - 6/60 in 8.7% (n=2) and worse than 6/60 in 4.3% (n=1) at six months follow up^[6] whereas the present study had better visual outcomes

Evereklioglu C conducted a retrospective study in which the most common complication during surgery was hemorrhage 20/57 cases (35.08%)^[7] whereas in the present study astigmatism (24%) was the most common complication. Rest of the complications like uveitis and CME had similar prevalence with our study. This might be due to mild IOL tilt contributing to the astigmatism as a consequence of 2 point fixation technique

Kanigowska K et al showed mild intraoperative intravitreal hemorrhage was in 3 eyes (5.77%). Early postoperative complications included transient elevated intraocular pressure (IOP) in 5 eyes (9.62%) and hypotony in 1 eye (1.92%). Long term complications includes secondary epimacular membrane in 5 eyes (9.62%) and retinal detachment (RD; 3 years postsurgery), subconjunctival suture knot exposure (5 years postsurgery), and persistent elevated IOP (in a GRAVES patient) occurred in 1 eye (1.92%) each.^[11] These complications are quite contradictory to our complications which might be due to long term follow up and case selection in their study which was the limitation in our study.

CONCLUSION

The technique of Ab-externo SFIOL implantation showed good visual outcome in the absence of serious complications. The outcomes and safety profile of SFIOL implantation is valuable for the management of aphakia in the absence of capsular support. However, long-term suture related problems should be discussed with the patients before surgery.

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