

To Assess Visual Outcome and Complication After Implantation of Scleralfixated Intraocular Lens

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Abstract: This was a prospective study done on 25 patients with total absence of capsular bag & history of trauma leading to traumatic cataract, dislocated lens or complicated cataract surgery causing aphakia were included in the study which was conducted at Ophthalmology department of R.N.T Medical College, M.B Hospital, Udaipur from May 2019 to December 2020. These patients were assessed for visual outcome and complications after implantation of scleral- fixated intraocular lens (SFIOL). A detailed ocular examination was done for all patients. SFIOL implantation showed good visual outcome in absence of any complication.

Keywords: SFIOL, Ab-Externo, Aphakia, BCVA

Date of Submission: 05-07-2022

Date of Acceptance: 19-07-2022

I. Introduction

SFIOL is a standard procedure both in post-traumatic and post-operative aphakia. The status of posterior capsule after aphakia may vary from intact to partially deficient or totally absent. Thus, the technique of implanting intraocular lens may vary from putting the lens into the bag to suturing of IOL to iris or implantation in anterior chamber or posterior chamber¹. Scleral fixation offers more physiological position for IOL implantation. There are two surgical techniques for scleral fixation, namely Ab-interno (Inside out) and Ab-externo (Outside in). The Ab-interno technique involves the passage of needle from the inside of the eye to the outside through the sclera. Ab-interno is more complicated and blind technique. Abexterno fixation refers to scleral fixation in which sutures are passed from the outside to the inside of the eye.

Whereas early lens designs & fixation sites were associated with an unacceptably high rates of complications² IOL implantation to correct aphakia, provides good visual rehabilitation in comparison to spectacles or contact lenses. The development of safe, effective IOLs to eliminate the optical problem of aphakia is one of the great successes of modern ophthalmology³. Whereas early lens designs & fixation sites were associated with an unacceptably high rates of complications,^{2,4} modern posterior chamber IOLs have a track record of remarkable safety & provide excellent visual outcome after insertion into capsular bag or sulcus after uncomplicated cataract surgery⁵. When there's no capsular support, posterior chamber SFIOL is preferred over ACIOL which has complications like corneal endothelial damage, damage to anterior chamber structures, pupillary block glaucoma, hyphaema, uveitis, iris chafing, dislocation of IOL & pseudophakodonesis^{6,7}.

Implantation of posterior chamber SFIOL doesn't disrupts eye's anatomy, protects the integrity of anterior chamber, minimises uveal contact & its outcome is independent of presence of iris tissue⁸.

SCLERAL FIXATED INTRAOCULAR LENS IMPLANTATION –Gess⁹ first described scleral fixation of one haptic of a posterior chamber lens. In 1986, Malbran and colleagues¹⁰ described an open-sky technique for sutured PCIOLs, and in 1988, Cowden and Hu¹¹ reported secondary PC lens implantation with scleral fixation of both haptics through scleral stab incisions.

COMPLICATIONS OF SCLERAL FIXATION IOLs –

Despite its anatomic advantage, trans-sclerally fixated IOL is associated with complications primarily because of haptic contact with uveal tissue and the need for haptic fibrosis to ensure long-term stability. Even without suture fixation, sulcus placement of a lens implant carries the risks of lens decentration, pigment dispersion, uveitis, recurrent hemorrhage, ciliary body erosion^{12,13,14,15,16,17}, and, in one reported case, occlusion of the major arterial circle of the iris (located in the ciliary body), with devastating results. Trans scleral fixation introduces additional risks caused by needle penetration of uveal and scleral tissue, abnormal positioning of the haptic external suture exposure; these risks include lens tilt and decentration, lens subluxation, episcleritis, corneal decompensation, hypotony, PAS formation, secondary glaucoma, hyphema, vitreous hemorrhage, suprachoroidal hemorrhage, choroidal effusion, CME, RD, external suture erosion, and endophthalmitis^{18,19}.

