Original Article

# Assessment of Visual outcome of Sutured and Sutureless scleral fixated posterior chamber intraocular lens implantation during aphakic management

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## Abstract

**Background:** Cataract surgery, a widespread ophthalmic procedure, addresses cloudy lenses to restore clear vision and improve the lives of millions worldwide. Sutured SFIOL, is typically used for complicated cataract cases. In contrast, sutureless SFIOL relies on innovative techniques like iris fixation or anterior chamber placement. **Objectives:** Aimed to assess the visual outcome after implantation of sutured and sutureless scleral fixated intra ocular lens during the management of aphakia. **Methods:** Prospective observational study was conducted from July 2022 to June 2023 among patients with aphakia without capsular support in the inpatient department of vitreo-retina, NIO&H, Dhaka. Randomly selected 70 patients were able to complete the follow-up during study period. Upon obtaining their informed written consent they were divided into two groups by lottery method, group I (Sutured SFIOL; n=35) and group II (Suture less; n=35). Preoperative visual acuity, slit lamp examination, fundus examination were done for both groups. Follow-up was done on 7$^{th}$ and 45$^{th}$ post-operative day. Statistical analysis was performed using SPSS software (v26.0). Statistical significance was set at p-value ≤ 0.05. **Results:** In group I (sutured) majority were male 19 (54.3%) and 16 (45.7%) were female and in group II (sutureless) more than half were male 20 (57.1%) and 15 (42.9%) were female. The mean (±SD) age was similar in both groups of sutured (52.06±4.3) and suture less (51.89±4.2) SFIOL procedures. Mean (±SD) post-operative intraocular pressure (IOP) at 45$^{th}$ day in group I was (16.2±1.4) and group II was (15.8±1.3) showed no significant difference. Aphakia was the most common lens status in both groups in group I (82.9%) and group II (71.4%). The most frequent per-operative complication was hyphema 7 (20.0%) patients in group I and 4 (11.42%) patients in group II. Common post-operative complications included Decentration 2 (5.71%) and cystoid macular oedema 2 (5.71%) patients in group I and in group II had Decentration 1 (2.85%) and Cystoid macular oedema 1 (2.85%) patient. There was a significant difference in operation time, with the group II (sutureless) having shorter surgery duration, mean (±SD) operation time was 47.1±4.7 minutes. A significant difference was noted in visual acuity at 45$^{th}$ postoperative day, with the group II (sutureless) exhibiting slightly better visual acuity, mean (±SD) was 0.34±o.116 in LogMAR unit than group I (sutured) mean (±SD) was 0.43±0.175 (P=0.013). **Conclusion:** This study showed that most of the patients experience satisfactory visual outcome following SFIOL implantation. Among the two methods used in this study visual outcome was found to be better in sutureless SFIOL group than sutured SFIOL group during the aphakic management.

***Keywords:*** Aphakia, cataract, scleral fixated IOL.

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## Introduction

Over 50% of cases of blindness globally are caused by cataracts, which are also the primary cause of visual impairment and blindness. According to population-based surveys conducted among older populations in Bangladesh, cataracts are the primary cause of severe vision impairment and blindness. In Bangladesh, the yearly count of cataract operations increased from 1.2 million in 1990 to 4.8 million in 2006. Cost, lack of information regarding cataracts, lack of transportation are the main obstacles to cataract surgery.[1]

Cataract is the clouding of the lens of the human eye, which impairs vision and the major cause of both blindness (51%) and poor vision (33%), respectively. According to some estimates,

50-80% of the bilateral blindness in a nation, cataract is mainly accountable for this blindness, using the definition in which vision on presentation below 20/200 in the better eye constitutes blindness. Currently, the only effective treatment for cataracts is surgery, which has a high rate of success in restoring vision. After the cataractous lens of the eye has been removed, an IOL is typically implanted in the capsular bag.[2]

The capsular bag and zonular fibres may suffer damage as a result of complications during cataract surgery or trauma. The effective implantation of an intraocular lens (IOL) in such instances might be challenging, especially if the support offered by the capsular bag is insufficient to provide a secure location of the IOL. Surgery can be used to repair the lack of capsular support in eyes with aphakia using a variety of techniques, either as part of the first procedure or as a planned subsequent surgery.[3]

