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Novel technique of sutureless glueless intrascleral fixation of single piece intraocular lens

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Abstract
Aim: To report single centre results of sutureless intrascleral fixation of single piece posterior chamber Intraocular Lens (IOL)
Methods: In this prospective study, 50 cases were evaluated. Preoperative & post-operative visual acuity, Slit lamp & Fundus examination, Applanation tonometry, Keratometry, Biometry, Optical Coherence Tomography (OCT), Scheimpflug imaging was done for extensive evaluation.
Results: All IOLs were successfully implanted at desired position without intraoperative complications. Postoperative complications included corneal edema (2), raised Intraocular Pressure (IOP) (3), Cystoid macular edema (1) & decentration (2). All were managed to the level of good visual recovery. Surgery video were retrospectively evaluated in cases of post-operative complications. There was no significant change in corneal astigmatism.
Conclusion: After extensive 6 month follow up with evaluation of variety of parameters, our technique of sutureless, glueless scleral fixation of IOL using single piece IOL has shown favorable results and a potential option in visual rehabilitation.

Keywords: scleral fixation, single piece IOL, Scheimpflug imaging

Introduction

Till now, endocapsular placement of Intraocular lens (IOL) is undoubtedly most preffered site after cataract surgery. Various techniques have been devised to offer optimum visual rehabilitation in cases with poor or no capsular support such as anterior chamber IOLs (ACIOLs); Iris fixated IOLs and Scleral fixated IOLs (SFIOL) [1]. Placement of the IOL in the posterior, rather than the anterior chamber reduces the risk of damage to anterior chamber angle structures & corneal endothelium [2].

Suturing the IOL to sclera using non‑absorbable sutures has been the traditionally accepted technique of IOL placements, but associated with various complications like suture-induced inflammation, suture degradation and delayed IOL subluxation or dislocation due to broken suture [3]. Recently, Scharioth *et al*. developed a technique of sutureless scleral fixation of a multipiece IOL using permanent incarceration of the haptics in a scleral tunnel parallel to the limbus [4]. Agarwal *et al* popularized the similar surgical technique using fibrin glue for adherence of scleral flaps [5]. Both these techniques used three piece IOL.

Our aim is to assess clinical efficacy, safety, and complexity of sutureless glueless scleral fixation of single piece IOL in aphakia.

Material and Methods

The ethical committee of the hospital approved the study and followed the tenets of the declaration of Helsinki. Informed consent was obtained from all patients prior to surgery. It was hospital based Descriptive type of Observational study included 50 eyes of 50 patients. All aphakic patients above 12 years who were ready to give consent were included in study. Exclusion criteria included patients with corneal opacity, retinal disorder, optic atrophy, bleeding disorder, pregnancy & those who were unwilling to give consent. Preoperative & post-operative visual acuity, Slit lamp & Fundus examination, Applanation tonometry, Keratometry, Biometry (CARL ZEISS MEDITEC IOL MASTER), optical coherence tomography (OCT) (TOPCON 3D OCT-2000) was done for extensive evaluation of anterior & posterior segment.

Statistical analysis- with the use of Software-IBM SPSS 19.0, Qualitative data was summarized in form of proportion. Quantitative data was summarized in form of mean and SD. The significance of difference in proportion measured by chi-square test. The significance of difference in mean measured by unpaired t-test or ANOVA whichever is appropriate, $p< 0.05$ was considered as significant.

Surgical technique [6]

Under Peribulbar anesthesia, 5.0 mm conjunctival peritomy was done at the 2 o'clock and 8 o'clock positions. Then, 2 T-shaped incisions were made 2.0 mm from the limbus exactly 180 degrees apart diagonally. An infusion cannula or anterior chamber maintainer was inserted. To prevent interference with creation of the T-shaped incision, the infusion cannula should be positioned at 4 o'clock. Anterior vitrectomy (deep core) was performed, if necessary. Sclerotomy was done parallel to the iris at the T-shaped incision with a 23-gauge angled microvitreoretinal (MVR) knife and a scleral tunnel was made parallel to the limbus at the branching point of the T-shaped incision. 2.8 mm keratome was used to make a corneal incision at 10 o'clock through which single piece foldable IOL was implanted with an injector; the trailing haptic was left outside the incision. The tip of the haptic was then grasped with 24-gauge IOL haptic gripping forceps, pulled through the Sclerotomy, and externalized on the left side. After the trailing haptic was inserted into the anterior chamber & the haptic tip was grasped with a 24-gauge forceps, pulled through the second sclerotomy and externalized on the right

side. The haptic insertion into the anterior chamber may be difficult depending on the material or shape of the haptics, which can cause the IOL to rotate clockwise and the leading haptic to slip back into the eye. To prevent such risks, the IOL optic was pushed to the back of the iris and moved to the 2 o'clock position with a push-and-pull hook inserted through the side port at the 1 o'clock position. The tip of the haptic was subsequently inserted into the limbus–parallel scleral tunnel. Conjunctival peritomy closed.

