Scheimpflug imaging for evaluation of intraocular lens position in modified flanged scleral fixated intraocular lens

Avadhesh Oli ២, Anil Yadav, J. Ganesh Babu and Divya Balakrishnan ២

Abstract

Background: Scleral fixation of intraocular lens (IOLs) is the most preferred technique for the management of aphakia and the techniques have evolved over the years. These methods have their advantages and disadvantages, however, the major concern being the position of the intraocular lens, its stability and complications. The final IOL position is the major determinant of the final visual acuity, and various imaging modalities have been used to quantify the IOL tilt. **Objectives:** Use of Scheimpflug imaging to evaluate the IOL tilt in modified flanged scleral-fixated intraocular lens (MFSIOL).

Design: Retrospective chart review of 41 consecutive patients who underwent MFIOL. **Methods:** We conducted a retrospective chart review of 41 consecutive patients who underwent MFIOL. The baseline and final best-corrected visual acuity (BCVA), refractive error, and clinical examination findings were recorded. The vertical and horizontal tilts of the IOLs were calculated using the Scheimpflug image. The IOL tilt (in degrees) in the vertical and horizontal axes was the primary outcome and the BCVA, residual refractive error, intraocular pressure, and surgical complications were secondary outcome measures.

Results: The mean baseline BCVA was logMAR 0.49, which improved to logMAR 0.356 (p < .005) after the surgery. The mean IOL tilt in the vertical axis was 3.40° (range of 0.0°-8.5°, interquartile range: 1.21–5.66) and in the horizontal axis was 1.35° (range of 0.60°-4.620°, interquartile range: 0.44–1.86), respectively. There was no correlation between angle of IOL tilt and UCVA (r=0.089, p=0.580), BCVA (r=0.109, p=0.498), final spherical error (r=0.081, p=0.615), cylindrical error (r=0.207, p=0.195), axial length (r=0.105, p=0.514), and IOL power (r=-0.139, p=0.388) **Conclusion:** Modified flanged IOL (MFIOL) is an alternative technique for intrascleral fixation of IOL resulting in good lens stability. The IOL tilt achieved by this technique is minimal and did not influence the final visual outcome or spectacle correction. Scheimpflug imaging is simple and non-invasive method to measure the IOL tilt.

Plain Language Summary: Scheimpflug imaging for modified flanged scleral fixated lens position

This study on 41 eyes was aimed to analyze the lens tilt using Scheimpflug imaging in cases of modified flanged scleral fixation of intraocular lens (MFSFIOL), which is a novel technique to minimize the complications and simplify the procedure. The intraocular lens (IOL) remained stable with an acceptable range of vertical and horizontal tilt. There was no significant effect of IOL tilt on the final best-corrected visual acuity (BCVA) or spectacle correction. Scheimpflug imaging is an accurate and non-invasive technique for assessment of lens position in the patients with intrascleral fixation of IOL.

Keywords: aphakia, flanged IOL, glued IOL, Scheimpflug image, SFIOL

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Introduction

Management of aphakia has evolved over time and scleral fixation of intraocular lens (SFIOL) has been one of the most performed surgical procedure.1 Though the scleral fixation of intraocular lens (IOL) using sutures is a time-tested technique, the procedure is tedious, time-consuming, and is frequently associated with suture-related complications.² Current methods of performing SFIOL involve fixation of the haptics of three-piece IOL directly into the sclera.3 Various modifications of IOL haptic fixation are in vogue with their own merits and demerits. Though the results following the glued IOL (GIOL) are promising, the haptic fixation into the scleral tunnels can be difficult due to haptic deformation caused by the use of forceps during exteriorization that may lead to IOL tilt in the post-operative period. The creation of the partial thickness scleral flaps in conventional GIOL technique may be associated with occasional flap amputation and globe perforation.⁴

Flanged IOL, a recently described technique of SFIOL, helps to overcome some of the common surgical problems encountered in conventional GIOL.⁵ However, as the haptic exteriorization is done transconjunctival, it is not possible to accurately mark entry points on to the sclera, which might lead to tilting of the IOL in the post-operative period. In addition, as a formal scleral tunnel is not fashioned, the haptics may lie just beneath the conjunctiva. The superficial location of haptics might lead to haptic exposure, scleral melt, and endophthalmitis.