In cases where the eyes lack sufficient capsular support, a scleral-fixated intraocular lens (IOL) serves as an alternative for restoring vision. There are differing opinions regarding whether scleral-fixated IOLs offer superior long-term visual outcomes and lower complication rates compared to open-loop anterior chamber (AC) IOLs.[3]

Anterior chamber intraocular lens (ACIOL), iris fixed intraocular lens (IFIOL), sutured and sutureless scleral fixated intraocular lens (SFIOL) implantation have all been used for many years in the absence of capsular support. Compared to anterior or iris fixed lenses, IOLs placed in the posterior chamber are associated with a lower risk of problems such as keratopathy, damage to the anterior chamber angle structure, pupillary block glaucoma, hyphema, uveitis, iris chafing, dislocation and pseudophakodonsis.[4]

Sutured and sutureless are two categorizations that can be applied to SFIOLs. Complications that may arise from the use of sutured SFIOLs including suture breakage, lens dislocation, as well as more serious complications including retinal detachment, suprachoroidal hemorrhage and suture-related endophthalmitis. Sutureless procedures have been developed with the aim of minimizing difficulties associated with sutures by utilizing scleral tunnels or flaps to secure the intraocular lens (IOL) haptics. However, dislocation of these IOLs remains a possibility and there is a lack of long-term evidence.[5]

Sutured and sutureless are both implant methods for SFIOL. In the postoperative phase, suture erosion/breakage, suture knot exposure, and other issues are possible with sutured SFIOLs. Therefore, sutureless SFIOL procedures were used to decrease the risk of problems from sutures. Haptical points can be flanged with cautery or glued below scleral flaps or they can be externalised and embedded in scleral tunnels.[6]

The aim of the sutureless fixation technique was to reduce the risk of problems associated with sutures. Although pupil capture, IOL haptic exposure through subconjunctival approach and IOL dislocation have all been documented, the majority of cases of sutureless intrascleral posterior chamber IOL implantation have short (1-55 months) follow-up durations.[7]

This study was aimed to assess the safety, effectiveness and the visual outcomes of sutureless SFIOL implantation compared with sutured SFIOL in Bangladesh over short term.

## Materials & Method

**Study design:** Prospective observational study.

**Place of study:** National Institute of Ophthalmology and Hospital (NIO & H), Dhaka.

**Period of study:** 12 months (From July 2022 to June 2023).

**Study population:** All the patients having aphakia without capsular support admitted in NIO & H, Dhaka during this study period.

**Sampling technique:** Random sampling technique. The enrolled patients was divided into two groups using lottery method, Group I sutured SFIOL and Group II sutureless SFIOL.

## Operational definitions

**SFIOL (scleral fixated intraocular lenses):** When in-the-bag IOL implantation is not

possible, SFIOL is used. The two main methods used for SFIOLs are sutured and sutureless. Aphakia with insufficient capsular support resulting from any cause is one of the main indicators. IOLs can be attached to the sclera either with sutures or without sutures by tunnelling the IOL haptics into the sclera.

**Primary procedure:** When the lens extraction and SFIOL implantation are completed in one sitting, this is referred to as a primary procedure.

**Secondary procedure:** SFIOL implantation is considered a secondary procedure if it was carried out as a follow-up stage to a primary procedure.

**Visual outcome:** Visual acuity on 45$^{th}$ post-operative days after SFIOL surgery regarded as visual outcome and recorded in Snellen chart then categorized into four groups as follows:
Group A = Normal or mild visual impairment (VA 6/6 to 6/18)
Group B = Moderate visual impairment (VA <6/18 to 6/60)
Group BI = Severe visual impairment (VA <6/60 to 3/60)
Group AV = Blindness (< 3/60 to NPL)

