The Egyptian Journal of Hospital Medicine (July 2019) Vol. 76 (3), Page 3718-3723

Evaluation of Flanged Haptics Intrascleral Sutureless Intraocular Lens Fixation

Younis Alsaeid Abd-Elhafez, Ali Ahmed Ali Ghali, Ahmed El Sayed Hodib, Ahmed Anwer Sadat Ali*
Department of Ophthalmology, Faculty of Medicine, Al-Azhar University
***Correspondence author:** Ahmed Anwer Sadat Ali, **Mobile:** (+20) 01022131987, **E-mail:** ahmedophth89@gmail.com

ABSTRACT

Background: successful intraocular lens (IOL) placement in patients undergoing cataract surgery has become synonymous with the IOL being placed in the capsular bag.

Purpose: to evaluate the flanged haptic sutureless intrascleral intraocular lens fixation with double needle technique as a method of scleral fixation of posterior chamber IOL (PCIOL) as regard to its stability and safety as well as its complications. **Patients and Methods:** this is a prospective study, which included 20 eyes of 20 patients with aphakia with no adequate capsular support. **Results:** post-operatively the best corrected visual acuity (BCVA) was improved to reach up to 0.8 decimal unit. Intra-operatively, haptic breakage was reported in 3 cases where the IOLs were explanted and new IOLs were implanted and sclerally fixated. The post-operative complications included iris capture in 2 cases (10%), haptic deformation in 2 cases (10%), exposure in 5 cases (25%) and slippage in 2 cases (10%), corneal edema in 6 cases (30%), IOL decentration in 4 cases (20%) one of them was significantly decentered and needed for reoperation where one point fixation by a stitch of the slipped haptic , spontaneous IOL dislocation in 2 cases (10%) 1 month and 3 months post-operatively, both required re operation where the slipped IOL was explanted and new one is re implanted and sclerally fixated. There were no incidents of post-operative ciliary body injury, retinal tear or detachment or endophthalmitis.

Conclusions: the flanged haptics intrascleral sutureless IOL fixation with double needle technique can be done for aphakic cases with no adequate capsular support.

Keywords: Aphakia, Flanged haptics, Sutureless, Scleral fixation.

INTRODUCTION

Optimal placement of an intraocular lens (IOL) is within an intact posterior lens capsule with good zonular support. However, ophthalmic surgeons are faced with situations during cataract surgery in which an occasional inadvertent, extensive lens capsular tear may remove the option of placing the lens in the capsular bag, requiring a different location to make the eye pseudophakic[(1)].

Alternatively, a patient who has been aphakic with an aphakic contact lens may elect to have a secondary IOL placement due to a recent inability to wear the contact lens, or there may be situations in which an IOL exchange may be required when dealing with a subluxated IOL[(2)].

In these situations, and others, the choices for a secondary IOL placement include the anterior chamber, iris-fixation and scleral-fixation using transscleral sutures. Based on a literature review, **Wagoner *et al.*[(3)]** suggested that all three IOL location options are safe and effective choices in the absence of lens capsular support for IOL implantation.

When the surgeon elects to place an IOL in the ciliary sulcus, away from the corneal endothelium, the options include fixating the IOL to the sclera using sutures or tucking the haptics within scleral pockets without the use of sutures [(4)].

Surgical expertise, prolonged surgical time, suture-induced inflammation, suture degradation, and delayed IOL subluxation or dislocation due to broken suture are some of the limitations in sutured scleral-fixated IOL. It is also difficult and time-consuming, requiring perfect adjustment of suture length and tension to ensure good centration of the scleral-fixated IOL [(5)].

Yamane *et al.*[(5)] described a new technique for sutureless intrascleral fixation of a PCIOL using 27-gauge needles. This technique requires no special instruments for the IOL fixation and provides good IOL fixation with good wound closure without leakage.

