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ORIGINAL ARTICLE

# Flanged Scleral Fixated Intraocular Lens for Correction of Aphakia in Zagazig University Hospitals

***Mohammad Elsayed Hasan[1*], Adel Abdel Razik Farag[1], Medhat Mohamed Shawky[1], Basem Mohamed Ibrahim[1], Tamer Gamal Elsayed[1].***

[1] *Department of Ophthalmology, Faculty of Medicine, Zagazig University, Zagazig, Egypt.*

*** Corresponding author:**
Mohammad Elsayed Hasan Ophthalmology department, faculty of medicine, Zagazig University, Zagazig, Egypt
mohammadsheta@hotmail.com

## ABSTRACT

**Background:** Intraocular lens (IOL) implantation in the absence of capsular support represents a surgical challenge. Several techniques have been used for IOL implantation in aphakic eyes without adequate capsular support. The aim of this study was to compare the efficiency and visual results of the Yamane technique with the glued IOL technique in the correction of aphakia without adequate capsular support in Zagazig University Hospitals.

**Methods:** Forty-eight aphakic eyes of 48 patients without adequate capsular support were included in this study. All eyes were planned to be corrected with posterior chamber foldable IOL implantation using either the Yamane flanged scleral fixated IOL technique (Group A) or the glued scleral fixated IOL technique (Group B), and 24 aphakic eyes were enrolled randomly in each group. Pre-operative, intra-operative, and post-operative data, including uncorrected and best corrected visual acuity, intraocular pressure, and endothelial cell count, were recorded. Surgical time, intra-operative difficulties, and post-operative complications were recorded. Patients were monitored for at least six months.

**Results:** Forty-eight aphakic eyes without adequate capsular support following complicated phacoemulsification were enrolled randomly in two groups (A and B). In all cases, three-piece foldable hydrophobic IOLs were used. There is a clear statistically significant difference between pre- and post-UCVA ($p< 0.001$) in both groups. Complications included captured IOL in one case in group A, IOL decentration in 2 cases in group A and 3 cases in group B, and significant IOL tilt due to haptic slippage in one case in group A. Ther e was no significant difference in endothelial cell count and IOP before surgery and after 6 months in both groups. Apart from the shorter surgical time in group A, there was no clinically significant difference between the two groups.

**Conclusion:** Flanged intrascleral fixation of three-piece IOLs (Yamane technique) and glued scleral fixated IOLs are both safe and efficient methods for correction of aphakia.

**Keywords:** Scleral fixation; Aphakia; Flanged IOLs; Yamane technique; Glued IOLs.

## INTRODUCTION

Intraocular lens (IOL) implantation in the absence of capsular support is always a surgical challenge in cataract surgery. Several optical rehabilitation methods have been used in patients with inadequate capsular support following cataract surgery, post-traumatic lens subluxation, or posterior lens dislocation. Under such conditions, aphakia can be effectively corrected by several surgical techniques, including anterior chamber angle IOL and iris fixated IOL, as well as scleral fixation of posterior chamber IOL **[1]**.

Suture-assisted trans-scleral IOL fixation provides good visual acuity, but it has been reported to have little IOL stability, resulting in IOL decentration, tilt, or dislocation due to suture slipping off or long-term suture erosion **[2]**.

Intra-scleral fixation technique has been introduced to cataract and refractive surgery practice. This technique was first described by Gabor and Pavlidis in 2007 by externalizing the haptics of a foldable 3-

piece IOL through two sclorotomies and tucking them in a long scleral tunnel parallel to the limbus **[3, 4]**.

Intrascleral fixation of an IOL is classified into those with and those without a scleral flap. The technique without a scleral flap is simpler and requires neither sutures nor fibrin glue. However, it is not easy to insert the IOL haptic into the scleral tunnel by this method. On the other hand, it is easy to fix the IOL haptics with the scleral flap technique, but the surgical procedure is complex. Similarly, there are 2 techniques for externalizing the haptic of the IOL. The technique of using forceps to externalize the IOL haptic is relatively easy; however, it has a potential risk of damaging the ciliary body and the IOL. The second technique consists of externalizing the haptics of the IOL with a 25, 27, or ultra-thin 30-gauge needle **[5, 6]**.

