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Original article

Visual Outcomes of Scleral Fixated Rigid and Foldable Intraocular Lens Implantation in eyes with Absent Capsule support: A Prospective Comparative Clinical Study

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Abstract

Scleral fixation of Intraocular lenses (IOLs) is the suitable technique of placing the lenses when the capsule bag is damaged or absent. The choice ofrigid polymethyl methacrylate (PMMA) posterior chamber intraocular lenses (PCIOLs)in the most widely used lenses but it comes with certain limitations. Large corneoscleral incision of approximately 8 mm and utilisation of large instruments during the PMMA implantation often increase the risk of anterior chamber collapse and vitreous haemorrhage. Foldable Intraocular lens is the preferred choice for transscleral fixation since smaller incisions of approximately 3.2 mm are enough to implant the lens thus leading to minimal trauma in the cornea. Very few comparison studies have been carried out between scleral fixation of rigid PMMA lenses and foldable lenses in eyes devoid of capsule support. Thus, the present study compares the visual outcomes of scleral fixated rigid PMMA lenses and two types of foldable lenses (hydrophilic acrylic and hydrophobic acrylic) in order to get an insight about the better lens option for scleral fixation in eyes of patients lacking capsule support. This is a prospective comparative clinical study where a total of 45 patients without capsule support were divided into three groups and each group underwent scleral fixation with one group fixing rigid PMMA, one group fixing hydrophilic acrylic lens and the other group with hydrophobic acrylic lens fixation.Both rigid and foldable single piece trans-scleral fixation procedures were safe, efficacious and provided considerable improvement in Best Corrected Visual Acuity(BCVA) in the post-operative period for achieving fairly good visual recovery in eyes with absent or insufficient capsular support.

Keywords: *Cataract, Intraocular lens, Polymethyl Methacrylate, Foldable lens, Capsule support*

Introduction

Cataract surgery is essentially placing Intra Ocular Lens (IOL) inside the capsular support. This placement gives good refractive results and enables faster visual recovery. Also, this procedure gives stability, correct placement and optical alignment.But often the capsular support is lost due to several conditions such as lens dislocation in the vitreous chamber, posttraumatic cataract surgery, pseudo exfoliation, and Marfan and Ehlers–Danlos syndromes [1]. In circumstances of compromised capsular support, other ways of creating lens support becomes necessary to prevent cataract complications like glaucomatous damage.

In order to overcome this issue, Scleral fixation of intraocular lens (SFIOL) emerged as the alternative procedure [2]. Polymethyl methacrylate (PMMA) is an inert, non-biodegradable polyacrylate which is commonly used material for IOL cataract surgery. However, certain limitations such as rigidity, non-foldableness, and the inability to pass through smaller corneoscleral incisions make them less opted material. PMMA IOL employment in surgery sometimes might lead to posterior capsule opacification [3]. The employment of PMMA IOL also increases the chances of complications like anterior chamber collapse, choroidal or vitreous hemorrhage, and surgically induced astigmatism.

Latest advancements in the cataract surgery lens technology have led to the development of foldable IOLs. Foldable IOLs come in many types. This type of lens has certain advantages such as creation of smaller

incisions in the sclera, minimal risk of complications because of the surgery, less induced astigmatism [4]. The post operative vision recovery happens earlier as compared to rigid PMMA's postoperative visual recovery duration. The corneal architecture is also preserved in case of foldable IOL lens surgery.

Latest trends in the field of sutureless intrascleral fixation techniques—such as the Yamane flanged method and fibrin glue-assisted intrascleral haptic fixation—has given many options to the type of fixation technique to be used in surgery. A systematic review provides the increasing interest in the employment of sutureless techniques, which gave rise to faster visual rehabilitation and minimal post operative surgical trauma to the eye [5]. A case series explained that the surgery of foldable three-piece acrylic IOLs by sutureless option showed considerable safety and there were little postoperative complications which are most common. These were vitreous hemorrhage (20 %), pressure spikes (15 %), and hypotony (10 %) [6]. Another study by Bedda etal. after six months, sclerally fixated three-piece foldable IOLs showed less complications and axial stability didn't get altered [7, 8].

So, the aim of the study is to compare the visual outcomes of rigid PMMA and foldable hydrophilic and hydrophobic acrylic Intra Ocular lens without capsule support in order to better understand which type of lens gives better centration, minimal post operative complications to the eyes and faster visual rehabilitation.