Two lamellar scleral incisions 1.5 mm in length and about 50% scleral thickness were made 1.7 mm from the limbus at 180˚ from each other. A 3-piece IOL was inserted into the anterior chamber with an injector and the trailing haptic was kept outside. An angled sclerotomy was made at the end of lamellar scleral dissection with a 27-gauge needle. The leading haptic was threaded into the lumen of the needle using forceps. The IOL was rotated and the trailing haptic was inserted into the anterior chamber. A second sclerotomy was then made, the trailing haptic was passed into the lumen of the second needle and both haptics were externalized onto the sclera with the double needle technique[(6)].

AIM OF THE WORK

To evaluate the flanged haptics sutureless intrascleral intraocular lens fixation with double needle technique as a method of scleral fixation of posterior chamber IOL (PCIOL) as regard to its stability and safety as well as its complications.

PATIENTS AND METHODS

This is a prospective study in which 20 eyes of 20 patient with aphakia without adequate capsular support due to complicated cataract surgery,

Received:19/4/2019
Accepted:18/5/2019

subluxated lens (>180˚), posteriorly dislocated lens and patients with anteriorly or posteriorly dislocated IOL who had given their consent were enrolled, they attended the outpatient Ophthalmology clinic or Emergency department of Al-Azhar University hospital, Damietta during the period from January 2018 to April 2019.

The study was approved by the Ethics Board of Al-Azhar University. The following inclusion and exclusion criteria were used**:**

Inclusion Criteria: Patients with aphakia with no adequate capsular support.

Exclusion Criteria:

- Patients who refuse to participate or continue to participate in our study.
- Patients of congenital and infantile cataract.
- Patients with scleromalacia or with history of scleral inflammation.
- Patients with uncontrolled IOP.
- Patients with hazy or decompensated cornea or active uveitis.
- Patients with non-dilating pupil, macular scar and glaucoma.

Pre-operative evaluation:

(1) History taking:

- Onset, course and duration of diminution of vision.
- History of ocular trauma, ocular surgery, systemic disorder and drug intake.

(2) General examination:

- Review for systemic diseases as hypertension, bleeding tendency and renal impairment.

(3) Laboratory investigation:

- Fasting blood glucose, 2hour postprandial blood glucose, coagulation profile, liver and kidney function tests.

(4) Preoperative opthalmological examination:

- Best corrected visual acuity (BCVA), were evaluated by landot C optotype using Snellen`s chart.
- Pupil reaction.
- Refraction using Nidek automated refractometer.
- Slit lamp examination to assess corneal clarity, depth of anterior chamber, state of pupil dilatation, lens morphology, and any pathological finding.
- Intraocular pressure (IOP) by Topcon CT-800 non-contact tonometer.
- Fundus examination: slit lamp biomicroscopy using non-contact Volk 90 Diopter lens.
- Assessment of ocular motility in all direction of gaze.
- Examination of ocular adnexa.

(5) Pre-operative medication monitoring

- Topical NSAIDS are given three days before surgery and topical antibiotics (Moxifloxacin) 1week before surgery.

(6) Preoperative investigations:

- Calculation of IOL power and axial length by (4 Sight Accutom Ultra-sound, USA) and (Zeiss 500 IOL Master, Germany).
- Ultra sound to assess the posterior segment especially in traumatic cases.
- All patients had informed written consent.

(7) Operative details:

- Before surgery, all pupils were dilated with 1% tropicamide and ocular sterilization with povidine iodine 5% was used**.**
- Under general or peribulbar anesthesia, two limbal horizontal points were marked 180° apart using an axis ring at 3'o clock and 9'o clock meridians.
- With an inked caliber, the conjunctiva was marked 2 mm posterior to each of the limbal marks, then another two conjunctival marks were placed. One was two mm above and the other was two mm below the previous two conjunctival marks respectively. These four marks were the landmarks for scleral needle puncture Active infusion was used in most cases to maintain the globe firm for needle placement, and in preparation before the case both needle were bent at an angle about 80 degree with the bevel facing upward in the direction of the bend.
- A 2.8 mm keratome was then used to create a standard shelved limbal incision superiorly at the 12'o clock position, and after filling the anterior chamber with a dispersive viscoelastic two paracentesis incisions were created at the 10'o clock and 2'o clock positions.
- All patients underwent anterior vitrectomy and those with significant subluxation or dislocation of the nucleus or IOL underwent complete pars planavitrectomy before scleral fixated IOL implantation.
- Following adequate vitrectomy, the three-piece IOL was injected with the cartridge and injector into the eye through the limbal incision leaving the trailing haptic outside the eye while the leading one was in the anterior chamber.
- Using the previous conjunctival marking, an angled sclerotomy was made with 27-gauge needle.
- A 23-gauge end gripping micro forceps was introduced from a paracentesis to insert the tip of the leading haptic into the lumen of the needle.
- The haptic was pushed deeper into the needle ensuring that at least half of the haptic length was inside the needle and keeping it tangential with the