The aim of this study was to compare the efficiency and visual results of trans-conjunctival intrascleral fixation of a three-piece foldable IOL using the flanged scleral fixated IOL technique of Yamane with the glued suture less scleral fixated IOL technique for correction of aphakia without adequate capsular support in Zagazig University Hospitals, describing IOL position, stability, post-operative visual outcome, and intra- and postoperative complications.

## METHODS

### Study design

This was a prospective interventional study that was performed in the Ophthalmology Department, Zagazig University Hospitals, Egypt. This study was conducted between March 2019 and January 2021. It included aphakic eyes with inadequate capsular support after an accidental posterior capsule rupture during phacoemulsification, in which no primary sulcus fixed IOL could be implanted due to the absence of adequate capsular support.

A fully informed consent was obtained from each patient. The study was approved by the research ethics committee of the Faculty of Medicine at Zagazig University (ZU-IRB #4992-19-12-2018). The study was done according to the Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

### Subjects

Forty-eight aphakic eyes of 48 patients—24 eyes in each group—were collected from the outpatient clinics of Zagazig University Hospitals and admitted to the Ophthalmology Department, where they were randomly assigned to receive either a flanged scleral fixated IOL (Yamane technique) (Group A) or a glued scleral fixated IOL (Group B). Patients with anterior segment complications such as corneal opacity, active inflammation, posterior segment pathology, and patients with poor pre-operative visual acuity (BCVA less than 0.05) were excluded from the study. Also excluded were patients who missed their follow-up (less than 6-month) evaluation. All surgeries were performed under general anesthesia by the same surgeon.

### Methods

A full history was taken from each patient before surgery. Complete ophthalmic examinations were performed on all patients, including UCVA, BCVA, and slit lamp biomicroscopy of the anterior segment for examination of the cornea and sclera for wound site, size, and presence of uveal prolapse or vitreous incarceration, as well as capsular remnants. The anterior chamber was examined for the presence of vitreous, cells, flare, and hyphema and to determine its depth.

Intraocular pressure (IOP) measurement using an applanation tonometer, fundus examination using an indirect ophthalmoscope, and slit lamp biomicroscopy for the exclusion of an intraocular foreign body, vitreous hemorrhage, retinal detachment, optic neuropathy, or maculopathy were done.

Accurate PC-IOL calculation was done using the SRK/II, SRK/T, or HOLLADAY formulas with a reduction of IOL power of 0.5 D to compensate for the more anterior IOL location (in the ciliary sulcus instead of the capsular bag), and axial length was calculated using the IOL Master (Carl Zeiss Meditec, Germany). A three-piece foldable hydrophobic acrylic Acrysof® MA60AC IOL was used in all eyes.

### Operation:

The operation was done in all cases as a secondary IOL implantation procedure. Application of antiseptic povidone-iodine (10%) to the surgical site was done, followed by draping and application of an eyelid speculum. Then, povidone-iodine 5% drops were applied into the conjunctival sac, which was washed after 2 minutes. Inserting the infusion cannula or anterior chamber maintainer was done, and then triamcinolone-assisted anterior vitrectomy using an automated vitreous cutter was done in both groups.

In group A, a corneal marker was used for marking the sites of the sclerotomies at 3 and 9 o'clock, and a 3 mm clear corneal incision was done at 12 o’clock. Two corneal side ports were done using the microvitreoretinal (MVR) blade at 10 and 2 o'clock.

The IOL was injected in the anterior chamber, leaving the trailing haptic outside the anterior chamber through the main corneal incision to protect the IOL from falling into the vitreous cavity **(Figure 1)**.