Materials and Methods

This is a prospective randomized comparative clinical interventional study conducted in Meenakshi Medical College Hospital and Research Institute. Patients were selected from Aphakic patients who attended Ophthalmology OPD based on the inclusion and excusion criteria. Totally 45 patients were selected and divided into three groups (power- 0.70, effective size-0.60, Critical F-2.065). Each group consists of 15 patients during the year of 2023-2024. In this present study was approved by Institutional Ethical committee. Detailed informed consent from the entire patients undergoing surgery was obtained.

BY USING BLOCK RANDOMIZATION METHOD, the patients were randomly assigned to 3 groups with 15 patients in each group.

Group A underwent rigid polymethylmethacrylate lens implantation

Group B underwent hydrophobic acrylic single piece lenses implantation

Group C underwent hydrophilic acrylic single piece lenses implantation

All the surgeries were performed by single surgeon.

In this method prior randomization of the three techniques among the total 45 cases was done by the statistician and the type of technique to be done for each case was placed in a sealed cover. Either the rigid PMMA lens implantation or hydrophobic acrylic lens implantation or hydrophilic acylic lens implantation was done on each case based on the type of technique specified in the sealed cover which was shown to the surgeon just before the surgery. By this randomization technique the type of surgery to be done for each case was decided only at the time of surgery and hence the bias towards choosing a case was avoided.

PREOPERATIVE CONSIDERATIONS:

Detailed assessment included thorough medical history & complete eye examination including Best Corrected Visual Acuity by Snellens and LogMAR charts, slit lamp examination, evaluation of anterior segment, IOP measurement with Goldman applanation tonometry, Keratometry, Pachymetry, Fundus examination, Biometry by A scan and axial length measurement. B mode USG was done to rule out posterior segment ocular pathologies.IOL power calculations were done using regression/ theoretical formulas.

INTRAOPERATIVE CONSIDERATIONS:

All procedures were done by a single surgeon. Patients' pupils were dilated fully prior to the surgery. The surgeries were done under peribulbar anaesthesia.Patients received the 3 types of SFIOL according to their respective groups. The characteristics of the types of IOL used are:

1. Rigid PMMA IOLs :

• Refractive index of 1.49
• Optic diameter : 6.5 mm
• Overall diameter of IOL : 13 mm
• Model : modified C loop lenses

2. Hydrophobic acrylic single piece foldable IOLs :

• Refractive index of 1.47
• Overall length of IOL: 12.5 mm

• Optic diameter : 6 mm
• Haptic design: force enduring haptics

3. Hydrophilic acrylic foldable IOLs :

• Refractive index of 1.43
• Double haptic designs, biconvex optic
• Optic diameter : 6 mm
• Overall diameter of IOL : 12 mm

INTRAOPERATIVE PARAMETERS STUDIED ARE:

• length of incision made
• operative time
• intraoperative complications

POST OPERATIVE FOLLOW UP:

Patients were assessed on day 1 for any immediate complications like hyphaema, inflammation, or suture related problems. All the Patients received standard post operative regimen. They were then examined on day 7 for early post operative complications (<1 month) like sutural erosions, endophthalmitis, IOL rotation/ tilting, optic capture. Then the patients were examined in 1st month, 3rd month and 6th month for late post operative complications (>1 month) which were rare like CME, RD etc. At each visit, measurement of Best Corrected Visual Acuity, slit lamp biomicroscopy for the position of IOL & inflammatory signs, Intraocular pressure measurements, keratometry readings were assessed.

Patients' symptoms were analysed subjectively by questionnaire assessment of pain, photophobia, FB sensation, itching, stinging, burning etc. signs are looked in for in slit lamp examination like conjunctival congestion, corneal edema, Descemet membrane folds, anterior hamber flare and cells, hyphaema, IOL position, centration, vitreous complications, choroidal and retinal detachment.

The Post operative changes in astigmatism were analysed with refraction and keratometric measurements at all the visits which was compared with preoperative mean values.

The spherical equivalent refraction (SE) is equivalent to the average refractive powers in both the meridians. It was calculated by

SE= spherical power + cylindrical power/2 .

For example: if the refraction value was +1D Sphere -3.00D cylinder*90 degrees; the SE should be calculated by 3 simple steps:

• Ignore the axis-90 degrees
• Divide the cylinder power by 2; -3.00/2= -1.50.
• Add to the spherical power; +1-1.50= -0.50 which is the spherical equivalent.

METHODS FOR STATISTICAL ANALYSIS: Data was analyzed using SPSS Version 20.0. Both descriptive and inferential data were statistically analysed. To test the significant difference between pre and post operative measurements in each group "paired"'t' test was used. Analysis Of Variance (ANOVA) was used to test the significant difference among three groups. P value was obtained; it was statistically significant when $P<0.001$.