iris plane to avoid ciliary body injuryThe haptic was externalized and the tip was heated with a thermal cautery by approximating the cautery to the haptic to create a flange, which was pushed back and fixed intrasclerally.

- In some cases the haptic was secured by a nylon 10-0 stitch, this stitch is either removed after threading the lagging haptic into the needle to avoid haptic slippage during manipulation of the lagging one or left without removal especially if the flange hadn't formed well to avoid post-operative haptic slippage as much as possible. The same technique was repeated 180° opposite to fixate the trailing haptic
- Viscoelastic material was aspirated and anterior chamber was formed with balanced salt solution (BSS). If a pars planavitrectomy was performed, the trocars were removed at the end and integrity of the incisions was ensured.
- Following surgery, the patients' eye was padded and shifted to the recovery room. The eye pad was removed after 6 hours and topical medication was started. Nepafenac eye drops three times a day for 2 weeks, moxifloxacin eye drops four times a day for 4 weeks, and topical prednisolone 1% eye drops in tapering dose for 6 weeks were given.
- The IOL used in our study was AcrSof MA60AC (Alcon, USA), this IOL is a soft multipiece IOL. Its optic is anterior asymmetric biconvex, 6 mm in length and made of ultra-violet absorbing Acrylate/ Methacrylate copolymer. The haptic has a modified-C configuration and made of blue colored PMMA.

(8) Post-operative follow-up:

- The patients reviewed at 1st day post operative then at 3 visits (1week, 4weeks and 12 weeks post operative). At each visit intra ocular pressure assessment, BCVA, slit-lamp examination, anterior chamber, bleb examination, intra ocular lens and wound assessment.

(9) Statistical analysis

The collected data were organized, tabulated and statistically analyzed using statistical package for social sciences (SPSS) version 19 (SPSS Inc, Chicago, USA). For qualitative data, frequency and percent distributions were calculated. For quantitative data, mean and standard deviation (SD) were calculated. For comparison between two groups, the independent samples (*t*) test was used. For all tests p value <0.05 were considered significant. For all tests p value >0.05 were considered insignificant**.**

RESULTS

The present study included 20 subjects; 8 of them (40.0%) were males and 12 (60.0%) were females (table **1**).

As regard age of the studied cases, it ranged from 50 to 72 years with a mean of 65.48±3.95 years; and there was no significant difference between male and female ages (57.63 and 61.75 years respectively).

Table (1): Age distribution in studied cases

	Mean	SD	Minimum	Maximum	Paired (t)	P value
Male	57.63	6.163	50.00	67.00	1.477	0.157(NS)
Female	61.75	6.092	55.00	72.00		
Total	65.48	5.95	50.00	72.00		

As regard preoperative uncorrected visual acuity, it ranged from 0.04 to 0.25 with a mean of 0.101±0.06; while postoperatively, it ranged from 0.1 to 0.5 with a mean of 0.237±0.10; and there was significant increase of UCVA postoperatively when compared to preoperative values.

Table (2): Uncorrected visual acuity in studied cases pre- and post-operatively

		Mean	S. D	Minimum	Maximum	Paired(t)	P value
UCVA	Preoperative	0.101	0.581	0.04	0.25	8.487	0.000*
	Postoperative	0.237	0.103	0.10	0.50		

As regard best corrected visual acuity preoperatively, it ranged from 0.18 to 0.5 with a mean of 0.304; while postoperative BCVA ranged from 0.10 to 0.80 with a mean of 0.424; and there was significant increase of BCVA postoperatively when compared to preoperative values.

