Flapless and sutureless intrascleral fixation of posterior chamber intraocular lens for correction of aphakia in absence of capsular support

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Received: 4-9-2023, Accepted: 5-11-2023, Published online:16-3-2024

EJO(MOC) 2024;4(1):29-39.

Short title: Intrascleral Fixation of PC IOL for Correction of Aphakia in Absence of Capsular Support

Abstract

Purpose: This study aimed to assess safety and efficacy of flapless and sutureless intrascleral fixation of posterior chamber intraocular lens (PCIOL) (Modified Yamane technique).

Patients and methods: This was a prospective, non-comparative, interventional case series study included 20 eyes with aphakia, dislocated IOL, or subluxated crystalline lens who underwent sutureless and flapless implantation of a PCIOL.

Results: Our study showed an improvement in uncorrected distance visual acuity (UCDVA) and corrected distance visual acuity (CDVA) that was maintained till the end of follow up period. Mean UCDVA and Mean CDVA improved to 0.4 and 0.3 LogMAR units respectively. Mean spherical equivalent was reduced from 10.4 preoperatively to -0.57 six months postoperatively. Corneal endothelial cell count (ECC) was reduced from 2062 ± 546 cells/mm² preoperatively to 1853 ± 618 cells/mm² 6 months postoperatively. The median IOL-induced astigmatism was -0.75. IOL decentration was noticed in five eyes (25%) and significant IOL tilt was noticed in two eyes (10%). The postoperative complication included transient increase in intraocular pressure (IOP) in five eyes (25%), hypotony and choroidal detachment in one eye (5%), iris capture of lens optic in only one eye (5%), Non buried flange in three eyes (15%), Cystoid macular edema (CME) in one eye (5%).

Conclusion: Yamane technique is a safe and effective method for Intrascleral haptic fixation (ISHF) with a new strategy of securing haptics to sclera, by melting haptics to create a flange. It carried out favourable surgical outcome and limited post operative complications.

Key words: Yamane, intrascleral fixation, PCIOL, Aphakia.

INTRODUCTION:

Sutureless techniques for scleral IOL fixation have multiple advantages. They provide better IOL stability than scleral sutured PCIOLs. They minimize IOL tilt and astigmatism. They also do not lead to suture degradation, late IOL dislocation caused by broken sutures or other suture-related complications[1]. In addition, it can be performed despite of iris and anterior segment abnormalities. It is a minimally invasive procedure with minimal contact to uveal tissue[2].

There are some technical variations of sutureless intrascleral fixation of PCIOL, although the basic idea is a fixation of the haptics of the IOL in a scleral tunnel with scleral flap or scleral tunnel only without scleral flap[3].

Gabor and Pavlidis were the first to describe intrascleral fixation of the PCIOL[4] followed by Agarwal et al. who introduced the glued IOL[5]. In 2014, Yamane et al. performed ISHF by docking haptics of a three-piece IOL within 27-gauge needles inserted under scleral grooves. The haptics were externalized by withdrawing the needles and tucked into scleral tunnels created with 27-gauge needles. This method required conjunctival peritomy over each scleral groove site, similar to glued IOL technique[6]. In 2017, Yamane et al.

modified this with a new technique of flanged ISHF where two 30-gauge thin-wall needles are passed transconjunctivally tunneled through sclera and passed into vitreous cavity. The haptics are docked into these needles which are simultaneously withdrawn. Externalized haptic ends are melted with low-temperature cautery, creating bulb-shaped flanges which are pushed back under conjunctiva[7].

The Yamane technique has gained popularity as it has advantages, including eliminating the need for sutures, glue, and scleral or conjunctival dissection with minimal surgical trauma, good IOL stabilization and a relatively shorter operation time[8].

Several modifications on the original technique have been published including modifications that we have adopted in our study.

PATIENTS AND METHODS

This study was a prospective, non-comparative, interventional case series study that aimed to assess safety and efficacy of flapless and sutureless intrascleral fixation of PCIOL (Modified Yamane technique). It was performed for 20 eyes with aphakia and inadequate capsular support at Mansoura ophthalmic center, Mansoura University, Egypt. The study was conducted for duration of one year from January 2021 to January 2022.

The Inclusion criteria were patients aged more than 18 years, aphakic eyes with inadequate capsular support either post-operative or post-traumatic, IOL dislocation, subluxated crystalline lens, normal posterior segment, and patients with normal IOP.