A 27-G needle was inserted through the conjunctiva 2 mm above the sclerotomy mark into the posterior chamber at 3 o'clock, making an angled scleral tunnel. The leading haptic was inserted in the lumen of the 27-G needle (docked) using a 23-G intraocular grasping micro-forceps, and the needle was left in place with the syringe resting on the eyelid.

The trailing haptic was inserted inside the anterior chamber using the microforceps. Another 27-G needle was inserted at 9 o'clock, 2mm below the sclerotomy mark, and the trailing haptic was docked inside the lumen of the second 27-G needle using the microforceps in a similar way to the leading haptic. Both haptics were externalized simultaneously by pulling the two needles at the same time in opposite directions (double needle technique).

Haptics flange creation by heating of the haptic tip using unipolar low temperature cautery to make a flange—a ball—about 0.3 mm at the haptic tip was done, then the flange was pushed posteriorly and buried under the conjunctiva inside the scleral tunnel by a non-toothed forceps. Viscoelastic washed from the anterior chamber, stromal hydration for all corneal incisions was done with checking for any leakage, and dressing of the eye was done after the instillation of antibiotic eye drops.

In group B, two partial-thickness limbal-based scleral flaps about 2.5 x 2.5 mm were created 180° diagonally apart at 3 and 9 o'clock and about 1.5 mm from the limbus using a crescent blade. Creating scleral pockets was done at the edge of the scleral flaps (3–4 mm in length) in an anticlockwise direction, the same as the haptics direction, preparing for subsequent haptic tucking using 27-gauge needles.

Two straight sclerotomies using 20-gauge MVR blades were done under the scleral flaps 1 mm from the limbus, a 3 mm clear corneal tunnel was done at 12 o'clock for injection of the three-piece IOL, and two side ports were done using MVR blades at 10 and 2 o'clock. Viscoelastic was injected, a foldable 3-piece IOL was injected in the anterior chamber; a grasping end microforceps was introduced through the sclerotomy under the scleral flap, the leading haptic tip was grasped with the microforceps and externalized while simultaneously injecting the IOL, leaving the trailing haptic outside the anterior chamber. The trailing haptic was similarly externalized through the opposite sclerotomy using the grasping microforceps, followed by the tucking of both haptics into the scleral pockets.

Fibrin glue sealing of the scleral flaps and conjunctiva was done after closure of the infusion fluid and drying the scleral bed, by application of the two components of the fibrin glue under the scleral flaps followed by local pressure for 30 seconds, then under the conjunctiva followed by local pressure for one minute till adhesion occurred. Stromal hydration for all corneal incisions was done with checking for any leakage, and then dressing of the eye was done after instillation of antibiotic eye drops **(Figure 2)**.

**Follow-up**

Follow-up visits were scheduled daily during the first week, then weekly during the first month, and then monthly up to 6 months. At each visit, eyes were subjected to a full ophthalmic examination, as was done before surgery, in addition to examination of the IOL for stability, tilt, and decentration. IOL decentration was measured by evaluating the distance between the edge of the IOL optic and the edge of the fully dilated pupil or the limbus if the pupil was distorted. IOL tilt was detected by the slit lamp beam method and confirmed by ultrasonic biomicroscopy (UBM).

**Statistical analysis**

The collected data were coded, entered, presented, and analyzed by computer using a database software program. The Statistical Package for Social Science (SPSS) version 20 was utilized to analyze the data. The chi-square test and t-test were used for the determination of significance. A p-value <0.05 is considered significant.

## RESULTS

The study included 48 aphakic eyes of 48 patients, each group included 24 aphakic eyes; all eyes were aphakic after complicated cataract surgery with inadequate capsular support. **Table 1** shows the preoperative and postoperative characteristic data.

There was a significant improvement in postoperative UCVA ($p < 0.001$) compared to preoperative UCVA in both groups, and there was a significant improvement in BCVA ($p < 0.001$) in both groups in the $6^{th}$ month of follow-up **(Table 1)**. **Table 2** shows the intraoperative data; apart from the operative time, there was no statistically significant difference between the two groups. Also, **Table 2** shows the postoperative complications; there was no statistically significant difference between the two groups.