To overcome the limitations of IOL tilt caused by inappropriate tucking of haptics into scleral channels in the traditional GIOL and the risk of exposure of haptics in flanged IOL technique, we describe a modified flanged IOL (MFIOL) technique in which the lamellar scleral tunnel is fashioned to cover the flanged ends of IOL haptics. Formal marking is done on the sclera for haptic exteriorization in contrast to traditional flanged IOL technique, which might reduce the IOL tilt and decentration.

This study was undertaken to evaluate the IOL tilt in this modified technique of flanged IOL using Scheimpflug imaging. This is the first report on the use of Scheimpflug imaging to calculate IOL tilt in MFIOL.

Materials and methods

This study was a retrospective chart review of the patients who had undergone MFIOL between

January 2018 and January 2019. The demographic and clinical data of patients were retrieved from the electronic medical record. Total 41 patients who met the study criteria were included in the study. Patients who underwent MFIOL with follow-up of more than 6 months and complete medical records were included in the study. Patients with other associated ocular pathology precluding Scheimpflug imaging and with followup of less than 6 months were excluded from the study. A detailed history and comprehensive ophthalmological evaluation findings, including unaided and best-corrected visual acuity (BCVA), slit-lamp examination, fundus evaluation, and intraocular pressure (IOP) measurement done at baseline and at all follow-up visits were recorded. The primary outcome measure was mean IOL tilt, while the secondary outcome measures were post-operative uncorrected visual acuity (UCVA), BCVA, surgical complications, and IOP.

Surgical technique

After the peribulbar anesthesia and surgical draping, the horizontal meridian of the cornea was marked at 4 and 10 O' clock meridian with a corneal marker. A 3-mm L-shaped incision was fashioned on the conjunctiva at the mark, and two points were marked on the sclera 2mm from limbus on this meridian. 1 mm lamellar scleral tunnel was made at 3 and 9 clock hours, 2mm superior, and 2mm inferior from this mark (Figure 1). For the left eye, the markings were done at 4 and 10 clock hours, so as to avoid the possible hindrance by nose for passing the needle on the nasal side (Figure 2(a) and (b)). Either a 25-gauge pars plana infusion or an anterior chamber maintainer (ACM) was started and a peripheral iridectomy (PI) was fashioned on the superior iris using the vitreous cutter with a low cut-rate (600-800 cpm). The IOL (Alcon MA60AC) or three-piece nonfoldable IOL (Aurolab, India) was placed into the anterior chamber after making a clear corneal entry. The leading haptic of IOL was placed on the inferior iris, and trailing haptic was kept outside the corneal entry.

A 26-gauge needle bent at approximately 60° was passed 2 mm behind the limbus through this lamellar scleral tunnel and the needle was visualized in the pupillary plane (Figure 2(c) and (d)). The leading haptic of IOL was tucked into the lumen of the needle with an intraocular forceps (Alcon Maxigrip) passed through a side port entry, and the needle was exteriorized. Small

 $5 \text{ mm} \times 5 \text{ mm}$ bit of silicone band (#240 band) as a stopper was used at the leading haptic of the IOL by passing it through the 26-gauge needle to reduce the risk of exteriorized leading haptic to slip back while manipulating the trailing haptic. It also helped to adjust the centration of IOL by manipulating both the haptics before flanging the tips. A thermal cautery (heated BP handle tip) was used to create a flange at the tip of the haptic. The trailing haptic was also similarly exteriorized, and the end was flanged with a heat cautery. When stoppers were used, the tips were flanged after exteriorizing both the haptics. The flanged haptic ends were gently pushed back into lamellar scleral tunnels. The ACM was removed, and the corneal wound was hydrated. The surgical field was dried, and conjunctiva was closed using fibrin glue. The eye was patched with a drop of betadine.