In this study we excluded patients who were younger than 18 years old and those who had posterior segment disease requiring treatment such as retinal detachment, macular pucker, or vitreous hemorrhage, aphakic glaucoma uncontrolled medically, collagen disease such as Rheumatoid Arthritis and Systemic Lupus Erythematosus. The amblyopic eye failed to improve with optical correction and eyes with dense corneal scar or distorted pupil also were excluded.

The study protocol was approved from the institutional review board (IRB) NO: MS.21.03.1423 of Mansoura Faculty of Medicine. An informed written consent was obtained from the participants after explanation of the aims, methods, anticipated benefits, and potential risk of the procedures.

All cases were subjected to a full history taking and ophthalmic examination was done at pre-operative and all post-operative visits including UCDVA, CDVA with Landolt C optotypes, Slit Lamp examination including condition of iris, pupil, and anterior chamber depth, tonometry, fundoscopy and refraction. Corneal ECC was measured using specular microscopy (EM-3000, Tomey Corporation, Japan) Central corneal thickness and keratometric readings (K1 and K2) using corneal topography (TMS-5, Tomey Corporation, Japan), Biometric data and IOL power calculation for all patients, IOL powers were calculated with SRK/T formula using the IOL Master (Carl Zeiss Meditec, Jena, Germany). The 3-piece IOLs used in our study were Sensar (AR40e, Johnson and Johnson Vision).

Surgical procedure

Under general anaesthesia or local posterior sub-Tenon's Mepivacaine HCL 3%, 2 limbal marks exactly 180° apart were placed at 3 and 9 o'clock with a toric marker and ink pen or a simple visco-cannula, The first conjunctival mark was placed 2mm from the limbal mark and the second mark was placed 2mm away from the first one and parallel to the limbus. Another set of similar marks was placed on the opposite side of the globe and in conter-clockwise direction, 3 mm corneal incision was made superiorly and slight to the left.

This position facilitates alignment of the trailing haptic with its fixation needle. Triamcinolone-assisted anterior vitrectomy was performed, and Anterior chamber maintainer (ACM) was placed in position for fluid infusion inside the eye during intrascleral needle pass. A pair of 27G needles, ½ inch (13 mm) long, with outer and inner diameters of 0.4 and 0.2 mm, respectively.

The left-hand needle was bent approximately 9 mm while the right-hand needle was bent 13 mm (at the hub). Both were bent about 70° and in a way so that the bevels would face the approach of haptic docking. The sclera was pierced at two points off-axis to 3 and 9 o'clock to avoid injury of long ciliary nerves. On the left side, the first needle was inserted 2 mm from the limbal mark, and advanced for 2 mm before it was rotated clockwise to penetrate the sclera towards the vitreous cavity, then rotated into view with its bevel facing towards the surgeon.

The IOL was loaded into a 3-piece intraocular lens injector

cartridge, introduced into the eye through the corneal incision. The lens is advanced through the cartridge until the leading haptic has exited the cartridge. The injector is then rotated so the end of the leading haptic can be docked inside of the ½ inch needle. At least one half of the haptic should be docked into the needle to maximize security. This step can be performed using intraocular forceps.

The IOL was further advanced, slowly unfolded leaving the trailing haptic hanging out through the main incision in C-shaped configuration. The needle was slowly withdrawn out of the scleral tunneland 2 mm of the haptic terminal end was measured and cauterized using the ophthalmic cautery pen (Optemp™ II; Alcon) to form a flange. Another scleral tunnel on the opposite side is made in a similar way to the first needle entrance.

The needle tip was advanced through the pupil and externalized through the main incision with the bevel facing the approach of the trailing haptic. Using the microforceps or McPherson's forceps, the trailing haptic was grasped from the elbow and docked into the needle. As the needle was drawn back into the eye, the haptic was further threaded into the needle lumen to ensure adequate docking.

The trailing haptic was then externalized and a flange was created at its distal end. The amount of haptic cauterized must be equal on both sides. The flanges were seated back into the sclerotomies. ACM was removed, viscoelastic material was aspirated, and the corneal incisions were closed by stromal hydration and Nylon suture if needed.