## Study procedure

All patients had ophthalmic examination, preoperative and postoperative visual acuity was determined by Snellen visual acuity chart, for purpose of analysis which was converted to logMAR, slit-lamp bio-microscopy to see eye lids, eyelashes, conjunctiva, cornea, pupil and lens, measurement of IOP with Goldmann applanation tonometer and peripheral retinal examination was done by +90D condensing lens. B-scan (Nidek, US 4000) and OCT (Nidek, RS 3000) was done wherever required. Biometry (Nidek, US 500) was performed before all procedure and SFIOL power was calculated by SRK II formula with A-scan (Pirop) biometry. The SFIOL implantation was done as a secondary procedure. In both group before SFIOL implantation anterior vitrectomy or PPV was done. In case of group I (sutured) SFIOL is implanted by using PMMA lens (Aurolab, india) with 9-0 prolene suture and in group II (sutureless) using 3 piece IOL (Aurolab, india). After operation all patients were advised to follow up on post-operative day 7 and day 45. For each and every patients, separate data collection sheet was prepared. All the relevant Data was recorded in a data collection sheet during baseline and follow-up periods.

## Statistical analysis

Statistical analyses were carried out by using computer based statistical software, SPSS 26.0 version. Results were shown as table, charts, diagram and expressed as frequency & percentage for qualitative data and mean ± SD for quantitative data and compared by chi-square test and fisher exact test for qualitative variables where was applicable. A 'p' value ≤ 0.05 was considered as statistically significant.

## Results

**Table I:** Socio-demographic characteristics of the patients between two groups (n=70)

| Socio-demographic characteristics | Sutured Scleral-Fixated IOL n (%) | Sutureless Scleral-Fixated IOL n (%) | p-valuea |
|---|---|---|---|
| **Age (years)** | | | |
| Less than 50 (<50) | 09 (25.7%) | 11 (31.4%) | 0.597a |
| 50 and above (≥ 50) | 26 (74.3%) | 24 (68.6%) | |
| Mean±SD in years | 52.06±4.3 | 51.89±4.2 | 0.868b |
| **Sex** | | | |
| Male | 19 (54.3%) | 20 (57.1%) | 0.810a |
| Female | 16 (45.7%) | 15 (42.9%) | |
| **Total** | **35 (100.0)** | **35 (100.0)** | |

a P value obtained from chi square test, [b] P value obtained from unpaired t test

Table I shows socio-demographic characteristics of the patients where mean age was almost similar in sutured scleral-fixated IOL (52.06±4.3) years and in sutureless SFIOL (51.89±4.2) years. All these findings were statistically non-significant (p≥0.05). Gender distribution of the patients between two groups where in sutured scleral-fixated IOL group (n=35) majority were male 19 (54.3%) and 16 (45.7%) were female and in suture less scleral-fixated IOL group (n=35) more than half were male 20 (57.1%) and 15 (42.9%) were female.

**Table II:** Lens status at presentation between two groups (n=70)

| Lens status at presentation | Sutured Scleral-Fixated IOL n (%) | Sutureless Scleral-Fixated IOL n (%) | p-valuea |
|---|---|---|---|
| Aphakia | 29 (82.9%) | 25 (71.4%) | |
| Dropped nucleus | 5 (14.3%) | 7 (20.0%) | 0.511a |
| Dropped IOL | 1 (2.9%) | 3 (8.6%) | |
| **Total** | **35 (100.0)** | **35 (100.0)** | |

[a] P value obtained from Fishers Exact test

Table II showed the lens status at presentation between two groups. In Sutured Scleral-Fixated IOL group majority had 29 (82.9%) had Aphakia followed by Dropped nucleus 5 (11.4%) and Dropped IOL 1 (2.9%). In Sutureless Scleral-Fixated IOL group more than half 25 (71.4%) had Aphakia followed by Dropped nucleus 7 (20.0%) and Dropped IOL 3 (8.6%). All these findings were statistically non-significant (p≥0.05).