Slit lamp image of well centralized flanged scleral fixated IOL and confirmed by the UBM scan at the 3rd postoperative month were presented in **Figure 3.**
As regarding the change in endothelial cell count (ECC), there was a statistically non-significant decrease in ECC at 3 months post-operatively.
As regarding post-operative IOL centration and stability, one case (4.2%) in group A showed iris capture by the IOL in the first post-operative day. The IOL decentration was reported in two cases (8.3%) in group A and three cases in group B, which were confirmed by UBM. One case (4.2%) in group A and three cases (12.5%) in group B showed significant IOL tilt **(Figure 4)**.
One case (4.2%) in group A and three cases (12.5%) in group B were reported with mild vitreous hemorrhage, and as regarding postoperative retinal detachment and post-operative endophthalmitis, no cases were reported in both groups.
Post-operative macular oedema, which was confirmed by slit lamp biomicroscopy and posterior segment OCT that showed central zone affection with thickness increase, was reported in 3 cases in group A and 4 cases in group B.

**Table 1:** Preoperative and postoperative characteristic data.

| | **Group A (N= 24)** | **Group B (N= 24)** | **p-value** | |
|---|---|---|---|---|
| Eye/Patients | 24/24 | 24/24 | ------- | |
| Mean age (years) | 52.42 ± 11.55 | 52.67 ± 11.96 | 0.972 | |
| Female/Male | 7/17 | 6/18 | 0.755 | |
| Mean preoperative IOP (mmHg) | 16.7 ± 4.3 | 15.33 ± 4.31 | 0.787 | |
| Mean postoperative IOP (mmHg) | 17± 5.2 | 17.85 ± 6.62 | 0.787 | |
| Mean follow up period (months) | 8 ± 2.5 | 8 ± 2.5 | ------- | |
| Mean preoperative UCVA | 0.05 (0.01 – 0.1) | 0.05 (0.01 – 0.1) | 0.688 | |
| Mean postoperative UCVA | 0.25 (0.1 – 0.7) | 0.20 (0.1- 0.5) | 0.856 | |
| Mean preoperative BCVA | 0.36 (0.1 – 0.5) | 0.25 (0.1 – 0.5) | 0.758 | |
| Mean postoperative BCVA | 0.5 (0.05 – 1) | 0.45 (0.1 – 1) | 0.195 | |
| Mean preoperative ECD (cells/mm2) | 2266 ± 137 | 2240 ± 132 | 0.597 | |
| Mean postoperative ECD (cells/mm2) | 2143±195 | 2146 ± 149 | 0.946 | |

IOP: intraocular pressure; UCVA: uncorrected visual acuity; BCVA: best corrected visual acuity; ECD: Corneal endothelial cells

**Table 2:** Intraoperative and postoperative data

| | **Group A (N= 24)** | **Group B (N= 24)** | **Test** | **p-value** |
|---|---|---|---|---|
| **Intraoperative data (events)** | | | | |
| Mean operative time (minutes) | 27.5 ± 6.5 | 40.8 ± 7.5 | -6.556 * | <0.001 |
| Ant. Vitrectomy | 17 (70.8) | 20 (83.3) | 0.886 * * | 0.666 |
| Hypotony | 4 (16.7) | 7 (29.2) | 1.061 * * | 0.303 |
| Bleeding | 3 (12.5) | 6 (25.0) | Fisher * * | 0.461 |
| IOL kink/ break | 3 (12.5) | 2 (8.3) | Fisher * * | >0.999 |
| **Postoperative complications** | | | | |