In all cases modified Yamane technique was done in a separate session except one case with posteriorly dislocated lens where combined Pars plana vitrectomy, lens extraction and modified Yamane were done.

All operated eyes were treated postoperatively with topical moxifloxacin HCL 0.5% (Vigamox; Alcon Laboratories) applied 4 times daily up to 1 week. A combination of tobramycin and dexamethasone (Tobradex; Alcon Laboratories) was prescribed 4 times daily for 4 weeks with gradual withdrawal. The patients were instructed to use nepafenac 0.1% (Nevanac; Alcon Laboratories) 3 times daily one day before surgery and for 2 weeks postoperatively. Patients were evaluated 1, 3 and 6 months postoperatively.

Early and late postoperative complications were defined as surgical complications developing within and beyond 1 month after surgery, respectively. Postoperative hypotony and IOP elevation were defined as an IOP of less than 6 mmHg and and IOP of more than 25 mmHg, respectively.

Statistical analysis

Data were entered and analyzed using IBM-SPSS software (IBM Corp. Released 2019. IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp) and MedCalc® Statistical Software version 20 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2021). Qualitative data were expressed as N (%).

Quantitative data were initially tested for normality using Shapiro-Wilk's test with data being normally distributed if $p>0.050$. The presence of significant outliers (extreme values) was tested for by inspecting boxplots.

Quantitative data were expressed as mean, standard deviation (SD) if normally distributed with no significant outliers, otherwise, data were presented as median, and range (maximum - minimum).

Visual acuity measurements were calculated as inverted LogMAR units. Fisher's exact test was used to compare nominal data between groups. Paired-Sample t-test was used to compare normally distributed quantitative paired data. One-Way repeated measures ANOVA was used to compare normally distributed quantitative data over time. Friedman's test was used to compare non-normally distributed quantitative data over time. The Kruskal-Wallis test was used to compare non-normally distributed data between three or more groups. For any of the used tests, results were considered as statistically significant if p value ≤ 0.050.

RESULTS

Twenty eyes with an average age of 45.9 years were enrolled in this study with follow up till six months post-operatively. Half of the cases had surgical aphakia, 20% had traumatic aphakia, another 20% had IOL dislocation / subluxation, and 10% had lens dislocation / subluxation. Five patients had a history of blunt trauma and three patients had history of ruptured globe. Associated comorbidities were observed in four patients (20%), one of them had diabetes, hypertension, ischemic heart disease, and chronic liver disease and another one had Marfan syndrome.

Two cases had nasal pterygium and another two had

paracentral corneal wound scar. Vitreous in Anterior chamber (AC) was noticed in six eyes. Iris examination revealed traumatic mydriasis in two eyes and traumatic iridectomy in three eyes. One eye has non proliferative diabetic retinopathy and another one has myopic chorioretinal degeneration. The Baseline characteristics of the studied cases are included in Table 1.

Table 1: Baseline characteristics of the studied cases (N=20)

Characteristic	
Categorical	**N (%)**
gender	
Male	14 (70%)
Female	6 (30%)
Laterality	
Right	12 (60%)
Left	8 (40%)
Quantitative	**Mean ± SD**
Age (years)	45.9 ± 15.8
Duration of lens condition (months)	5.7 ± 3.8
Axial length (mm)	24.5 ± 1.9
IOL power (D)	18.5 ± 4.9

Notes: SD = standard deviation. D = Diopter.

Repeated measures of UCDVA showed statistically significant difference between preoperative and each of three post-operative values, but not between the three postoperative values. On the other hand, there was no statistically significant difference between repearted measures of CDVA. Higher preoperative spherical equivalent compared to the three post-operative values with no statistically significant difference between the three postoperative values. There was statistically significant drop in ECC after one month, and such ECC continued to statistically drop at 3 months and 6 months postoperatively. Bonferroni-adjusted P values of repeated IOP measurement revealed no statistically significant difference between the preoperative and each of the three postoperative reading. There was also no statistically significant difference between IOP readings in all follow up points. Repeated measures of UCDVA, CDVA, Spherical equivalent, corneal ECC, and IOP were demonstrated in table 2.