The patients were followed up on the first postoperative day, 1 week, 1 month, and 3, 6, and 12 months. Hypotony was defined as IOP less than 9 mmHg and high IOP as more than 25 mmHg.

The Scheimpflug image was obtained at the routine follow-up, 3 months after the surgery with Allegro Oculvzer (WaveLight, GmbH, Erlangen, Germany), and the images were analyzed using Matlab software as described earlier in the literature using optical coherence tomography (OCT) or ultrasound biomicroscopy (UBM) images for IOL tilt.6 Two separate Scheimpflug images were acquired in horizontal and vertical axes. The iris plane was marked with a straight line joining two iridocorneal angles, and the IOL plane was marked with a line passing through the center of the IOL in the long axis (Figure 3). A perpendicular line drawn to the iris plane was used to calculate IOL tilt in the horizontal or vertical axis, depending on the Scheimpflug image. The data were tabulated in the excel sheet and was analyzed using SPSS version 21 (SPSS Inc., Chicago).

Statistical analysis

The normality of data was checked with the Shapiro–Wilk test. Mean and standard deviation were calculated. Chi-square test was used for dichotomous data. Spearman's rank correlation was calculated for IOL tilt and spherical equivalent. Linear regression analysis was used to find the correlation between IOL tilt and other variables using the coefficient of determination R^2 ,

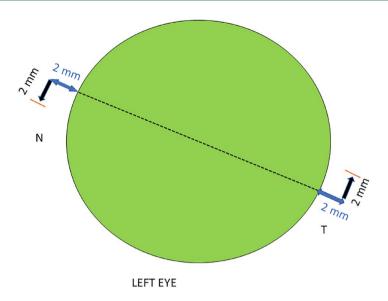


Figure 1. Horizontal meridian of the cornea was marked at 4 and 10 0' clock meridian with a corneal marker (black dotted line). A 3-mm L-shaped incision was fashioned on the conjunctiva at the mark, and two points were marked on the sclera 2 mm from limbus on this meridian (blue arrow); 1 mm lamellar scleral tunnel was fashioned at 3 and 9 clock hours, 2 mm superior, and 2 mm inferior from this mark (black arrow).

regression coefficient β and p value. A p value of <0.05 was considered as significant.

Results

A total of 41 eyes were included in this study. The mean age was 27.63 (SD=21.42, range=4-69) years. Other demographic details are described in Table 1.

The mean duration of follow-up was 7.59 months (range = 6–15 months); however, 17.5% of the patients completed more than 10 months of follow-up. The mean baseline BCVA was logMAR 0.49 that improved to logMAR 0.35 that was clinically and statistically significant (p < 0.005) paired *t* test (Table 2).

The IOP at baseline and final follow-up are shown in Table 1. The mean IOP on day 1 post-operative was 12.39 mmHg that was lower as compared with the baseline mean IOP 16.57 (p=0.006) and final mean IOP of 15.00 mmHg (p=0.019). Eleven patients had IOP less than 10 mmHg on the first day after surgery, which returned to normal at the end of 1 week on topical steroids. One patient had high IOP (39 mmHg) on the first day after the surgery, which was controlled medically.