| | Group A (N= 24) | Group B (N= 24) | Test | p-value |
|---|---|---|---|---|
| Corneal edema | 5 (20.8) | 7 (29.2) | Fisher * * | 0.74 |
| Ant chamber reaction | 3 (12.5) | 5 (20.8) | Fisher * * | 0.701 |
| Hypotony | 2 (8.3) | 4 (16.7) | Fisher * * | 0.666 |
| Captured IOL | 1 (4.2) | 0 (0) | Fisher * * | >0.999 |
| Vitreous hemorrhage | 1 (4.2) | 3 (12.5) | Fisher * * | 0.608 |
| Cystoid macular edema | 3 (12.5) | 4 (16.7) | Fisher * * | >0.999 |
| IOL decentration | 2 (8.3) | 3 (12.5) | Fisher * * | >0.999 |
| IOL tilt | 1 (4.2) | 3 (12.5) | Fisher * * | >0.999 |
| High IOP | 3 (12.5) | 4 (16.7) | Fisher * * | >0.999 |

Data were presented as mean ± SD or absolute (percentage)

*: Independent sample t –test, * *: Chi square test.

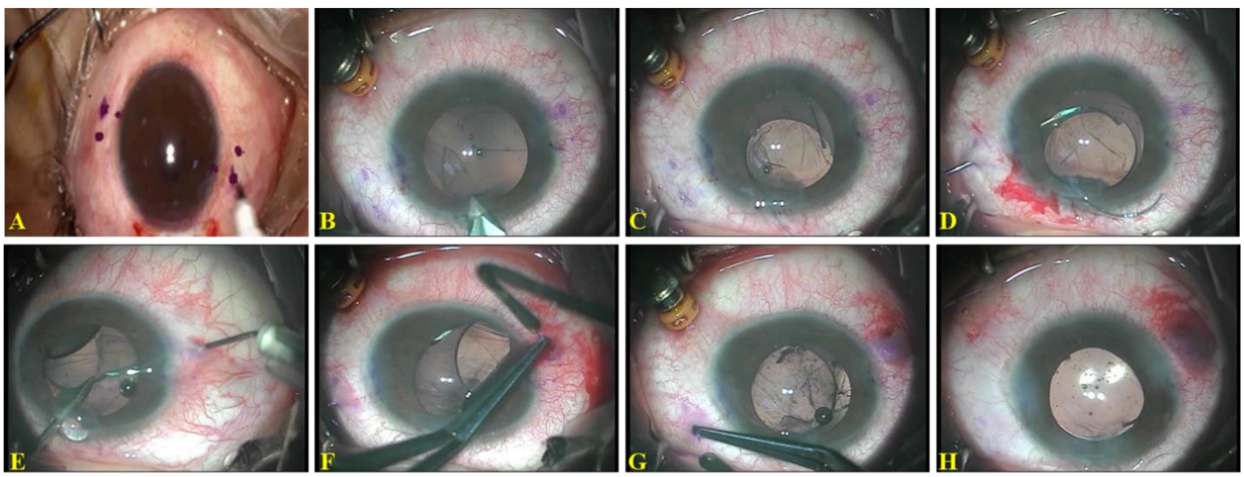


**Figure 1:** Yamane technique; (A) Marking of angled sclerotomy site 2 mm from the limbus at 3 and 9 o'clock, 2 mm above (temporally), 2 mm below (nasally). (B) Making the main corneal incision after insertion of infusion cannula. (C) Injection of a 3-piece IOL leaving the trailing haptic in the main corneal incision outside AC. (D) Docking of the leading haptic inside the 27-G needle. (E) Docking of the trailing haptic inside the second 27-G needle. (F) Externalization of the trailing haptic and flange creation using a heated strabismus hook. (G) Externalization of the leading haptic and flange creation using a heated strabismus hook. (H) Burying of the flanges in the scleral tunnels and removal of the infusion cannula with well centered IOL.

