

Original article:

Post operative visual outcome and complications in patients undergoing secondary intraocular lens implantation by scleral fixation

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ABSTRACT:

PURPOSE The purpose of this study is to observe patients, undergoing secondary IOL implantation by scleral fixation, for post-operative visual outcomes and complications.

METHODS: This was a hospital based descriptive(observational) longitudinal study involving 70 eyes of 70 patients undergoing secondary intraocular lens implantation by scleral fixation, at Rural Medical College and hospital, Loni between September 2017 to August 2019. Aphakic patients with BCVA more the 6/60 on Snellen's chart were included. 56 out of 70 eyes underwent sutured scleral fixation and 14 out of 70 eyes underwent suture-less scleral fixation of lens. The post-operative visual outcomes and complications were analysed.

RESULTS: Out of 70 patients 42 were females (60%) with a mean age of 62.11±8.10 and 28 were males (40%) with a mean age of 62.21±13.03. There was significant post-op visual improvement after sutured and suture-less scleral fixation of lens. 47 out of 70 (65.7%) patients had a post op BCVA of 6/12 or better on Snellen's chart. But on comparing the post op mean log-Mar of the sutured (0.37±0.13) and the suture-less group (0.35±0.13), the difference was not statistically significant (P: 0.49). The most common immediate post-op complication was transient raised intraocular pressure with corneal oedema. On follow-up at one month there was one case of suture erosion in the sutured group and one case of exteriorisation of haptic in the suture-less scleral fixated group.

CONCLUSION: The sutured and the suture-less technique of scleral fixated lens are both equally effective for visual rehabilitation after aphakia. Sutured scleral fixated lens ensures placing the lens in the most natural position, but it is a technically tougher surgery to practice.

INTRODUCTION

Cataract extraction surgery is one of the most commonly performed surgery worldwide. Intraocular lens implantation has revolutionised visual outcomes and has almost replaced spectacles. An intact posterior capsule is a must for primary intraocular lens implantation. This posterior capsular (PC) support is compromised in case of a sub luxated lens, PC rent during surgery, vitreous loss during surgery or due to trauma. Thus, despite all advances in surgical techniques some patients are left aphakic at time of primary cataract extraction surgery. This postoperative aphakic disability can be corrected by spectacles, contact lenses or secondary intraocular lens implantation.

Aphakic spectacles give improved vision but their disadvantages include image enlargement, prismatic and peripheral aberrational effects leading to spectacle intolerance and clumsiness in performing the simple daily tasks. ⁽¹⁾ Contact lens wear is also not well accepted by aphakic patients. The major problem with contact lens

wearing is corneal hypoxia. Also, poor maintenance of the contact lenses can cause conjunctivitis and microbial keratitis. ⁽¹⁾ Thus, to overcome the above-mentioned problems, secondary intraocular lens implantation is a procedure of choice for visual rehabilitation in aphakic patients⁽¹⁸⁾

Secondary intraocular lens implantation is defined as insertion of an intraocular lens into an aphakic eye. It can be achieved by an Iris fixated intraocular lens, Anterior chamber intraocular lens (ACIOL), sutured or suture less trans scleral fixated intraocular lens. Draw backs of an iris fixated intraocular lens are pinching of tissue, pigment dispersion, chances of subluxation and decentralisation of the lens. With secondary ACIOL there can occur corneal decompensation and secondary glaucoma. The suture less trans scleral intraocular lens is associated with problems like dislocation of the IOL from the scleral pocket or extrusion of the haptic via the scleral pocket ⁽¹⁾ Thus, sutured scleral fixated intraocular lens is preferred because lens is fixed with sutures in its most natural position, so lens stability is good. Also, it has been successfully used to correct aphakia in children ⁽⁴⁾

The purpose of this study was to determine effectiveness of secondary IOL implantation by scleral fixation. The patients undergoing secondary intraocular lens implantation by scleral fixation, at Rural Medical College and hospital, Loni between September 2017 to August 2019 were observed for post-operative visual outcomes and post-operative complications for a follow up period of six weeks.

MATERIALS AND METHODS

The study was approved by institutional review board. This was a hospital based descriptive(observational) longitudinal study involving 70 eyes of 70 patients. The indications of surgery included aphakia as a complication of cataract surgery with loss of capsular and/or zonular support, post traumatic aphakia and preoperative BCVA of at least 6/60 on Snellen's chart. Patients with posterior segment pathology and decompensated cornea were excluded from the study. Pre-operative evaluation included best corrected visual acuity on Snellen's chart, slit lamp bio microscopy for the anterior segment and fundus examination to rule out posterior segment pathology. Intraocular lens power was calculated after keratometry and biometry readings using SRK II formula. The IOL power was adjusted for sulcus fixation by a reduction of 0.50 D from the calculated value. Out of 70 patients, 56 patients underwent sutured scleral fixation of lens and 14 patients underwent suture-less scleral fixation of lens. The method of surgery was based on preference of the surgeon and was not randomised. Despite this, the two groups were comparable in baseline characteristics, post op visual outcomes and complication rates.