II. Material And Methods

This was a prospective study done on 25 patients with total absence of capsular bag & history of trauma leading to traumatic cataract, dislocated lens or complicated cataract surgery causing aphakia were included in the study which was conducted at Ophthalmology department of R.N.T Medical College, M.B Hospital, Udaipur from May 2019 to December 2020. The detailed history of each patient was taken about any Systemic and other ophthalmic problems. Detailed ophthalmic examination was carried out including visual acuity using snellen's chart, anterior segment examination, IOP measurements by Goldmannapplanation, A scan, keratometry, detailed fundus examination with direct & indirect ophthalmoscope to rule out fundus pathologies. B scan and OCT was done whenever required. All the patients with history of trauma resulting in dislocated lens, subluxated lens, traumatic cataract or complicated cataract surgery resulting in aphakia were included in this study.

Those patients with significant ocular pathologies involving angle structure (glaucoma), corneal opacities, retinal pathologies like diabetic retinopathy, CRAO, Macular scar, diseases of optic nerve were excluded from the study.

In this study, total of 25 patients were included based on inclusion criteria. Pre operative evaluation in these patients includes visual acuity using snellen's chart, anterior segment examination, IOP measurements by Goldmannapplanation, A scan, keratometry, detailed fundus examination with direct & indirect ophthalmoscope to rule out fundus pathologies. B scan and OCT was done whenever required.

III. Observation

In our study, 9 patients were in the age group between 60-80 years, accounting for 36%. The mean age of patient was 65 years. There were 19 males & 6 females, accounting for 76% & 24% respectively. Right eye was affected more than the left eye accounting for 15 & 10 eyes respectively. The most common diagnosis at the time of presentation was traumatic cataract (36%) followed by post surgical aphakia (32%). The mean duration between trauma/cataract surgery & SFIOL was 4 months. In post surgical aphakia, majority of the patients had undergone SICS. In trauma group, blunt injury was the most common mode of injury in our study. In our study, 4 patients had undergone primary SFIOL & 21 had undergone secondary SFIOL. All post surgical aphakia patients had undergone secondary SFIOL.

TABLE 1 - PRE OPERATIVE IOP

PRE OP IOP	NO. OF CASES	%
<10 mmHg	4	16%
10 - 20mmHg	14	56%
20 -30mmHg	6	24%
>30mmHg	1	4%

In our study, 56% of patients had an normal IOP (10-20mmHg)

TABLE 2- PRE OP BCVA

PRE OP BCVA	NO. OF CASES	%
<6/60	23	92%
>6/60	2	8%

Pre operative visual acuity was measured in all the cases. Out of these 92% had visual acuity of <6/60 & 8% had visual acuity of >6/60

TABLE 3- POST OP BCVA AFTER A MONTH

POST OP BCVA (1MONTH)	NO. OF CASES	%
6/6 - 6/9	0	0
6/12	1	4%
6/18	7	28%
6/24	5	20%
6/36	7	28%

6/60	5	20%
<6/60	0	0%

In our study, BCVA of 6/18 was observed in 28% of cases after a month of surgery.

TABLE 4 - BCVA AT 6 MONTHS

POST OP BCVA (6MONTHS)	NO. OF CASES	%
6/6 - 6/9	0	0
6/12	8	32%
6/18	8	32%
6/24	6	24%
6/36	3	12%
6/60	0	0%
<6/60	0	0%

In our study BCVA of 6/12 was observed in 32% at 6 months of surgery

TABLE 5: COMPLICATIONS WITHIN 24 HRS POST OPERATIVELY

COMPLICATIONS	NO. OF CASES	%
AC reaction	11	44%
Increased IOP	9	36%
Corneal oedema	3	12%
Subconjunctival hemorrhage	1	4%
Hyphaema	1	4%
Vitreous hemorrhage	0	0%
AC leak	0	0%

In our study, majority of the cases had an anterior chamber reaction (44%) post operatively onday1.

TABLE 6: COMPLICATIONS WITHIN 24 HRS POST OPERATIVELY

COMPLICATIONS	NO. OF CASES	%
AC reaction	11	44%
Increased IOP	9	36%
Corneal oedema	3	12%
Subconjunctival hemorrhage	1	4%
Hyphaema	1	4%
Vitreous hemorrhage	0	0%
AC leak	0	0%

In our study, majority of the cases had an anterior chamber reaction (44%) post operatively onday1.