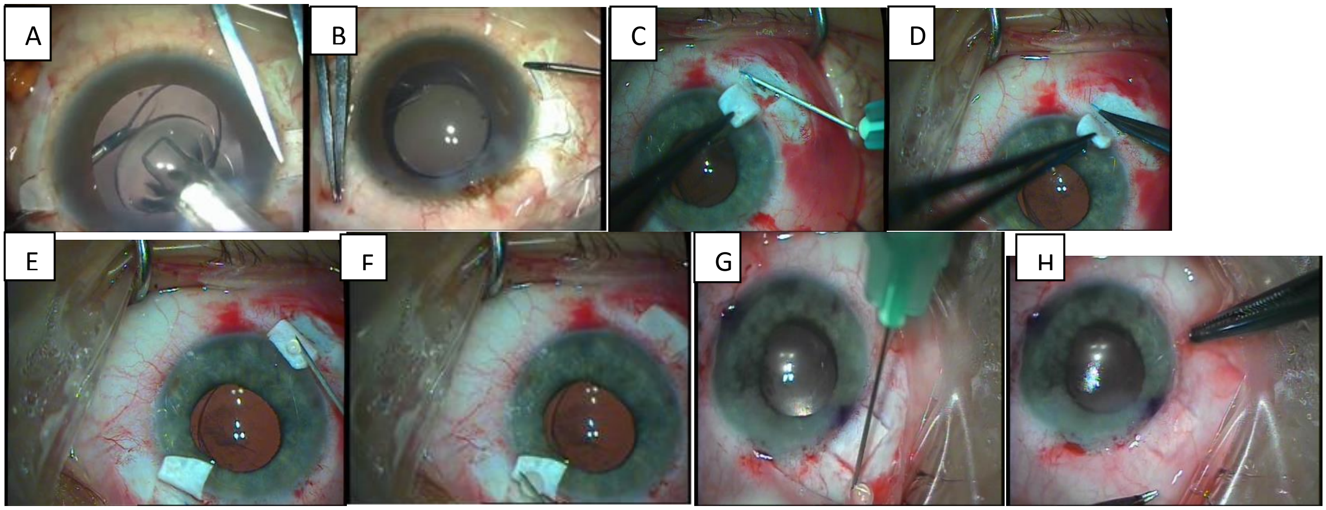


**Figure 2:** Glued IOL technique; (A) A 3-piece IOL implantation with the leading haptic being grasped by the microforceps for externalization. (B) Externalization of the trailing haptic through the 2nd sclerotomy. (C) Scleral groove or tunnel creation using 27-gauge needle about 3-4 mm length parallel to the limbus. (D) Prolene haptic tucking into the scleral tunnel with good IOL centration. (E&F) fibrin glue application into the bed of the scleral flaps after adequate drying and fine pressure for one minute. (G&H) Application of fibrin glue into the conjunctival wound after adequate drying and pressure application for one minute.


**Figure 3:** Slit lamp image of well centralized flanged scleral fixated IOL and confirmed by the UBM scan at the 3rd postoperative month.