PROCEDURE FOR SUTURED SCLERAL FIXATION OF LENS

All surgeries were performed under peribulbar anaesthesia. Fornix based conjunctival flap was made at 12 o'clock, previous surgical wound explored and sutures if any, were cut. Similarly, fornix based conjunctival flaps were made at 3 o'clock and 9 o'clock. Superficial scleral vessels were cauterised with an electric cautery. Vertical half thickness scleral incisions of about 2.0 mm were made 1.0 mm away from the limbus, this coincides with the sulcus where the IOL position is desired. To achieve exact horizontal position of the IOL, 180 degree apart at 3 o'clock and 9 o'clock coinciding points were marked on the vertical incisions with Wernier's Callipers. 1.0mm above and below this point of intersection, the needle of the double armed 10-0 polypropylene suture was introduced, and brought out from the other end, with help of a 26gauge needle, at similar landmarks. Similar step repeated to bring out the other needle. The surgical wound at 12 o'clock was opened with a crescent blade. Anterior vitrectomy was done. Both the threads of the 10-0 polypropylene suture were exteriorised

through the surgical wound, cut and tied to the eyelets of the IOL, using a 3-1-1 surgeon's knot. Suture ends were trimmed. The haptics of the IOL were placed into the ciliary sulcus by passing the inferior and then the superior haptics behind the pupil while gently drawing the sutures through the sclera. Once the IOL is centred, the suture loops at 3 and 9 o'clock were tied using a 3-1-1 surgeon's knot. The suture ends were trimmed. Anterior vitrectomy was repeated if needed and centration of the lens confirmed. An air bubble was instilled to form the anterior chamber. The surgical wound was closed with 10-0 Ethilon sutures. Conjunctival flaps were repositioned and the bridle sutures were cut. A subconjunctival injection of gentamycin and dexamethasone was given.



The needle of the double armed 10-0 polypropylene suture being introduced and brought out from the other end with help of a 26gauge needle. The suture threads are tied to the haptics of the lens.

PROCEDURE FOR SUTURE-LESS SCLERAL FIXATION OF LENS

All surgeries were performed under peribulbar anaesthesia. Fornix based conjunctival flap was made at 12 o'clock, previous surgical wound explored and sutures if any, were cut. Similarly, fornix based conjunctival flaps were made at 3 o'clock and 9 o'clock. Superficial scleral vessels were cauterised with an electric cautery. Vertical half thickness scleral incisions of about 2.0 mm were made 1.0 mm away from the limbus, this coincides with the sulcus where the IOL position is desired. To achieve exact horizontal position of the IOL, 180 degree apart, at 3 o'clock and 9 o'clock, coinciding points were marked on the vertical incisions with Wernier's Callipers. Partial thickness scleral tunnels were made tangential to the limbus with a Crescent blade, corresponding to the vertical incisions. Sclerotomy done with 24gauge needle, corresponding to the points marked 180degree part, to allow exteriorisation of the lens haptics later. The lens was introduced through the surgical wound into the anterior chamber and the leading haptic was exteriorised through the sclerotomy. The tip of this exteriorised haptic was tucked into the previously constructed tangential scleral tunnel. The same procedure was repeated on the other side. Centration of the lens was confirmed. An air bubble was instilled to form the anterior chamber. The surgical wound was closed with 10-0 Ethilon sutures. Conjunctival flaps were repositioned and the bridle sutures were cut. A subconjunctival injection of gentamycin and dexamethasone was given. Wire speculum was released and the eye was patched.



Vertical half thickness scleral incisions and scleral tunnels being made 180 degree apart. Haptics of the lens exteriorised with help of 26gauge needle.

For both groups of patients, post operatively antibiotic and steroid eyedrops were instilled 6 times/day which were tapered gradually over the next six weeks. Post-operative visual outcome and complications, if any, were recorded on –

1. The post-operative day one,
2. On the day of discharge from the ward,
3. At first follow up in the OPD after 1 week
4. At six weeks from the day of surgery.

Refraction was done at six weeks and best corrected visual acuity and astigmatism, if any, was recorded.

Statistical analysis of collected data was done. A p value less than 0.05 was considered statistically significant.