**Table III:** Operation time between two groups (n=70)

| Operation time (minute) | Sutured Scleral-Fixated IOL n=35 | Sutureless Scleral-Fixated IOL n=35 | p-valueb |
|---|---|---|---|
| Mean±SD | 60.1±10.3 | 47.1± 4.7 | <0.001b |
| (Min-Max) | (48.0-80.0) | (40.0-58.0) | |

[b] P value obtained from independent t-test

Table III showed that a significant difference was observed in operation time between two groups where mean operation time in Sutureless Scleral-Fixated IOL group was lower, (47.1± 4.7) min than that of Sutured Scleral-Fixated IOL (60.1±10.3) min (P<0.001).

**Table IV:** Mean visual acuity at pre-operative, at 7th postoperative and 45th postoperative period between two groups (n=70)

| Mean visual acuity In LogMAR | Sutured Scleral-Fixated IOL n=35 | Sutureless Scleral-Fixated IOL n=35 | p-valueb |
|---|---|---|---|
| **At Pre-operative period** | | | |
| Mean±SD | 2.01± 0.48 | 1.93±0.47 | 0.463b |
| **At 7th Postoperative day** | | | |
| Mean±SD | 0.58± 0.22 | 0.53±0.20 | 0.394b |
| **At 45th Postoperative day** | | | |
| Mean±SD | 0.43± 0.175 | 0.34±0.116 | 0.013b |

[b] P value obtained from unpaired t test

Table IV showed that pre-operative mean visual acuity between the two groups where mean visual acuity in LogMAR sutureless SFIOL group were (1.93±0.47) and sutured SFIOL group were (2.01± 0.48) (P=0.463). At 7th postoperative period mean visual acuity in LogMAR sutureless SFIOL group were (0.53±0.20) and sutured SFIOL group were (0.58± 0.22). A significant difference was observed in visual acuity at day 45 between the two groups where mean visual acuity in LogMAR, sutureless SFIOL group was better (0.34±0.116) than that of sutured SFIOL (0.43±0.175) (P=0.013).

**Figure 1:** per-operative complications between two groups

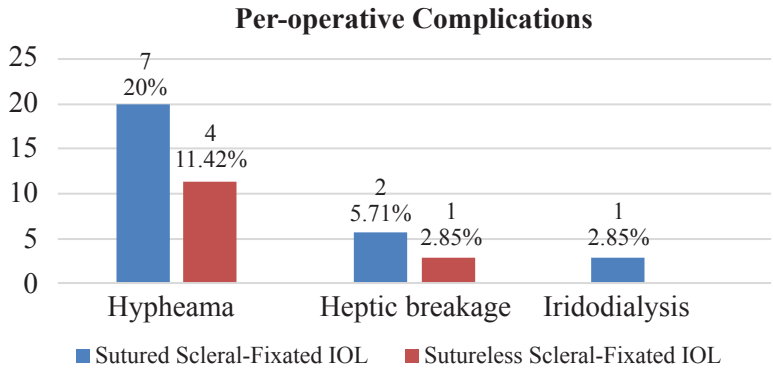


Figure 1 showed that the most common per-operative complications in Sutured SFIOL group (n=35) was Hypheama 7 (20.0%) followed by iridodialysis 1 (2.85%) and Heptic breakage 2 (5.71%). Among the patients in Sutureless SFIOL group (n=35) 4 (11.42%) had Hypheama and Heptic breakage occurred in 1 (2.85%) patient.

**Table V:** Postoperative complications at 7th and 45th postoperative day between two groups (Sutured Scleral-Fixated IOL n=35, Sutureless Scleral-Fixated IOL n=35)

| Postoperative complications | Sutured Scleral-Fixated IOL n (%) | Sutureless Scleral-Fixated IOL n (%) |
|---|---|---|
| **At 7th postoperative day** | | |
| Corneal oedema | 6 (17.14%) | 4 (11.42%) |
| Raised IOP | 1 (2.85%) | 2 (5.71%) |
| Decentration | 2 (5.71%) | 1 (2.85%) |
| Cystoid macular oedema | 2 (5.71%) | 1 (2.85%) |
| **At 45th postoperative day** | | |
| Decentration | 2 (5.71%) | 1 (2.85%) |
| Cystoid macular oedema | 2 (5.71%) | 1 (2.85%) |
| **Total** | **35 (100.0)** | **35 (100.0)** |