Table (3): Best corrected visual acuity in studied cases pre- and postoperatively

		Mean	S .D	Minimum	Maximum	Paired(t)	P value
BCVA	Preoperative	0.304	0.819	0.18	0.5	2.772	<0.014*
	Postoperative	0.424	0.195	0.10	0.8		

As regard decentered IOL, it was reported in 4 cases (2 males and 2 females) and there was no significant difference between males and females.

Table (4): Decentered IOL in studied cases

		Sex				Total		Statistics	
		Male (8)		Female (12)				X^2	p
		n	%	n	%	n	%		
Decentered IOL	Yes	2	25.0%	2	16.7%	4	20.0%	2.552	0.11(NS)
	No	6	75.0%	10	83.3%	16	80.0%		

Regarding IOL stability, spontaneous IOL dislocation was reported in 2 cases (10.0%) (1 male and 1 females) and there was no significant difference between males and female.

Table (5): spontaneous IOL dislocation in studied cases

		Sex				Total		Statistics	
		Male (8)		Female (12)				X^2	p
		n	%	n	%	n	%		
spontaneous IOL dislocation	Yes	1	12.5%	1	8.3%	2	10.0%	0.093	0.761(NS)
	No	7	85.5%	11	91.7%	18	90.0%		

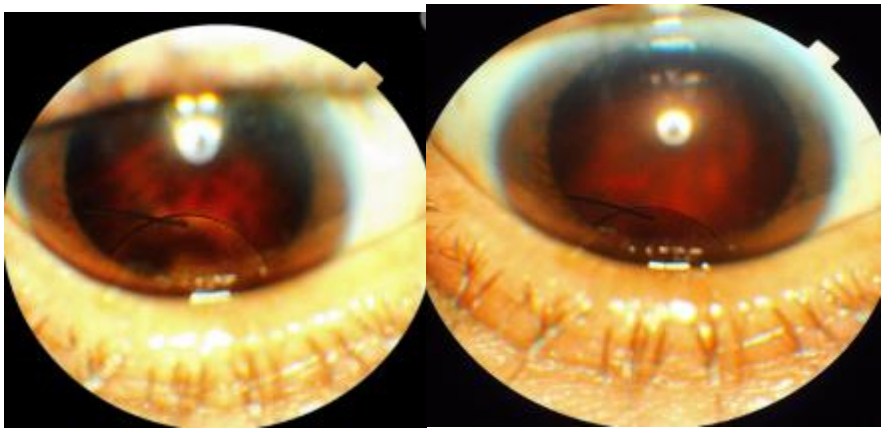

Figure (1): Male patient with spontaneous dislocation of the IOL.

As regard iris capture it was reported in 2 cases (1 male and 1 female) with no significant difference between males and females.

Table (6): Postoperative iris capture in studied cases

		Sex				Total		Statistics	
		Male (8)		Female (12)				X^2	p
		n	%	n	%	n	%		
Postoperative iris capture	Yes	1	12.5%	1	8.33%	2	10.0%	0.093	0.761(NS)
	No	7	87.5%	11	91.7%	18	90.0%		

Regarding vitreous hemorrhage, it was reported in 2 cases (10.0%) (1 male and 1 females) and there was no significant difference between males and females.

Table (7): Vitreous hemorrhage in studied cases

		Sex				Total		Statistics	
		Male (8)		Female (12)				X^2	p
		n	%	n	%	n	%		
Vitreous hemorrhage	Yes	1	12.5%	1	8.3%	2	10.0%	0.093	0.761(NS)
	No	7	85.5%	11	91.7%	18	90.0%		

As regard need for reoperation, it was reported in 5 cases (3 male and 2 females); 2 cases due to post-operative hypotony, 2 cases due to post-operative spontaneous IOL dislocation (1 month and 3 months postoperatively) and 1 case due to significant IOL decentration.

Table (8): Need for reoperation in studied cases

		Sex				Total		Statistics	
		Male (8)		Female (12)				X^2	p
		N	%	n	%	n	%		
Need for reoperation	Yes	3	37.5%	2	16.7%	5	25.0%	1.111	0.292(NS)
	No	5	62.5%	10	83.3%	15	75.0%		

AC reaction was reported in 1 case (female patient); and there was no significant difference between males and females.