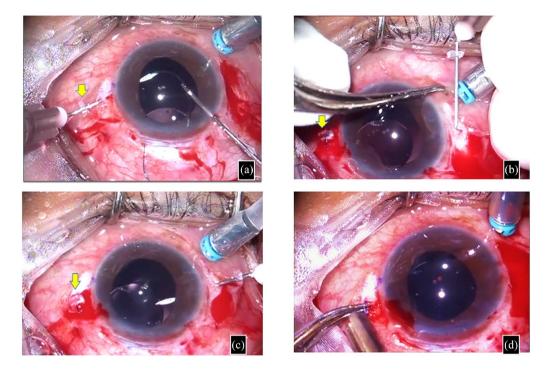


Figure 2. (a) The leading haptic of IOL was tucked into the lumen of the needle with an intraocular forceps (Alcon Maxigrip) passed through a side port entry, and the needle was exteriorized. Small 5×5 mm bit of silicone band (#240 band) (yellow arrow) as a stopper was used at the leading haptic of the IOL by passing it through the 26-gauge needle to reduce the risk of exteriorized leading haptic to slip back while manipulating the trailing haptic. (b, c) The trailing haptic was also similarly exteriorized, using the 26-gauge needle. (d) A thermal cautery (heated BP handle tip) was used to create a flange at the tip of the haptic.

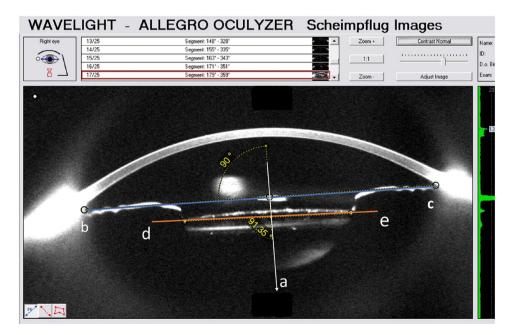


Figure 3. Scheimpflug image in a case with SFIOL in situ. The Iris plane is marked by a line (b-c, blue line) joining two iridocorneal angles and the IOL line (d-e, orange line) is marked passing through the center of IOL optic. The perpendicular line (marked as a, white line) to iris plane (b-c) passes through the corneal vertex and meets the IOL line (d, e). The angle formed by this white line a, with the IOL plane is used to measure the IOL tilt.

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Parameter	Remarks		
1. Total number of eyes (<i>N</i>)	41		
2. Age (mean), years	27.63 (21.42)		
3. Sex			
Male	15 (36.6%)		
Female	26 (63.4%)		
4. Eye			
Right	23 (56.1%)		
Left	18 (43.9%)		
5. Etiology			
Trauma	9 (22%)		
Post-surgery	5 (12.2%)		
Congenital causes	27 (65.9%)		
6. Lens status			
Aphakia	5 (12.2%)		
Dislocated lens	26 (63.4%)		
Dislocated IOL	5 (12.2%)		
Post-cataract surgery	5 (12.2%)		
7. Anesthesia			
LA	19 (46.3%)		
GA	22 (53.7%)		
8. Type of IOL			
Foldable	39 (95.1%)		
Non-foldable three-piece IOL (Aurolab)	2 (4.9%)		
9. Axial length (mm)			
Mean (<i>SD</i>)	23.91 (1.74)		
95% CI	23.36-24.46		
10. IOL power (diopter)			
Mean	20.99 (4.76)		
95% CI	19.49-22.49		
11. Follow-up			
Mean	7.59 months		

Table 1. Demographic and clinical details.

Table 1.	(Continued)
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Parameter	Remarks			
Range	6–15 months			
12. IOP (mmHg)				
Baseline	16.57 (7.16), 95% CI (14.31–18.83)			
Post-opeartive D1	12.39 (6.49), 95% CI (10.34–14.44)			
Final	15 (4.25), 95% CI (13.66–16.34)			
CI, confidence interval; IOL, intraocular lens; IOP, intraocular pressure ; LA, local anaesthesia; GA, general anaesthesia.				

The mean IOL tilt in the vertical axis was 3.40° (range of $0.0^{\circ}-8.5^{\circ}$, interquartile range = 1.21-5.66) and in the horizontal axis was 1.35° (range of $0.60^{\circ}-4.620^{\circ}$, interquartile range = 0.44-1.86), respectively, as shown in Table 2.

The data were further analyzed to look for any correlation between the degree of IOL tilt and various ocular parameters. However, no correlation was found with UCVA (r=0.089, p=0.580), BCVA (r=0.109, p=0.498), final spherical error (r=.081, p=0.615), cylindrical error (r=0.207, p=0.195), axial length (r=0.105, p=0.514), and calculated IOL power (r=-0.139, p=0.388).