Table V showed that the most common post-operative complications at day 7 in Sutured SFIOL group had Corneal oedema 6 (17.14%) followed by Cystoid macular oedema 2 (5.71%), Decentration 2 (5.71%) and Raised IOP 1 (2.85%). Among the patients in Sutureless SFIOL group had Corneal oedema 4 (11.42%) followed by Raised IOP 2 (5.71%), Decentration 1 (2.85%) and Cystoid macular oedema 1 (2.85%). At day 45 after surgery complication found in Sutured SFIOL group was Decentration 2 (5.71%) and Cystoid macular oedema 2 (5.71%). Among the patients in Sutureless SFIOL group post-operative complications were also Decentration 1 (2.85%) and Cystoid macular oedema 1 (2.85%).

## Discussion

Management of aphakia in the absence of capsular support remains a challenge. The choice of IOL implantation includes ACIOL, iris claw IOL, Sutured SFIOL and sutureless SFIOL. This study was conducted to compare between sutured and sutureless SFIOL techniques. These two groups were comparable in baseline characteristics and as well as postoperative visual outcomes and complications rates.

In this study mean age was almost similar in sutured SFIOL (52.06±4.3) years and in sutureless SFIOL (51.89±4.2) years. Among the total patients 35 eyes (50.0%) had sutureless SFIOL and 35 (50.0%) had sutured SFIOL. In sutured SFIOL group majority were male 19 (54.3%) and 16 (45.7%) were female. In suture less scleral-fixated IOL group more than half were male 20 (57.1%) and 15 (42.9%) were female. A similar study conducted by Sindal et al., (2016) revealed that, mean age was 55.2 ± 17.8 years whereas 63 (58%) men and 46 (42%) women. Of these, 59 eyes (54%) had sutureless scleral-fixated IOLs and 50 had sutured scleral-fixated IOL.[3] Another study conducted by Goel et al., (2020) shows mean age of sutured group had 69.4±3.7 and there were 15 (37.5%) female and 25 (62.5%) males and in sutureless group had mean age 73.9±3.1 where 18 (45%) were female and males were 22 (55%).[5]

Mean pre-operative IOP was almost similar in both sutured SFIOL (16.7±2.1) mm of Hg and suture less SFIOL (16.7±2.1) mm of Hg. In sutured SFIOL group mean intra ocular pressure at 7th postoperative day were (17.5±2.7) mm of Hg and at 45th postoperative day were (16.2±1.4) mm of Hg. Among the patients of sutureless SFIOL group mean intra ocular pressure at 7th postoperative day were (17.1±3.0) mm of Hg and at 45th postoperative day were (15.8±1.3) mm of Hg. Mean of IOP between two groups were almost similar which was statistically non-significant.

In Sutured Scleral-Fixated IOL group majority had 29 (82.9%) had aphakia followed by dropped nucleus 5 (14.3%) and dropped IOL 1 (2.9%). Among the patients of sutureless scleral-fixated IOL group more than half 25 (71.4%) had aphakia followed by dropped nucleus 7 (20.0%) and dropped IOL 3 (8.6%). Sindal et al., (2016) in their study stated that in sutured scleral-fixated IOL group majority had 37 (74.0%) had aphakia followed by dislocated crystalline lens 9 (18.0%) and dropped IOL 4 (8.0%). 3 Among the patients of sutureless Scleral-Fixated IOL group more than half 34 (58.0 %) had aphakia followed by dropped crystalline nucleus 10 (17.0%), dropped IOL 12 (20.0%) and dropped cortex 3 (5.0%) that supports the findings of the present study.[3]

In this study a significant difference was observed in the comparison of operation time between two groups where mean operation time in sutureless SFIOL group was lower (47.1± 4.7) min than that of sutured SFIOL group (60.1±10.35) min. A study conducted by Yamane et al., (2014) stated that sutureless technique was simple and less time consuming than conventional trans-scleral suture method. 8 Sindal et al., (2016) also stated that sutureless method is quickly gaining popularity because of less time consuming allowing tucking the heptics of 3 piece IOL into the scleral pocket.[3]