Results

We conducted a prospective comparative clinical interventional study where we divided a total of 45 patients into three groups, 15 patients in each group.

Group I received implantation of rigid Polymethylmethacrylate (PMMA) intraocular lenses.

Group II received implantation of hydrophobic acrylic foldable lenses.

Group III received implantation of hydrophilic acrylic lenses.

The visual outcomes and the complications of the 3 groups were studied.

The results of the study are as follows:

Table 1: Mean Age distribution of study participants in three intraocular lenses(IOL) groups

Age Group in Years	RIGID PMMA			HYDROPHOBIC ACRYLIC			HYDROPHILIC ACRYLIC		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
40-49	1	45	2.07	1	49	00	1	45.0	00
50-59	6	53.5	2.75	5	54.6	0.89	1	57.0	00
60-69	6	62	0.71	6	63	3.46	10	63.0	2.86
70 above	2	74	8.33	3	72	2.64	3	76.33	1.52

The range of age in this study was 45- 78 years.

In group I, 1 patient was between 40-49 years, 6 patients were between 50-59 years, 6 patients were between 60-69 years, 2 patients were between 70-79 years.

In group II, 1 patient was between 40-49 years, 5 patients were between 50-59 years, 6 patients were between 60-69 years, 3 patients were between 70-79 years.

In group III, 1 patient was between 40-49 years, 1 patients was between 50-59 years, 10 patients were between 60-69 years, 3 patients were between 70-79 years.

As a whole, in the 45 patients, the hydrophilic acrylic foldable IOLs were implanted more in the age groups of 60-69 years. (66.6%)

Table 2. Mean value of preoperative Best Corrected Visual Acuity(BCVA) among three groups

Groups	N	Mean	SD
RIGID PMMA	15	.70	.11
HYDROPHOBIC ACRYLIC	15	.62	.12
HYDROPHILIC ACRYLIC	15	.60	.14
Total	45	.64	.13

The mean BCVA preoperatively was 0.70± 0.11 in group I ; 0.62± 0.12 in group II and 0.60 ±0.14 in group III which were comparable in the 3 groups.

Table 3. Mean preoperative Intra Ocular Pressure (IOP) among three groups:

Groups	N	Mean	SD	F value	Sig
RIGID PMMA	15	11.26	3.78	.402	.672
HYDROPHOBIC ACRYLIC	15	12.66	4.74		
HYDROPHILIC ACRYLIC	15	11.93	4.25		
Total	45	11.95	4.22		

The mean preoperative IOP in the 3 groups were 11.26± 3.78 in group I, 12.66± 4.74 in group II and 11.93 ±4.25 in group III which when compared within groups were comparable and not statistically significant when compared by ANOVA (P= 0.672).

Table 4. Mean value of postoperative BCVA in different time period among three Groups

BCVA	RIGID PMMA			HYDROPHOBIC ACRYLIC			HYDROPHILIC ACRYLIC		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
1 Day	15	1.0	0.28	15	0.91	0.42	15	0.87	0.15
1 Week	15	0.72	0.27	15	0.71	0.26	15	0.82	0.19
1 Month	15	0.58	0.23	15	0.57	0.17	15	0.67	0.18
3 Month	15	0.50	0.22	15	0.45	0.18	15	0.53	0.23
6 Month	15	0.44	0.21	15	0.31	0.09	15	0.47	0.21

The follow up in our study was 6 months. It was seen that upto postoperative week 1, there was no significant improvement in vision due to cornel complications and anterior chamber inflammation. At 1st month, there was considerable improvement in vision, unlike in week 1. After 1st month, vision improved significantly in almost all the patients and remained stable from 3rd month onwards.

Table 5. Mean comparison of Pre operative and 1 Week postoperative BCVA in three groups

Groups	BCVA pre Pre test		BCVA Post test		t value	Sig
	Mean	SD	Mean	SD		
RIGID PMMA	0.700	0.11	0.726	0.273	0.344	0.735
HYDROPHOBIC ACRYLIC	0.620	0.12	0.706	0.260	1.178	0.259
HYDROPHILIC ACRYLIC	0.600	0.14	0.653	0.216	0.738	0.473

The preoperative Best Corrected Visual Acuity(BCVA) was compared with the week 1 BCVA, it was observed that there was approximately a half to one line drop in the vision from 0.70± 0.11 to 0.72± 0.27 (P=0.735)in group I, 0.62± 0.12 to 0.70± 0.26 in group II(P=0.259), and from 0.60± 0.14 to 0.65 ±0.21 in group III(P=0.473). This was due to early postoperative complications like transient corneal edema, acute anterior chamber inflammation and vitreous hemorrhage. But there was no statistically significant drop in vision.