Eight of 41 (19.5%) patients had vertical IOL tilt more than 6°. On subgroup analysis, the difference of mean between the groups with IOL tilt more than 6° was not significant for final UCVA (p=0.486), BCVA (p=0.852), final sphere (p=0.599), and final cylindrical correction (p=0.367; Mann–Whitney U test)

Complications

Intraoperative vitreous hemorrhage (VH) was noted in two eyes (4.9%) and post-operative VH was seen in four eyes (9.8%) that resolved over 4weeks. None of the eyes had optic capture, unusual inflammation, haptic exposure, or IOL decentration or dislocation. No retinal complications like macular edema or retinal detachment were noted. No additional procedures were required to be performed over the follow-up period.

Table 2. Visual acuity and IOL tilt.

	Pre-operative mean (<i>SD</i>)	Pre-operative (95% CI)	Post-operative mean (<i>SD</i>)	Post-operative (95% CI)	p value		
UCVA (logMAR)	1.554 (0.63)	1.353–1.754	0.490 (0.41)	0.361-0.620	<i>p</i> = 0.000		
BCVA (logMAR)	0.949 (0.76)	0.708-1.190	0.356 (0.29)	0.264-0.448	<i>p</i> = 0.000		
Vertical tilt (°)			3.40 (2.44)	2.63-4.17			
Horizontal tilt (°)			1.35 (1.21)	0.967-1.73			
BCVA, best-corrected visual acuity; CI, confidence interval; IOL, intraocular lens; UCVA, unaided visual acuity.							

Discussion

This study was aimed to quantify the IOL tilt using Scheimpflug image in a modified technique of intrascleral haptic fixation of three-piece IOL. The mean IOL tilt in the current series did not influence the final visual acuity, spherical, or cylindrical correction.

Numerous techniques are being described in the literature to measure the IOL tilt, like use of Purkinje images, anterior-segment OCT (AS-OCT), UBM, and Scheimpflug imaging with comparable results.⁷ Although the data on IOL tilt after cataract surgery are well documented, the literature is sparse on the degree of IOL tilt following intrascleral fixation of IOL haptics.

Previous studies published have evaluated the IOL tilt using AS-OCT or UBM in patients after cataract surgery or SFIOL;8 however, this is the first study to look into the IOL tilt based on the analysis of Scheimpflug images in patients with intrascleral haptic fixation of IOL. As mentioned in the literature, slight variation in the value of IOL tilt could be due to the difference in the modality and technique of estimation.9 Some of the previous studies have taken the iris plane as the reference plane for calculating IOL tilt,¹⁰ however, this reference plane might be distorted due to primary disease processes like trauma or multiple surgeries. To overcome this variation, we used the iridocorneal line joining the two angles as the reference plane, which is less likely to get affected by multiple surgeries or trauma and seems to be a constant landmark.¹¹

In another study on the use of UBM to quantify IOL tilt, the difference of distance between IOL and iris plane was used as an indicator of IOL tilt, and 22% of the eyes included in the study had IOL tilt.⁸ However, this distance might vary depending on the configuration of the iris.

In a series of eyes with flanged IOL, similar methodology was used by Yamane *et al.*⁵ using the AS-OCT. The mean IOL tilt was 3.4° , which is comparable with the values obtained in the current study. In addition, we found that IOL tilt in the vertical axis was greater than the IOL tilt in the horizontal axis, and the plausible reason could be due to the fixation and orientation of the IOL haptics in the horizontal axis that resulted in reduced tilt in that axis. It would be interesting to look at IOL tilt values when the IOL haptics are placed in the vertical axis in cases of vertical GIOL.