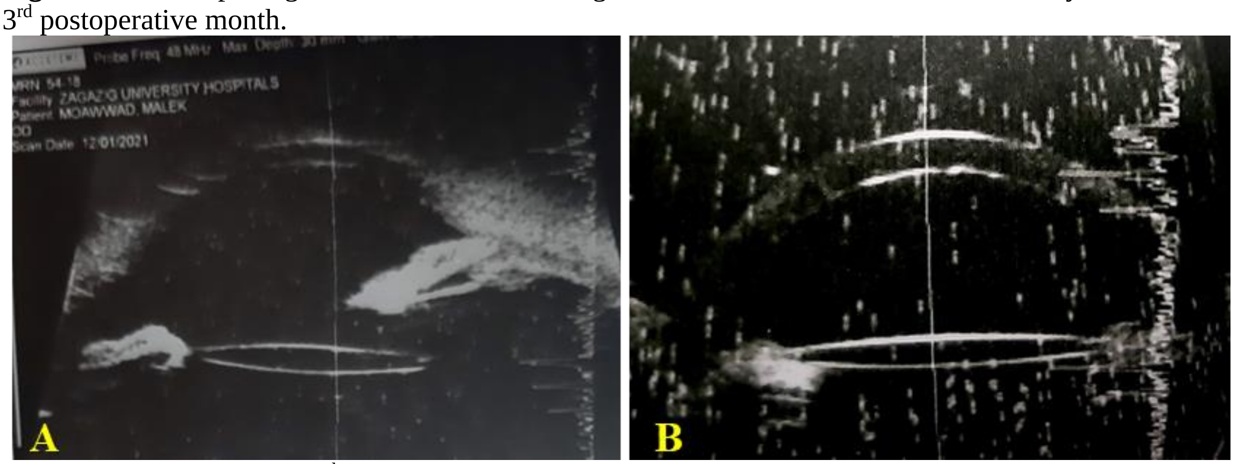


**Figure 4:** UBM image at 3rd month showing A. tilted flanged IOL, B. anteriorly iris captured by flanged IOL.

## DISCUSSION

Suture fixation of the IOL to the scleral wall through the ciliary sulcus or pars plana has a steep learning curve. However, unlike anterior chamber IOLs, sutured posterior chamber IOLs are placed away from the corneal endothelium and anterior chamber angle, making them less likely to cause endothelial cell loss, anterior synechia, or angle closure glaucoma.

Although experienced surgeons have achieved excellent results with various trans-scleral suturing techniques, complications may arise. Suture-related complications like suture erosion, suture breakage, and suture-related endophthalmitis are unique to the sutured scleral fixated intraocular lenses **[7]**. To prevent these complications, there is a need to bury, or rotate the knot in all techniques. Use of a scleral flap, autologous cornea, dura mater, or fascia lata patches have been described to cover the ends, and rotation of the knot into the tissue has been reported. Some of the technical problems may be overcome by the use of newer technologies. Also, using a method such as the Hoffman scleral pocket technique or rotation of the sutures may help to prevent suture problems **[8]**. Some studies show the advantages of endoscopic or endo-illuminator guided fixation for precise fixation of the haptics in the sulcus **[9]**.

In 2014, ***Yamane et al.*** **[5]** developed a double-needle technique that can minimize the sclerotomy to 27-G and decrease the risk of postoperative hypotony. In 2017, they described a newer technique, "flanged haptic intraocular lens fixation", in which a three-piece intraocular lens is implanted, haptics are externalized using the double needle technique by threading the haptics inside the lumen of a thin-walled 30-G needle, and the haptics are then fixed in the scleral tunnels by making a flange—a small ball—at the end of each haptic using unipolar cautery **[6]**.

In the current study, we compared "the flanged suture less scleral fixated IOL **(Yamane technique)**" with "the glued scleral fixated IOL technique" for correction of aphakia in Zagazig University Hospitals, monitoring the intraoperative and postoperative complications, postoperative visual outcome, and IOL stability.

We observed a highly significant improvement of postoperative UCVA ($p<0.001$) compared to preoperatively, and there was a highly significant improvement of BCVA ($p<0.001$) at the 6$^{th}$ month follow-up in both groups. The mean of BCVA was 0.5 (0.05–1) in group A and 0.45 (0.1–1) in group B. These results are consistent with the results of ***Kumar and Agarwal*** **[10],** who reported postoperative BCVA in eyes with the rigidly glued IOL was 0.38 ± 0.27, and also match the results of ***Yamane et al.*** **[5],** ***who*** reported a mean BCVA of 0.37 ± 0.26 preoperatively and 0.57 ± 0.35 at 3 months postoperatively. Also, ***Yamane et al.*** **[6]** reported that the mean preoperative BCVA was 0.25 log MAR (0.5), and it improved to 0.11 log MAR (0.8) and 0.04 log MAR (0.9) at 6 and 36 months, respectively ($P < 0.01$, $P = 0.10$, respectively).