Table 2: Repeated measures of UCDVA, CDVA, Spherical Equivalent, corneal ECC, and IOP

Parameter	Preoperative	Postoperative			P	Pairwise comparisons (Adjusted P values)					
		1-month	3-months	6-months		P1	P2	P3	P4	P5	P6
UCDVA (Inverted LogMAR)	0.56 (0.5-0.68)	2.1 (1.3-2.1)	2.2 (1.7-3.3)	2.1 (1.7-3.3)	<0.001	0.001	<0.001	<0.001	0.224	0.668	1.000
CDVA (Inverted LogMAR)	2.2 (1.7-4.5)	3.3 (2.0-5.7)	3.3 (2.2-5.7)	3.3 (2.1-5.7)	0.091	-	-	-	-	-	-
Spherical equivalent (Diopter)	10.4±2.7	-0.38 ± 1.2	-0.53 ± 1.4	-0.57 ± 1.4	<0.001	<0.001	<0.001	<0.001	1.000	1.000	1.000
ECC (cells/mm²)	2062 ± 546	1883 ± 614	1860 ± 618	1853 ± 618	<0.001	<0.001	<0.001	<0.001	0.021	0.004	<0.001
IOP (mmHg)	16.5 (16.5-16.5)	16.5 (16.5-22.2)	16.5 (16.5-16.5)	16.5 (16.5-16.5)	0.007	1.000	1.000	1.000	0.755	0.455	1.000

Notes: Data is median (Q1-Q3) [test of significance is Friedman's test] for UCDVA, CDVA, and IOP and mean ± SD [test of significance is One-Way repeated-measures ANOVA] for Sph.E, and ECC. Pairwise comparisons: P1 = Preoperative vs. 1-month Postoperative, P2 = Preoperative vs. 3-month Postoperative, P3 = Preoperative vs. 6-month Postoperative, P4 = 1-month Postoperative vs. 3-month Postoperative, P5 = 1-month Postoperative vs. 6-month Postoperative, P6 = 3-month Postoperative vs. 6-month Postoperative.

The results of Wilcoxon Signed Rank test which was run to compare pachymetry at 6-months postoperative vs. preoperative showed no statistically significant difference between the two readings (Table 3).

Table 3: Preoperative pachymetry vs. 6-months postoperative pachymetry

Parameter	Preoperative	Postoperative	Z	p-value
Pachymetry	553 (534-583)	551 (525-571)	-1.111	0.266

Notes: Data is median (Q1-Q3). Test of significance is Wilcoxon signed rank test.

Paired-Samples t-test showed no statistically significant difference between preoperative and 6-months post-operative keratometry readings and corneal astigmatism (table 4).

Table 4: Preoperative vs. 6-months postoperative keratometry readings amd corneal astigamtism

Parameter	Preoperative	Postoperative	Mean difference	95% CI	t	P value
K1	41.5 ± 2.3	41.4 ± 2.5	0.058	-0.37 to 0.49	0.281	0.782
K2	43.4 ± 2.5	43.2 ± 2.2	0.144	-0.41 to 0.69	0.547	0.591
Corneal Astigmatism	-1.64 ± 1.04	-1.54 ± 0.93	-0.092	-0.65 to 0.47	-0.346	0.733

Notes: Data is mean ± standard deviation. Test of significance is Paired-Samples t-test.

None of the cases developed pseudophacodenosis. Decentration, capture, and tilt occurred in 25%, 5%, and 10% of cases, respectively. IOL decentration was detected in five eyes. It was clinically insignificant except in one patient with upwards decentration. He was complaining only on looking downwards, However the patient refused further interference. IOL tilt occurred in two eyes. Repositioning was performed for one of them, but there was a residual tilt after re-surgery. The second case with IOL tilt didn't require repositioning because fortunately IOL tilt despite being significant neutralize the effect of pre-exisiting corneal astigmatism from paracentral corneal wound scar. UCDVA and CDVA were 0.4 and 0.2 Log MAR respectively. Iris capture of lens optic was detected in one eye that developed reverse pupillary block. Repositioning was done.