OBSERVATIONS AND RESULTS

Out of 70 patients, 42 were females (60%) with a mean age of 62.11 ± 8.10 and 28 were males (40%) with a mean age of 62.21 ± 13.03 . Right eye was operated in 43 patients (61.4%) and left eye was operated in 27 patients (38.6%). Fifty-six (80%) patients underwent sutured scleral fixation of lens and fourteen (20%) patients underwent suture-less scleral fixation of lens. In the fifty-six patients who underwent sutured scleral fixation of lens, the post op mean log-Mar BCVA at six weeks was 0.35 ± 0.13 as compared to the preoperative mean log-Mar BCVA of 0.63 ± 0.15 . On application of Wilcoxon Signed Rank test this difference was statistically significant ($P: 0.0001$). Also, in the fourteen patients who underwent suture-less scleral fixation of lens, the difference between the pre-operative mean log-Mar BCVA (0.65 ± 0.15) and postoperative mean log-Mar BCVA (0.37 ± 0.13) was statistically significant ($P: 0.001$). On comparing the post op mean log-Mar of the sutured (0.37 ± 0.13) and suture-less group (0.35 ± 0.13), the difference was not statistically significant ($P: 0.49$).

On post op refraction at six weeks, amongst patients who underwent suture-less scleral fixation of lens, 7 out of 14 (50%) had an astigmatism of 1D, 4 out of 14 (28.7%) had no astigmatism, 2 out of 14 (14.2%) had an astigmatism of 2D, 1 out of 14 (7.1%) had an astigmatism of 3D, on refraction at six weeks after surgery. In patients who underwent sutured scleral fixation of lens, 27 out of 56 (48.2%) had an astigmatism of 1D, 21 out of 56 (37.5%) had no astigmatism, 7 out of 56 (12.5%) had an astigmatism of 2D and 1 out of 56 (1.7%) had an astigmatism of 3D. There was no significant difference in post op astigmatism between the suture-less and sutured scleral fixated lens. ($P: 0.70$)

Intraoperatively hyphema occurred in 3 out of 56 cases undergoing sutured scleral fixation of lens. In one of these three cases, vitreous haemorrhage was documented on post op Day 1 and in the other two cases streak hyphema was documented on Post op day 1, which resolved within a week without any deleterious effect. Also,

in the patients who underwent sutured scleral fixation of lens, in the immediate post op, raised intraocular pressure with transient corneal oedema was seen in 18 out of 56 cases (32.14%) , transient hypotony was noted in 2 out of the 56 cases (3.5%), uveitis and formation of an exudative membrane was documented in 2 out of 56 patients (3.5%). In 8 out of these 56 patients (14.2%) IOL tilt was documented.

Also, at one month follow up, one case of macular oedema and one case of suture erosion with uveal tissue prolapse was documented. The patient with suture erosion was taken up for IOL explantation and left aphakic.

In patients who underwent suture-less scleral fixation of lens, in the immediate post op, raised intraocular pressure with transient corneal oedema was seen in 6 out of 14 cases (42.8%), transient hypotony was noted in 1 out of 14 cases (7.1%) and there was one case of exteriorisation of haptic, which was managed by a sutured scleral fixated lens.

There were no cases of persistent hypotony, persistent vitreous haemorrhage, retinal detachment, suprachoroidal haemorrhage, choroidal effusion or endophthalmitis in any of the patients.

Table 1: Comparison of visual acuity			
	Pre-Op Log	Post-Op Log	Wilcoxon Signed Rank Test
	Mean ± SD	Mean ± SD	
	(median)	(median)	
Suture-less Scleral fixated (n=14)	0.65 ± 0.15 (0.60)	0.37±0.13 (0.13)	P:0.001: Significant
Sutured scleral fixated (n=56)	0.63±0.15 (0.60)	0.35±0.13 (0.30)	P:0.0001 Significant

Table 2: Comparison of Post Op visual acuity			
Suture-less scleral fixated Vs. Sutured scleral fixated			
	SL Post Op Log	SS Post Op Log	Mann Whitney U test
Mean ± SD (median)			
	0.37±0.13 (0.13)	0.35±0.13 (0.30)	P: 0.49 Non-Significant

Table 3: Post-op complications in sutured and suture-less scleral fixated.		
Immediate Post-operative complications	Sutured SFIOL (n=56)	Suture-less SFIOL (n=14)
Transient corneal edema	18 (32.14%)	06 (42.8%)
Temporary hypotony	02(3.5%)	01 (7.1%)
Transient Vitreous hemorrhage	01(1.7%)	00
Transient Hyphema	02 (3.5%)	00
Temporary intraocular	18 (32.14%)	06 (42.8%)

pressure elevation		
Uveitis	02 (3.5%)	01 (7.1%)
Delayed post-operative complications		
Suprachoroidal hemorrhage	00	00
Suture knot erosion	01 (1.7%)	00
Cystoid macular edema	01 (1.7%)	01 (7.1%)
Haptic related complication	00	01(7.1%)
IOL tilt (5 to 10 degrees)	08(14.2%)	03 (21.4%)
IOL decentration (0.5 to 1 mm)	00	00
Endophthalmitis	00	00