Scheimpflug imaging (OCULUS PENTACAM) was done to evaluate proper centration of IOL. Follow up was done on 1st, 7th, 28th post-operative day, at 3 month & 6 month.

Results

The study population consisted of 50 patients (22 female & 28 male). Baseline demography & preoperative ocular characteristics of patients is shown in Table 1.

Table 1: Patient demography and preoperative characteristics

Variable	Scleral Fixation
Age (year)	55.23 ±15.81
Sex (M/F)	28/22
Laterality (OD/OS)	26/24
Underlying etiology of aphakia	
Complicated cataract surgery	26
Nucleus drop	6
IOL drop	4
ICCE for subluxated crystalline lens	8
Traumatic dislocation of lens	4
Subluxated traumatic cataract with IOFB	2
Preoperative UCVA	1.76 ±0.51
Preoperative IOP (mm Hg)	14.78 ±3.20
Mean preoperative astigmatism (D)	1.89 ±1.72

#IOL- Intraocular lens, ICCE- Intracapsular cataract extraction, IOFB- Intraocular foreign body, UCVA- uncorrected visual acuity, IOP- Intraocular pressure

Cases of aphakia due to complicated cataract surgery underwent deep core anterior vitrectomy. Anterior chamber maintainer was used and a single 23-gauge pars plana incision was made 3.5 mm behind the limbus to allow the unidirectional flow of vitreous (anterior to posterior chamber). Thereafter secondary IOL was implanted. In rest of the cases, 23- gauge primary pars plana vitrectomy with 360° endolaser was done. Secondary IOL was implanted after 4 weeks.

Change in uncorrected visual acuity (UCVA) in LOGMAR from pre-operative (1.76 ±0.51) value to 6 month post operatively (0.47±0.29) was highly significant (p=0.0000) (Figure 1).

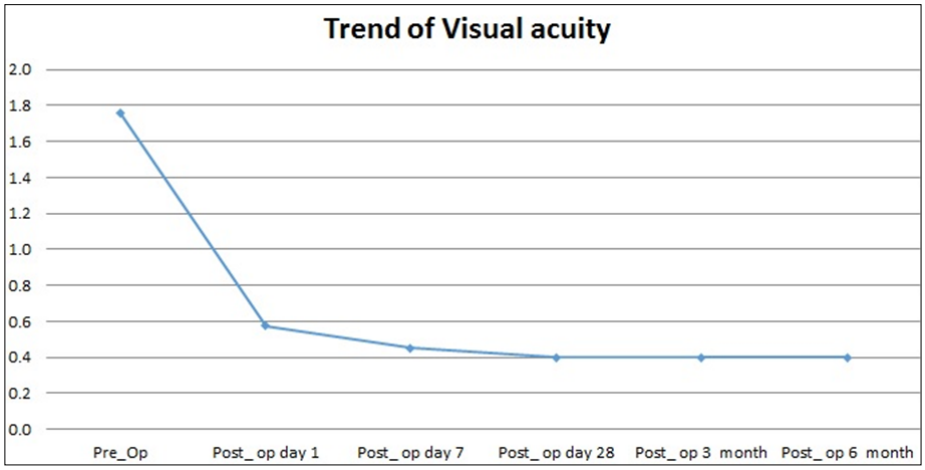

Fig 1: Uncorrected visual acuity on various follow up

Changes in best corrected visual acuity (BCVA) in LOGMAR from preoperative (0.55±0.19) to day 1 follow up (0.59±0.29) was not significant (p=0.8707) but at the end of 6 month (0.34±0.30) change was highly significant (p=0.0000).

Changes in Astigmatism (preoperative=1.89 ±1.72 D & after 6 month= 1.72±1.48 D) as measured by scheimpflug imaging was found insignificant (p value =0.6028), showing that scleral tunnel made in this technique do not effect corneal astigmatism.

Mean Intraocular Pressure (IOP) was 14.78 ±3.20 mmHg preoperatively while it was 14.80±1.66 mmHg postoperatively at 6 month (Figure 2). Mean IOP change from preoperative period to 6 months postoperative period was not statistically significant p=0.9688. Mean change in IOP from preoperative period to post op day 1 (16.24±2.23) (p=0.0096) and post op day 7 (16.42±4.66) (p=0.0429) was found significant as there were some case of raised IOP due to inflammation or pigment release due to maneuvering. These cases were treated medically and on next follow up their IOP came out normal.

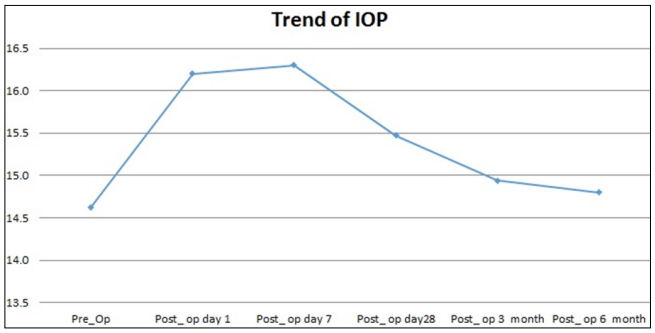

Fig 2: Intraocular pressure on various follow up

On day 1, there were 2 (4%) cases of corneal edema due to surgical manipulations which got resolved on next follow up, on day 7 there were 3(6%) cases of raised IOP which were managed medically and 1 (2%) case of decentration which was recentered surgically, at 3 month, there was 1 (2%) case of Cystoid Macular Edema (CME) which was managed medically and 1 (2%) case of decentration which was recentered surgically.