Both early and late complications occur in 45% of cases (Table 5). Transient increase in IOP (>25mmHg) occurred in five eyes, only two eyes developed secondary glaucoma throughout follow up period of 6 months. One eye with previous sub scleral trabeculectomy (SST) developed hypotony (<6 mmHg) and choroidal detachment. It was persistent for 3 weeks post-operative. Reformation was done with viscoelastic injection. After reformation, the IOP normalized with improvement in UCDVA and CDVA to 0.4 and 0.2 Log MAR, respectively. Transient anterior uveitis was detected in four eyes. It was treated with frequent topical steroids and cycloplegic eye drops. Three of them developed IOL pigment deposits. None of these eyes developed iris transillumination defects, pigment dispersion glaucoma, or CME throughout the follow-up period. One eye developed CME and was successfully managed with single sub-Tenon's triamcinolone injection, topical steroids and topical NSAIDs that were discontinued after 6-8 wk. Unburied Flange was detected in three eyes and after one month they were repositioned under topical anaesthesia using a blunt-tipped forceps after application of betadine eye drops. Recurrence was observed in one eye. Subconjunctival scleral erosion by haptic was detected in one eye and was kept under follow up. None of cases enrolled in this study developed vitreous Haemorrhage, Hyphema, Endophthalmitis, IOL dislocation or Retinal Detachment during the follow up period.

Table 5: Frequency of early and late complications

Complication	N	%
Early	9	45%
Hypotony and choroidal detachment	1	5%
Transient corneal edema	5	25%
Transient anterior uveitis	4	20%
Transiently increased IOP	5	25%
Late	9	45%
Secondary glaucoma	2	10%
Unburied flange	3	15%
IOL pigment deposits	3	15%
Cystoid macular edema	1	5%
Scleral erosion by haptic (subconjunctival)	1	5%

There was no statistically significant difference in all studied parameters between the three eye trauma subgroups (Table 6). However, in the three cases of ruptured globe, there were evident more early and late complication incidence.

Table 6: Comparisons of complications in the three eye trauma subgroups

Parameter	Eye trauma subgroup			P value
	No trauma N=12	Blunt trauma N=5	Rupture globe N=3	
Early complications	4 (33.3%)	2 (40%)	3 (100%)	*0.164
Late complications	3 (25%)	3 (60%)	3 (100%)	*0.039
IOL decentration	4 (33.3%)	1 (20%)	0 (0%)	*0.787
IOL capture	0 (0%)	1 (20%)	0 (0%)	*0.400
IOL tilt	1 (8.3%)	1 (20%)	0 (0%)	*0.653
IOL induced astigmatism	-0.75 (-4.0 to 0)	-0.5 (-1.75 to -0.25)	-2.0 (-2.25 to -0.25)	$0.582

Notes: Data is * N (%), and test of significance is Fisher's exact test, or $ Median (minimum – maximum), and test of significance is Kruskal-Wallis H-test.

There was no statistically significant difference in all studied parameters between the three lens condition subgroups (Table 7) except late complications which occurred in 80% of subluxation/dislocation cases and in 75% of traumatic aphakia cases vs. only 10% in surgical aphakia cases.

Table 7: Comparisons of post-operative complications in the relation to the pre-operative lens condition

Parameter	Lens condition subgroup			P value
	Traumatic aphakia N=4	Surgical aphakia N=10	Dislocation / subluxation N=6	
Early complications	3 (75%)	2 (20%)	4 (66.7)	*0.0.086
Late complications	3 (75%)	1 (10%)	5 (83.3%)	*0.006
IOL Decentration	0 (0%)	4 (40%)	1 (16.7%)	*0.420
IOL capture	0 (0%)	0 (0%)	1 (16.7%)	*0.500
IOL tilt	0 (0%)	0 (0%)	2 (33.3%)	*0.111
IOL induced astigmatism	-1.13 (-2.25 to 0.25)	-0.75 (-2.0 to 0)	-0.88 (-4.0 to -0.25)	$0.784

Notes: Data is * N (%), and test of significance is Fisher's exact test, or $ Median (minimum – maximum), and test of significance is Kruskal-Wallis H-test.

DISCUSSION:

Intrascleral fixation was first described by Gabor and pavlidis[4] followed by Agarwal et al. who introduced the glued IOL[5]. In 2014, Yamane et al. performed sutureless 27-Gauge Needle Guided intrascleral IOL implantation with Lamellar Scleral Dissection[6]. In 2017, Yamane modified the previous technique using ab externo sclerotomies, simultaneous externalization of the lens haptics with two separate needles, and thermocauterization to flange the distal haptics. They have reported excellent visual results, predictable postoperative refractive errors, low endothelial cell loss, and relatively few complications[7].