TABLE 7 - COMPLICATIONS AFTER 6 MONTHS OF SURGERY

COMPLICATIONS (6 MONTHS)	NO. OF CASES	%
Persistent uveitis	2	8%
Pupil deformation	2	8%
Suture erosion	1	4%
Glaucoma	0	0
Retinal detachment	0	0
Endophthalmitis	0	0

In our study, long term complications observed were persistent uveitis and pupil deformation

TABLE 8- COMPARISION OF VISUAL OUTCOME IN PRIMARY & SECONDARY SFIOL

SURGERY	NO. OF CASES	NO. OF CASES WITH VISION >6/18 (AFTER 6MONTHS)	%
PRIMARY SFIOL	4	2	50%
SECONDARY SFIOL	21	13	61.90%

In our study secondary SFIOL implantation was associated with significant visual outcome compared to primary SFIOL implantation with P value (0.661)

IV. Discussion

Pre operative intraocular pressure was normal in most of the patients (56%) as K/C/O glaucoma patients were excluded from the study. The pre operative visual acuity of <6/60 found in 92% in our study &>6/60 was found in 8% of the patients.

Immediate complications seen after surgery were, AC reaction found in 11 patients, raised intraocular pressure was found in 9 patients, corneal edema was found in 3 patients &subconjunctivalhaemorrhage&hyphaema was found in 1 each. Late complications seen in this study were, pupil deformation & persistent uveitis in 2 patients each & suture erosion in 1 patient. There were no cases of secondary glaucoma, retinal detachment, endophthalmitis or vitreous haemorrhage in our study as these were excluded from our inclusioncriteria.

Out of 25 patients, 10 patients (40%) had visual acuity of 6/60 on post operative day 1 followed by <6/60 in 6 patients (6%) & 6/24 in 4 patients (16%) & 6/18 in 3 patients (12%). The patients were followed up regularly on day 7, 1 month,3 months & 6 months later & checked for visual acuity & anterior segment examination. BCVA after 6 months was checked again after treating the post operative complications. BCVA of 6/12 & 6/18 was found in 8 patients each (32% each) followed by 6/24 in 6 patients (24%) & 6/36 in 3 patients (12%) Improvement in vision was due to treatment of complications followingsurgery.

COMPARISION WITH OTHER STUDIES

Chang and Lee²⁰ did a case series study of 18 cases of uncomplicated secondary suturing of scleral fixation IOL. Their study showed a Visual outcome of 20/40 or better in 14 (77.8%) and of 20/200 or worse in 3 (16.7%) of patients. Corneal edema was seen in 2 (11.1%) and Glaucoma escalation in 1 (5.6%). None of the patients had cystoid macular edema, retinal detachment and endophthalmitis. In our study 32% had BCVA of 6/12 and above .None had Retinal detachment, endophthalmitis or CME

Menezo et al^{21,22} did a case series study of 13 cases of uncomplicated secondary suturing of scleral fixation IOL. Their study showed a visual outcome of 20/40 or better in 10 (76.9%) and of 20/200 or worse in 2 (15.3%) of patients. Corneal edema was seen in 1 (7.6%) and Glaucoma escalation in 4 (30.7%). Cystoid macular edema was seen in 1 (7.6%). Lens tilt or dislocation was seen in 2 (15.3%) patients. Endophthalmitis was seen in 1 (7.6%). IOL decentration was seen in 1 patient in our series. Corneal edema was seen in the immediate postoperative period in 3 patients which resolved by two months.

V. Summary And Conclusion

In this study combined anterior vitrectomy and scleral fixated posterior chamber intraocular lens (SFIOL) implantation was found to have the following outcome:

1. Combined anterior vitrectomy and scleral-fixated sutured PC IOL implantation is an effective and safe procedure to correct aphakia in eyes without capsularsupport.
2. The most dreaded complication of retinal detachment, suture lysis and infection was not encountered.
3. Discomfort and anisekonion from wearing aphakic spectacles, and the devastating complications from ACIOL implantation (such as bullous keratopathy, glaucoma, CME etc...) are avoided with SFIOL implantation as there is anatomic placement of the IOL in the posteriorsegment.
4. If there is peripheral capsular support and an condensed anterior hyaloid phase a secondary PCIOL implantation can be tried .In a skilled surgeon it is a safer alternative than anSFIOL.

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