DISCUSSION

The most dramatic example of the benefit of an IOL is a case of monocular aphakia. A review by the American Academy of ophthalmology in 2003⁽²⁾ showed that the use of open-loop ACIOLs, Iris sutured posterior chamber IOLs or scleral fixated IOLs is safe and effective to correct aphakia in eyes without adequate capsular support. Use of sutures to fixate the IOLs to the sclera has been a time-tested method with various technical modifications. Though this technique is difficult to master it places the IOL in the ciliary sulcus. This keeps the IOL close to the natural anatomic position of the crystalline lens and is safe for corneal endothelium and iris. This also places the lens closer to the rotational centre of the eye, just anterior to the vitreous face, reducing the centrifugal forces on the lens, stabilizing the ocular contents and decreasing the probability of complications such as iritis, CME, and retinal detachment. Since the technique of sutured scleral fixation of lens requires passing the suture needle through the ciliary body, it carries the risk of haemorrhage from the ciliary body or root of iris.⁽¹⁸⁾

Several authors have reported a favourable visual outcome after sutured and suture-less scleral fixation of lens.^(10,12,15) In our study also, the difference between the pre-operative and postoperative mean log-Mar BCVA was statistically significant for both sutured and suture-less cases. But the difference between the post op mean log-Mar for the sutured scleral fixation (0.37 ± 0.13) and the post op mean log-Mar for the suture-less scleral fixation (0.35 ± 0.13) was not statistically significant (P: 0.49). Thus, the visual outcome was similar in both the groups and there was significant post-op visual improvement after sutured and suture-less scleral fixation of lens. Mc Allister et al (2011)⁽¹⁰⁾ retrospectively reviewed the records of 82 eyes that underwent sutured scleral fixation of lens and reported ocular hypertension to be the most common postoperative complication, seen in 25 eyes (30.5%). In our study, also, in patients who underwent sutured scleral fixation of lens, raised intraocular pressure with corneal oedema (ocular hypertension) was the most common immediate post op complication, seen in 18 out of 56 cases (32.14%). Other post op complications in the sutured group were transient hypotony in 2 out of the 56 cases (3.5%), IOL tilt in 8 out of these 56 patients (14.2%), 1 case of vitreous haemorrhage

and 2 cases of streak hyphema, which cleared uneventfully by two weeks post operatively. Abbie et al (2013)⁽¹³⁾ reported suture related complications in 25 out of 104 eyes that underwent sutured scleral fixation. In our study there was one case of suture erosion with uveal tissue prolapse documented on the one month post op follow up. The patient was taken up for IOL explantation and left aphakic.

Suture-less technique for scleral fixation of lens is gaining popularity because the technique is easy to master and has a shorter learning curve. But conditions like aphakia in a myopic eye with large limbus to limbus diameter and post-trauma eyes with significant corneoscleral and conjunctival scarring at the limbus still require sutured scleral fixation of lens.^(12,15) Agarwal A et al. (2007)⁽¹²⁾ achieved suture-less scleral fixation of lens by using fibrin glue to cover the sclerotomy along with externalized haptics with limbal based scleral flaps. However, fibrin glue might be not available everywhere. Yamane et al⁽²²⁾ reported the technique of suture less 27G needle-guided intrascleral IOL fixation.

Agarwal L et al (2016)⁽³⁾ reported hypotony and corneal oedema to be the most common complications in the 62 eyes that underwent suture-less and glue-less scleral fixation of lens and were followed up for one month. In our study, in patients who underwent suture-less scleral fixation of lens, in the immediate post op, raised intraocular pressure with transient corneal oedema was seen in 6 out of 14 cases (42.8%). Transient hypotony was noted in only 1 out of 14 cases (7.1%). Also, there was one case of exteriorisation of haptic, which was managed by a sutured scleral fixated lens. Sindal et al (2016)⁽¹⁵⁾ reported transient cystoid macular oedema (12%) as the most common complication in the patients who underwent suture-less scleral fixation. In our study, 2 out of 70 cases developed CME post op, it resolved with no deleterious effect on vision. There were no cases of persistent hypotony, persistent vitreous haemorrhage, retinal detachment, suprachoroidal haemorrhage, choroidal effusion or endophthalmitis in both the groups.

Limitations of this study are, its small sample size, single-centre nature and follow-up of up to three months only. A future prospective study incorporating a long term follow up and corneal endothelial cell count would be beneficial. In conclusion, intraocular lens implantation is a preferred method for visual rehabilitation to treat aphakia without capsular support. The sutured technique and suture-less technique for scleral fixation of the lens are equally effective. Sutured scleral fixated lens ensures placing the IOL in the most natural position, but it is a technically tougher surgery to practice.

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