Although long-term outcomes are not yet available, Yamane IOL fixation is an elegant method offering several advantages over other methos of ISHF[9].

The Yamane technique has gained popularity, and several modifications have been described[10].

In this study, we assessed safety and efficacy of one of modifications of Yamane technique. The modification includes direct threading of leading haptic into the lumen of 27 Gauge needle[11], Externalization and intra fixation of leading haptic before manipulation with trailing haptic[12] and docking of trailing haptic externally through the main corneal incision[13].

Kim modification includes direct threading of leading haptic into lumen that offers an advantage in eyes with inadequate iris support. Also, it avoids iris injury and pigment dispersion by the tip of the haptic[14].

Sequential haptic externalization that was described by Hwang et al., requires only one needle and eliminates the need for an assistant to stabilize the first needle. It also reduces the possibility of inadvertent trauma to the ciliary body or peripheral retina by the unsecured needle[12]. This was supported by the lack of vitreous hemorrhage in this current study. In addition, Fixing the leading haptic first prevent its slippage during manipulating trailing haptic. This can reduce the possibility of lens dislocation into the vitreous cavity[10].

Ifantides et al., described docking of trailing haptic externally through corneal incision that allows docking of trailing haptic even when there is loss of corneal clarity or other media opacity within anterior segment. It minimizes damage to intraocular structures, improves surgery speed and could potentially obviate the need for intraocular lens forceps[13].

The current study showed an improvement in UCDVA and CDVA that was maintained till the end of follow up period. Mean UCDVA and Mean CDVA improved to 0.4 and 0.3 Log MAR respectively. The mean spherical equivalent ± SD was reduced from 10.4 ± 2.7 D preoperatively to -0.57 ± 1.4 D 6 months postoperatively. These results are consistent with the studies carried out by Yamane et al.[7], Randerson et al.[10], and Ifantides et al.[13].

The most frequent postoperative complication in this study was transient increase in IOP that was encountered in five eyes (25%). Only two eyes (10%) developed secondary glaucoma and were controlled with medical treatment. On the other hand, Yamane reported only two eyes (2%) with transient increase in IOP and only one case developed glaucoma[7], while Randerson reported that transient increase in IOP was noticed in nineteen eyes (15.7%) and all were controlled with medical treatment[10].

Early hypotony and choroidal detachment was developed in one eye (5%) that previously had Sub scleral trabeculectomy. Reformation with viscoelastic injection was performed for this patient 3 weeks postoperatively. After reformation, the IOP normalized with improvement in UDVA and CDVA to 0.4 and 0.2 Log MAR, respectively. Similarly, Yamane reported hypotony in only 2 eyes (2%)[7].

The current study shows statistically significant reduction in Mean ECC ± SD from 2062 ± 546 cells/mm² preoperatively to 1853 ± 618 cells/mm² 6 months postoperatively. This result goes hand in hand with Besozzi's research that showed a significant decrease in the mean ECC from 1910.5 to 1508.8 cells/mm² 6 months postoperatively[15]. On the contrary, Yamane reported that the mean corneal endothelial cell density decreased from 2341 cells/mm2 to 2244 cells/mm2 that was statistically insignificant[7]. The reduction in the current study despite being statistically significant, it was clinically insignificant as it didn't affect the visual outcome.

IOL decentration was noticed in five eyes (25%). Four cases with slight downwards decentration didn't have a visual complaint. Only one patient with upwards decentration was complaining when looking downwards. On the other hand, Kelkar et al reported IOL decentration in 6.4%[16].

The current study reported that the median (minimum – maximum) IOL-induced astigmatism was -0.75 (-4.0 to 0.0). Significant IOL tilt was noticed in two eyes (10%). Repositioning was performed to one of them by cutting the flange of the leading haptic which was then re-internalized and new shorter (1.5mm) intrascleral tunnel was created using 27G needle, 1 mm from the limbus to compensate for haptic shortening. The haptic was re-docked into the needle, externalized and a smaller flange was created by heating only 1mm of its tip. Similarly, Miura et al reported IOL tilt in 5% and manage their cases in a similar fashion[17].