Table (9): AC reaction in studied cases

		Sex				Total		Statistics	
		Male (8)		Female (12)				X^2	p
		N	%	n	%	n	%		
AC Reaction	Yes	0	0.0%	1	8.3%	1	5.0%	0.702	0.402(NS)
	No	8	100.0%	11	91.7%	19	95.0%		

DISCUSSION

Many techniques have evolved over the decades ranging from anterior chamber IOL implantation, either supported on the anterior iris surface or the anterior chamber angle, scleral fixated IOLs (SFIOL) anchored either using sutures or by sutureless methods, and retropupillary iris claw IOL fixation [(7)]**.** Each technique has its merits and demerits; however, scleral fixated IOL is the most preferred technique in view of their long-term safety and efficacy[(8)]**.**

Compared to sutured SFIOL, performing sutureless SFIOL fixation as described by **Scharioth *et al.*[(9)]** is relatively simple where the exteriorized haptics of a regular three-piece IOL are fixated into scleral pockets. **Sindal *et al.*[(10)]** has shown comparable results using sutured SFIOL and sutureless SFIOL for post cataract and post-traumatic aphakia.

Similarly, Agarwal's technique of glued SFIOL exteriorizes the IOL haptic under a partial thickness scleral flap, which is then secured using fibrin glue. Although technically less challenging than sutured SFIOL, these techniques of sutureless SFIOL involve conjunctival dissection and related patient discomfort. In addition, it is always challenging to ensure adequate length of haptic fixation inside the scleral tunnels or under scleral flaps. Long-term impact of the exteriorized IOL haptic and fibrin glue on the scleral integrity and stability of IOL fixation is unknown at present[(11)]**.**

To address these concerns, **Yamane *et al.*[(5)]** described the elegant use of a 30-gauge thin wall needle to externalize the haptics of a three-piece haptic IOL before using heat from a cautery to create a flanged haptic tip that permits intrascleral fixation without slippage. He termed it the transconjunctival intrascleral IOL fixation with the double-needle technique using flanged haptics. Its advantages over the conventional SFIOL techniques make it an attractive choice for surgeons.

However, the haptics of routinely used lenses such as Tecnis ZA9003 (Abbott Medical Optics, Santa Ana, CA, USA), Sensar AR40e (Abbott Medical Optics, Santa Ana, CA, USA) and Acrysof MA60AC (Alcon, USA) cannot be negotiated through routine 30-gauge needle. Since the thin walled 30-gauge needle is not freely available in our setting, we used 26-gauge and 27-gauge needles to exteriorize the haptics of these IOLs. Even while using the 27-gauge needle, we found that it took efforts to thread the trailing haptic into the needle lumen. In view of this, we recommend using a 26-gauge needle for beginners so that the procedure is completed without haptic-related complications such as breakage and slippage in the initial cases.

We modified the **Yamane *et al.*[(5)]** technique where we exteriorized and fixed the leading haptic entirely by creating its flange coupled with or without a Nylon 10-0 stitch before manipulating the lagging haptic contrary to Yamane's description of exteriorizing both haptics simultaneously because we believe that if the needle is made to hang inside after engaging the leading haptic, then there is a probable risk of iris, ciliary body, and retinal damage andintra ocular pressure (IOP) fluctuations, which are inevitable during insertion of the lagging haptic enhance risk of intraocular tissue damage and disengagement. Also this secure the leading haptic from slippage during manipulation of the lagging one especially if the flange hadn't formed well as the used IOLs in our study was Acrysof MA60AC with PMMA haptics not PVDF as those used by Yamane in X-70 (Santen, Japan) and other types of 3-piece IOLs with PVDF haptics like CT LUCIA 602 IOL (ZEISS, Germany) andEC-3 (AerenSientific, USA) which are not present in our country and this problem was

reported by **Ganne*et al.*[12]** who exteriorized the leading haptic first andsuggested securing it with silicon stopper to avoid its intraocular rebound.