At the end, all cases have well centered IOL with good visual acuity (Figure 3& 4).

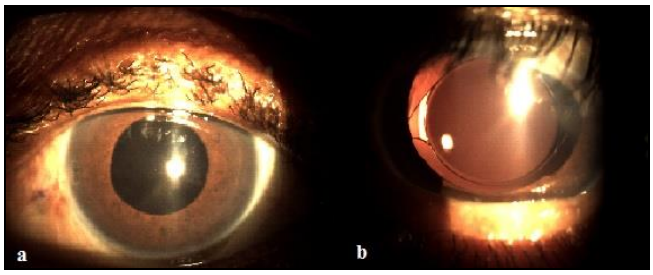

Fig 3: Well centered intraocular lens on slit lamp (a) undilated pupil (b) dilated pupil

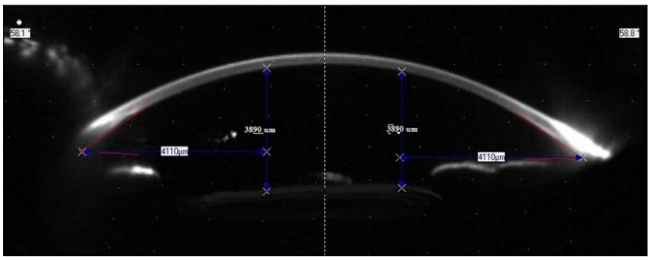

Fig 4: Well centered Intraocular lens on scheimpflug imaging

Discussion

Crystalline lens-zonule barrier provides a stabilizing effect to the eye. When our eye moves, kinetic energy is acquired from its muscles and attachments and this energy is dissipated to the internal fluids as it stops. So placing the IOL closer to the rotational centre of the eye i.e. just anterior to the vitreous face, reduces the centrifugal forces on the lens and stabilize the ocular contents, thereby decreasing the probability of complications such as iritis, CME, and retinal detachment. And also, there is superior optical quality when the lens is positioned closer to the nodal point and centre of rotation of the eye [7].

Sulcus fixation of single piece IOLs is not popular because of the fact that bulky single piece haptics are large and thick enough to contact the posterior iris when placed in the sulcus. Also, the haptics are planar rather than angulated and therefore do not vault the optic posteriorly from the iris, results in complications like pigment dispersion, iris transillumination defects, secondary glaucoma and dysphotopsia [8-10].

Single piece Tecnis®1 foldable lenses have an offset design and in our technique, greated part of haptic is externalized. So neither the optic nor haptics come in contact with the iris, thereby minimizing the above mentioned complications. Single piece IOL haptics are sturdy, this allows easy exteriorization. Sclerotomies are blocked completely by the thick stubby haptics and provides stable fixation; mitigating the need for suturing. However, sclerotomies can be sutured with absorbable suture when needed, preventing the haptics from early slippage. To avoid IOL tilt, sclerotomies should be placed exactly 180˚ apart and 1.5 mm behind the limbus on both sides. Adequate and equal amount of haptic should be inserted in the respective scleral pockets to ensure exact horizontal alignment.

Two most important requirement for ciliary sulcus placement of IOL are sufficient posterior iris clearance and secure fixation. Stable fixation ensures long-term centration and avoids lens movement or tilting that can cause uveal irritation, microhyphema, and pigment dispersion syndrome. The haptics should be angulated posteriorly to maximize iris clearance, otherwise posterior iris rubbing can cause chronic inflammation and pigment dispersion [11]. Ideally, the anterior optic surface should be smooth and have rounded edges to minimize iris chafing when any posterior iris contact occur.

It has been shown that the overall length (12.5–14.0 mm) of the IOL helps ensure firm, stable fixation at the posterior chamber behind the iris, where the average diameter in emmetropic eyes is approximately 13.0 mm. In addition, the large optics lowers the risk of clinically significant postoperative decentration [12, 13]. Externalization of the greater part of the haptic along its curvature and fixation in scleral tunnel (as in our technique) stabilizes the axial positioning of the IOL and thereby prevents IOL tilt.

In this study, we have seen favorable and safe results with stable and well centered single piece IOL. However, like any other technique, there is a learning curve involved. This technique is evolving and long term safety concerns especially regarding lens centration, haptic erosion, dislocation need to be addressed.

Conclusion

Single piece IOLs are equally safe and effective as multipiece IOLs for sutureless fixation in scleral pockets for visual rehabilitation in aphakia.

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