The insertion angle of needles, used to create the scleral tunnels, is important. Inappropriate positioning of the insertion points and angles of the two needles may cause decentration and tilting of the IOL. Also, the scleral tunnels must be similar in length, location, and direction. the amount of haptic cauterization must be equal on both sides[7,9]. Although sequential externalization of the haptics, complications associated with simultaneous withdrawal of the needles are inherently avoided[8], Simultaneous needle withdrawal described by Yamane provides a more favorable angle of approach for docking the trailing haptic and also enables final adjustment of both haptics to obtain proper IOL positioning and centration before haptic fixation[7].

The current study reported iris capture of IOL optic in only one eye (5%) which developed reverse pupillary block and repositioning was done. Yamane reported iris capture in eight eyes (8%). He speculated that flow of aqueous humor resulting from blinking and eye movement is likely to increase after vitrectomy and cause reverse iris block and iris capture. Younger patients seem more prone to movement of the iris for reasons that are not clear[7]. This was consistent with this current study as the patient with iris capture was 26 years old.

Non buried flange or distal haptic protrusion was noticed in three eyes (15%). Randerson reported that haptic tips that are clearly displaced and protruding beneath the conjunctiva can be successfully repositioned at the slit lamp under topical anaesthesia and in sterile conditions after application of betadine using a blunt-tipped forceps or sterile cotton swab to avoid tearing the overlying conjunctiva. He found this approach prevented further protrusion and haptic exposure in nine of eleven eyes with this complication in his study; the other two eyes required re-operation for surgical repositioning[10].

This study encountered one eye with CME. Post operative CDVA was 1 Log MAR and post operative spherical equivalent was +3.00 D despite normal anterior segment and well centralized IOL with no clinically significant tilt. Optical coherence tomography (OCT) showed increase in the central macular thickness. These results are consistent with the study conducted by Yavazir et al who reported CME in 4.7%[18]. Also, another study conducted by Ucar and Cetinkaya reported CME in 4.8%[19].

This current study shows no statistically significant difference in Keratometric readings, corneal astigmatism, and central corneal thickness. There was no corneal complication except transient corneal edema that was noticed in five eyes and accompanied transient anterior uveitis or transient increase in IOP. In a similar fashion, Yamane reported corneal edema in early postoperative period in only one eye (1%)[7], while Randerson reported it in 6 eyes (5%)[10].

No intraoperative complications were noted. Similar result was reported by Nowomiejska et al. who performed Yamane technique in 30 eyes with posttraumatic aphakia using 3-piece IOL with PMMA haptics (Alcon MA60AC)[20].

This study didn't report any case of vitreous hemorrhage or IOL dislocation. On the contrary Yamane et al. reported vitreous hemorrhage in 5%[7] while Ucar and Cetinkaya reported vitreous hemorrhage in 9.5% and IOL dislocation in 2.5%[18].

The Limitations of this study include limited sample size and short follow-up time. Longer time of follow-up in these eyes will make it possible to determine the long-term safety and efficacy of the modified technique.

Another shortcoming of this study was that no anterior segment imaging device (OCT) for measuring the optic tilt was used.

CONCLUSION:

Although long term follow up is not available, flapless and sutureless technique is an elegant method for ISHF with a new strategy of securing haptics to sclera, by melting haptics to create a flange. It carried out a favorable surgical outcome and limited post operative complications.

Flapless and sutureless technique proved to be a suitable

choice for intrascleral fixation of PCIOL in absence of capsular support, as it has advantages, including eliminating the need for sutures, glue, and scleral or conjunctival dissection with minimal surgical trauma, good IOL stabilization and a relatively shorter operation time.

Recommendations:

Based on the results of this study, it is recommended to perform further studies including larger number of patients for a longer period of follow up with different IOL types.

ACKNOWLEDGEMENT: None

Data Availability: The authors declare that all data supporting the findings of this study are available within the article and its supplementary information file.

Competing interests: The authors declare no competing interests.

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Ethics declarations: All procedures performed in the study followed the 1964 Helsinki declaration and its later amendments, University Ethics Committee approved the project.

Conflict of interest

Nashaat S. Zaky, Samy A. Abo ELkhair, Kholoud M. Abdo, Dina N. Laimon, Amr M. AbdelKader. All authors have no conflicts of interest that are directly relevant to the content of this review.

Funding: No sources of funding were used to conduct this review.

Reviewer disclosures: No relevant financial or other relationships to disclose.

Declaration of interest: No financial affiliations or financial involvement with any organization or entity with a financial competing with the subject matter or materials discussed in the review.

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