The PMMA haptics did not always flange as described by Yamane, in some cases it either melted or got distorted and this problem was reported by **Ganne *et al.*[12].** With PVDF haptics only 1 mm is needed to be heated using cautery as the post-operative OCT showed that 1 mm of the haptic is needed to make a flange diameter of 0.3 mm which is the perfect size for the scleral tunnel created by the 30-gauge needle

Though it is little difficult to manipulate the lagging haptic tip into the 27-gauge lumen once the leading haptic is outside the eye, we found that using an end gripping mico-forceps and inserting the lagging haptic from the side port lead to successful completion of surgery without too much difficulty.

The drawback of fixing the leading haptic first is that it becomes difficult to explant the IOL in toto if the trailing haptic gets damaged. In an unlikely event of such a complication, the externalized haptic can be cut and the IOL should be explanted.

Complications were comparable to the previously described techniques of SFIOL but with slightly higher incidence.

Complication	**Yamane *et al.*[5] 50 cases**	**Kelkar *et al.*[13] 31 cases**	**Our study 20 cases**
Hyphyma	Nil	2cases	4cases
Hypotony	2cases	1case	4cases
Macular edema	1case	2cases	3cases
Vitreous hemorrhage	5 cases	1case	2cases
Corneal edema	1case	2cases	6cases
IOL decentration	2 cases	2cases	4cases
Spontaneous IOL Dislocation	Nil	Nil	2cases
Iris capture	8cases	Nil	2cases

REFERENCES

1. **Gimbel HV, Sun R, Ferensowicz M *et al.* (2001):** Intraoperative management of posterior capsule tears in phacoemulsification and intraocular lens implantation. Ophthalmology, 108:2186-2189.
2. **Steven B (2011):** New method of transscleral fixation an alternative for securing IOLs. Ocular Surgery News, 111:186-189.
3. **Wagoner MD, Cox TA, Ariyasu RG *et al.* (2003):** Intraocular lens implantation in the absence of capsular support: a report by the American Academy of Ophthalmology. Ophthalmology, 110:840–859.
4. **Oh HS, Chu YK, Kwon OW (2007)**: Surgical technique for suture fixation of a single-piece hydrophilic acrylic intraocular lens in the absence of capsule support. J Cataract Refract Surg., 33:962-965.
5. **Yamane S, Inoue M, Arakawa A *et al.* (2014):** Sutureless 27-gauge needle-guided intrascleral intraocular lens implantation with lamellar scleral dissection. Ophthalmology, 121(1):61-6.
6. **Maggi R, Maggi C (1997):** Sutureless scleral fixation of intraocular lenses. J. Cataract Refract. Surg., 23(9):1289–1294.
7. **Zhang ZD, Shen LJ, Liu XQ *et al.* (2010):** Injection and suturing technique for scleral fixation foldable lens in the vitrectomized eye. Retina, 30:353–6.
8. **Takayama K, Akimoto M, Taguchi H *et al.* (2015):** Transconjunctival sutureless intrascleral intraocular lens fixation using intrascleral tunnels guided with catheter and 30-gaugeneedles. Br J Ophthalmol., 99:1457-9.
9. **Scharioth GB, Prasad S, Georgalas I *et al.* (2010):** Intermediate results of sutureless intrascleral posterior chamber intraocular lens fixation. J Cataract Refract Surg., 36(2):254-9.
10. **Sindal MD, Nakhwa CP, Sengupta S (2016):** Comparison of sutured versus sutureless scleral-fiated intraocular lenses. J Cataract Refract Surg., 42:27-34.
11. **Kumar DA, Agarwal A, Prakash G *et al.* (2010):** Glued posterior chamber IOL in eyes with deficient capsular support: a retrospective analysis of 1-year post-operative outcomes. Eye, 24: 1143–1148.
12. **Ganne P, Baskaran P, Krishnappa N C*et al.* (2017):** Flanged intrascleral intraocular lens fixation with double needle technique. Ophthalmology, 124:1136-1142.
13. **Kelkar JA, Mehta HM, Kelkar AS *et al.* (2018):** Precision pulse capsulotomy in phacoemulsification: Clinical experience in Indian eyes. Indian J Ophthalmol., 66(9):1272-1277.