Table 6. Mean Pre operative and postoperative 6 months BCVA comparison in three groups

Groups	BCVA	N	Mean	SD	t value	Sig
RIGID PMMA	Pre op	15	0.70	0.11	3.81	0.00**
	6 Month	15	0.44	0.21		
HYDROPHOBIC ACRYLIC	Pre op	15	0.62	0.12	8.951	0.00**
	6 Month	15	0.30	0.08		
HYDROPHILIC ACRYLIC	Pre op	15	0.60	0.14	2.044	0.06
	6 Month	15	0.46	0.20		

The preoperative BCVA was compared with BCVA at six months to look for visual improvement. It was observed that the BCVA improved in all 3 groups in which group I had improvement from 0.70± 0.11 to 0.44± 0.21 (P=0.00) and group II vision improvement was from 0.62± 0.12 to 0.30± 0.08(P=0.00) which were statistically significant; group III had improvement from 0.60 ±0.14 to 0.46± 0.20 which was not statistically significant(P=0.06). The reason for this decreased vision was due to development of cystoid macular edema (CME) on long-term follow-up.

Table 7.Pre and Postoperative comparison of Mean Spherical Equivalent (SE) in three groups

Groups	SE Pre test		SE Post test		t value	Sig
	Mean	SD	Mean	SD		
RIGID PMMA	10.07	1.03	1.96	0.14	14.26	0.00**
HYDROPHOBIC ACRYLIC	10.46	0.92	1.64	0.074	29.52	0.00**
HYDROPHILIC ACRYLIC	10.16	1.59	1.71	0.17	19.82	0.00**

Table 7a. Comparison of postoperative SE in the three groups.

Groups	SE Post test		F Value	Sig
	Mean	SD		
RIGID PMMA	1.96	0.14	33.92	0.00**
HYDROPHOBIC ACRYLIC	1.64	0.074		
HYDROPHILIC ACRYLIC	1.71	0.17		

The mean preoperative spherical equivalent in group Iwas 10.16± 1.59; group II was 10.07± 1.03 and group III was 10.46 ± 0.92.

The mean postoperative spherical equivalent at the end of 6 months in the 3 groups were studied and they were 1.96 ± 0.14, 1.64± 0.074, 1.71± 0.17 respectively. The postoperative refraction at 6 months was statistically significant in all the 3 groups.

The mean postoperative spherical equivalent was compared between the three groups. There was statistically significant improvement in refraction in the foldable groups compared to the rigid groups postoperatively. (P=0.00).

Table 8. Mean value of postoperative Intra Ocular Pressure in different time period among three groups

IOP	RIGID PMMA			HYDROPHOBIC ACRYLIC			HYDROPHILIC ACRYLIC		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
Pre op	15	11.27	3.78	15	12.66	4.75	15	11.93	4.25
1 Day	15	14.40	6.74	15	11.97	4.86	15	14.00	6.25
1 Week	15	13.00	5.90	15	10.86	3.48	15	12.40	5.15
1 Month	15	12.60	5.42	15	11.13	2.95	15	10.80	3.68
3 Month	15	13.80	5.62	15	10.53	3.52	15	10.80	3.07
6 Month	15	13.93	5.20	15	9.48	0.81	15	11.53	3.73

The preoperative IOP was compared to the IOP at 6 months follow-up. The IOP was 11.27±3.78 in group I and 12.66±4.75 in group II and 11.93±4.25 in group III and at the end of six months IOP was 13.93±5.20 in group I and 9.48±0.81 in group II and 11.53±3.73 in group III.

Therefore, no statistically significant rise in intracellular pressures after scleral fixation in all 3 groups was noted.

Discussion

Optical rehabilitation of patients with monoocular aphakia pose a therapeutic challenge to the operating surgeon [9]. Various methods of treating aphakia should be considered as per the patients' needs. In view of high patient expectations after cataract surgery, the use of aphakic spectacles or contact lenses to treat aphakia is not considered ideal [10]. In the surgical correction of aphakia, the techniques are directed towards preserving the normal anatomy of the eye. So, trans scleral suturing of IOL is the best technique and it is considered to be safe for corneal endothelial integrity because the position is very close to the nodal point of the eye [11].

There are various techniques that have been reported for Trans scleral fixation. However, the procedure is very cumbersome to perform, particularly after a primary intraocular surgery was performed with a poorly constructed scleral tunnel/ premature entry was made [12]. Large incisions and manipulations in the anterior chamber can lead to intraoperative hypotony and vitreous haemorrhage. The frequent need to pressurize the globe with viscoelastics often makes the procedure more time consuming [12].