The mean operative time was 27.5± 6.5 min in group A and 40.8 ± 7.5 in group B, with a statistically significant difference between the two groups. As regard IOP, there was a non-significant increase in the postoperative IOP in both groups with no difference between the two groups. Post-operative hypotony was recorded in 2 patients (8.3%) in group A and 4 patients (16.7%) in group B, which resolved spontaneously. ***Yamane et al.*** **[6]** reported early postoperative hypotony in 2 percent of cases that resolved spontaneously, while ***Samir et al.*** **[11]** recorded no cases of postoperative hypotony in their case series.

As regarding the change in endothelial cell count (ECC), there was a statistically non-significant difference between pre-operative and post-operative ECC at 3 months post-operatively in both groups with no difference between the two groups.

As regarding post-operative IOL centration and stability, one case (4.2%) showed iris capture by the IOL in the first post-operative day, was re-admitted with IOL repositioning after 1 week, and had a stable IOL on the next follow-up visits. During the 6 months of follow-up, IOL decentration was reported in 2 cases (8.3%) in group A and 3 cases (12.5%) in group B, which were confirmed by UBM; however, all of them showed a small degree of decentration with the IOL optic edge covered by the non-dilated pupil. One case (4.2%) in group A showed significant IOL tilt in the first week, with one haptic slipping due to an undersized flange **(figure 4A)**. The patient was re-admitted after exploration of the slipped haptic, cutting of the flange, externalization, and cauterization of the haptic with the formation of an adequately sized flange.

Clinical decentration occurs in many studies; it occurs in one eye of the ***Narang and Narang*** **[12]** study and in one case (4.2%) of ***Yamane et al.*** **[5]** study, 2 eyes (4.8%) of ***Kumar et al.*** **[13]** study, 3 eyes (8.6%) of ***Yamane et al.*** **[6]** study,

One case (4.2%) in group A showed significant IOL tilt due to one haptic slippage due to a small flange, requiring IOL repositioning, which was done 2 weeks post-operatively by retrieving the slipped haptic with some difficulty, cutting the haptic at its tip, docking in a 27-G needle, and reformation of a larger flange. Many studies determine different degrees of optic tilt at different angles **[5, 6, 11–15]**. ***Samir et al.*** **[11]** recorded the double-flanged prolene for suture less scleral fixation of a single-piece foldable IOL; they performed 17 eyes; one case showed IOL tilt with capture of the upper part of the optic, slippage of the prolene filament from the haptic happened in 2 cases after implantation. To prevent tilt or decentration, a 4-point scleral fixation technique may be chosen, which would facilitate burial of the knots by rotating the sutures in the sclera but is less commonly preferred since it requires 4 scleral entries **[15]**.

One case (4.2%) was recorded with mild vitreous hemorrhage that resolved spontaneously with conservative treatment, and as regarding postoperative retinal detachment and post-operative endophthalmitis; no cases were reported. ***Yamane et al.*** **[6]** also reported vitreous hemorrhage in 5% of their cases.

Post-operative macular edema confirmed by posterior segment OCT that showed central zone affection with thickness increase was reported in 3 cases (12.5%) in group A and 4 cases (16.7%) in group B, complete resolution occurred in all cases with conservative treatment.

Macular edema was reported in some studies; ***Narang and Narang*** **[12]** reported some cases of cystoid macular edema in their series, while chronic vitritis with macular edema was reported in one case. Also, ***Wilgucki et al.*** **[16]** reported cystoid macular edema in one case.

## CONCLUSION

The flanged scleral fixated IOL (Yamane technique) and the glued scleral fixated IOL technique are viable options for surgical correction of aphakia with deficient capsular support. Good results regarding visual outcome, IOL centering, stability, and fewer complications during the 6-month follow-up period were detected. The Yamane technique is characterized by a shorter operative time than the glued IOL technique, less operative trauma, and independence from special materials such as fibrin glue. However, haptic manipulation is somewhat difficult and requires good training.

**Author Contributions**

All authors contributed to data analysis, drafting or revising the article, have agreed on the journal to which the article will be submitted, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

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