AS-OCT was used in the evaluation of IOL tilt in patients with GIOL by Agrawal *et al.* and found that the mean IOL tilt was $3.2^{\circ} \pm 2.7^{\circ}$ and $2.9^{\circ} \pm 2.6^{\circ}$ in horizontal and vertical axes, respectively. In agreement with the current study, they did not find any significant correlation of IOL tilt with residual astigmatism or visual acuity.¹² In a study on 26 eyes with sutured SFIOL, the IOL tilt using the AS-OCT images was found to have a mean value $2.25^{\circ} \pm 1.93^{\circ}.^{9}$

Hypotony is a well-reported complication of GIOL surgery. In some of the previous studies, transient hypotony was reported in 56% of the eyes.⁴ In the present study, the mean IOP was 12mmHg that was higher as compared with traditional GIOL surgery. This could be attributed to the smaller sclerotomy fashioned with a 26-gauge needle in contrast to sclerotomy fashioned with a trocar or 23-gauge needle in conventional GIOL to facilitate the passage of intraocular forceps. The smaller sclerotomy made with 26-gauge needle not only helps in preventing hypotony in the post-operative period, but also circumvents chances of inadvertent ciliary body detachment caused during introduction of the blunt forceps. The margins of the entry point of the sclerotomy fashioned with the needle are clean cut self-sealing that further prevents trickling of blood from the entry wound, avoiding VH.

The use of a needle to exteriorize the haptics helps to maintain the smooth contour as the haptic remains inside the lumen of the needle, protected from the deforming forces. Maintaining smooth contour of haptic is vital to avoid any sharp edges, which may lead to erosion of the sclera or conjunctiva in the post-operative period.⁴

The proper marking for haptic exteriorization followed in this technique is an essential factor in reducing the IOL tilt. In contrast to traditional transconjunctival flanged IOL techniques, the exact needle entry points are visualized, ensuring adequate intrascleral tunnel of the haptic to provide additional stability to the IOL. The Yamane's technique appears to be less invasive as the conjunctival incision is avoided, however, the intrascleral length of the haptic may vary depending on the path of needle used to externalize the haptic. In the current modified technique, adequate intrascleral length of haptic is ensured, so that the vector forces help in the IOL stability and reduce tilt. In this technique, the haptic is supported by a lamellar scleral tunnel that would support the haptics better because of its self-sealing design.

Optic capture is reported to be an important complication in the post-operative period. However, we did not observe this complication in the current series. PI seems to have an important role to play in avoiding this complication, as reported earlier.¹³ A PI was made at the beginning of the procedure in all the patients, and it is recommended as a standard step in GIOL surgery.

One of the limitations of our study is the short follow-up period of 7 months. However, studies on long-term follow-up did not show significant changes in the IOL tilt values over time. IOL tilt and decentration might be essential determinants of final visual acuity in the post-operative period because of induced astigmatism,⁹ hence it is recommended to plan further studies on comparative models. The effect of higher order aberrations on final visual acuity was not taken into account, which could also be a possible limitation.

Conclusion

MFSFIOL is a novel simplified technique with minimal complications and an acceptable range

of vertical and horizontal IOL tilt. Scheimpflug imaging is an accurate and non-invasive technique for assessment of IOLs tilt in patients with SFIOL. Final BCVA or spectacle power is not much affected by the IOL tilt.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the institutional review board and ethics committee at LV Prasad Eye Institute Hyderabad (ethics approval # LEC07-18-104). The study protocol adhered to the Declaration of Helsinki. Informed written consent was obtained from the participants or the legally authorized representative of the subject (in case of minors) for the publication of this study.

Consent for publication

Written informed consent was obtained from the participants or the legally authorized representative of the subject (in case of minors) for the publication of this study.

Author contributions

Avadhesh Oli: Conceptualization; Data curation; Methodology; Writing – original draft.

Anil Yadav: Data curation; Investigation; Methodology; Resources.

J. Ganesh Babu: Data curation; Formal analysis; Methodology; Validation.

Divya Balakrishnan: Conceptualization; Supervision; Validation; Writing – review & editing.

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Competing interests

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