As the aim of this study was to study and compare 3 types of intraocular lenses, we divided the 45 patients into 3 groups of 15 patients each. They all underwent transscleral suture fixation of intraocular lenses.

Group I: Rigid Poly Methyl MethAcrylate(PMMA) lenses

Group II: Hydrophobic Acrylic single piece lenses

Group III: Hydrophilic Acrylic single piece lenses

The mean age in group I was 59.13 ± 8.33, group II was 61.06±7.62 and group III was 64.06 ± 8.25 which was comparable in the 3 groups. The mean age of 45 patients was 61.42 ± 8.15. A very similar age distribution was observed in various studies conducted. Taskapili et al showed a mean age of 25 patients to be 62.3 years [13]. Oh et al observed the mean age of 18 patients to be 58.2 years [11].Kaynak et al had a mean age of 20 patients to be 52.9 years [14].

The comparison of visual outcomes in the 3 groups was done by comparing the preoperative best corrected visual acuity (BCVA) with postoperative day 7 BCVA and 6 months BCVA. It was found that, at 1st week, the vision detoriated from 0.70± 0.11 preoperatively to 0.72± 0.27 at in group I(P=0.735), from 0.62± 0.12 to 0.70 ± 0.26 in group II(P=0.259), from 0.60 ± 0.14 to 0.82± 0.19 in group III(P=0.473). The drop in vision was 1-2 lines on snellen's chart, and was not statistically significant. The reason for decreased vision could be explained by presence of early postoperative complications like corneal oedema, acute iritis and vitreous haemorrhage at 1st week. Most of the complications resolved after the 1st week. BCVA at 1st month had considerable improvement from that of preoperative and 1st week BCVA. After 3rd month, vision improved and remained stable. Oshima et al have also done a comparison of BCVA at 1 week and then at 1 month. The BCVA was unchanged in 80% of patients at 1st week and 1st month as a result of the complications like secondary glaucoma and corneal oedema [15]. At the end of 6 months, BCVA improved in all the 3 IOL groups. The improvement noted in group I and group II was statistically significant(P=0.02 and P=0.00 respectively). In group III, the improvement in vision was not significant(P=0.06) due to development of cystoid macular oedema in these patients postoperatively. Very similar improvement of BCVA was present in various studies on SFIOL implantation: Oshima et al observed a good improvement in BCVA at 6 months [15].Jacobi et al had the mean preoperative vision to be 0.7 and postoperative improvement to 0.3 [12].Mutoh et al had their mean preoperative vision to be 0.62± 0.18 to 0.27± 0.42 at the end of 6 months [16].Kjeka et al evaluated the preoperative vision in their study to be 0.5 and postoperatively it improved to 0.3 [17].Lanzetta et al found that BCVA improved to 0.2 from 0.6 preoperatively with P<0.05 [18].

The improvement in BCVA after the surgery was evident from a statistically significant change in the refraction as expressed in mean spherical equivalent (SE) which improved from 10.16± 1.59 preoperatively to 1.96 ± 0.14 at 6 months in group I; from 10.07± 1.03 to 1.64± 0.074 at 6 months in group II and from 10.46 ± 0.92 to 1.71± 0.17 at 6 months in group III with P=0.00 in all the 3 groups.

The mean intraocular pressures (IOP) were examined and compared in the 3 groups preoperatively and at 6 months. There was no statistically significant rise in IOP in the 3 groups. Rho et al observed a reduction in IOP postoperatively in both rigid and foldable groups from 18.10± 4.63 to 17.36± 5.01 in rigid group, and from 17.00± 6.47 to 13.14± 5.10 [19].

The explanation for good postoperative IOP control in this study was due to good anterior vitrectomy with surgical peripheral iridectomy which was performed during SFIOL 8implantation. We also treated the patients with transient rise in IOP with antiglaucoma medications.

Conclusion

This study concluded that: Both rigid and foldable single piece trans-scleral fixation procedures were safe, efficacious and provided considerable improvement in Best Corrected Visual Acuity(BCVA) in the post-operative period for achieving fairly good visual recovery in eyes with absent or insufficient capsular support. However, when compared with conventional rigid scleral fixation intraocular lenses(IOL), both hydrophobic and hydrophilic foldable acrylic scleral fixation techniques provided with distinct advantage of working in closed chamber with small incision size and minimal vector forces needed for IOL centration with reduced

complication rate and early post-operative visual rehabilitation**.**Therefore, trans-scleral foldable IOL procedures are preferable, which offer encouraging visual results with low rate of complications and it remains as a better alternative to conventional rigid polymethylmethacrylate(PMMA) procedures.

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