In this study pre-operative mean visual acuity in LogMAR sutureless SFIOL group were (1.93±0.47) and sutured SFIOL group were (2.01± 0.48) (P=0.463). At 7th postoperative period mean visual acuity in LogMAR sutureless SFIOL group were (0.53±0.20) and sutured SFIOL group were (0.58± 0.22) (P=0.394). At 45th postoperative day follow-up between the two groups where mean visual acuity in LogMAR, sutureless SFIOL group was (0.34±0.116) and sutured SFIOL (0.43±0.175) (P=0.013). There was a statistically significant improvement postoperatively in both groups, there sutureless group had better visual acuity than sutured group. In this study sutureless group had better outcome due to stability of the lens in position, less time required procedure, minimum manipulation and less inflammatory reaction occurred. A similar finding was observed by Sindal et al., (2016) where mean visual acuity in sutureless SFIOL group was better (0.27±0.25) than that of sutured SFIOL (0.34±0.44). Study also stated that sutureless technique had some advantages, IOL heptics are bimanually fixated using microincision trocher cannula and then

fixed into scleral tunnel. Tucking of the heptics into the sclera fixed the IOL in position, which is easier to perform.3 Goel et al., (2020) stated that sutured SFIOL have some problems such as pseudophacodonesis and suture related complications like knot exposure, breakage or IOl subluxation, which is less common in sutureless SFIOL. Those findings are supports this study.[5]

The most common per-operative complications in Sutured SFIOL group was Hypheama 7 (20.0%) followed by iridodialysis 1 (2.85%) and Heptic breakage 2 (5.71%). Among the patients in Sutureless SFIOL group 4 (11.42%) had Hypheama and Heptic breakage occurred in 1 (2.85%) patient. The most common post-operative complications at day 7 in Sutured SFIOL group had Corneal oedema 6 (17.14%) followed by Cystoid macular oedema 2 (5.71%), Decentration 2 (5.71%) and Raised IOP 1 (2.85%). Among the patients in Sutureless SFIOL group had Corneal oedema 4 (11.42%) followed by Raised IOP 2 (5.71%), Decentration 1 (2.85%) and Cystoid macular oedema 1 (2.85%). Corneal oedema was mas managed by conservative treatment, Raised IOP was managed by antiglaucoma drugs topical timolol and cystoid macular oedema patients were given frequent steroid drop and topical NSAID. At day 45 after surgery complication found in Sutured SFIOL group was Decentration 2 (5.71%) and Cystoid macular oedema 2 (5.71%). In Sutureless SFIOL group post-operative complications were also Decentration 1 (2.85%) and Cystoid macular oedema 1 (2.85%). Sindal et al. (2016) in their study informed that for sutured SFIOL preoperative complication were post cataract and trauma and post-operative complication were RD, ERM and persistent CME.[3] Dev et al., (2021) reported that the vision improved significantly after surgery, with most patients achieving a final vision score in LogMAR was 0.3 or better in their eyes. Only a few patients had worse vision, and they had other eye problems. Two patients had high intraocular pressure after surgery but were treated successfully with eye drops. Six patients had swelling in the center of the retina, and one patient had a hole in the retina that got worse over time. For sutureless SFIOL preoperative complication were post cataract and trauma and post-operative complication were RD and ERM. Suture breakage with dislocation of sutured scleral fixated IOLs has been described as a common complication also mention.[6] The present study support the observation of Sindal et al., (2016) where the use of 9-0 polypropylene sutures has been recommended because of the higher tensile strength, due to less suture degradation and breakage.3

## Conclusion

This study showed that most of the patients experience satisfactory visual outcome following SFIOL implantation. Among the two methods used in this study visual outcome was found to be better in sutureless SFIOL group than sutured SFIOL group during the aphakic management.

## Limitations

This study has got some limitations:

1. SFIOL implantation can leads to corneal endothelial cell loss like any other intraocular surgery. Preoperative and postoperative cell counts were not investigated in this study.
2. Immediate postoperative complications were noted in this study, so late postoperative complications like RD, are not reflected in this study.
3. Surgery was not performed by single surgeon rather by multiple competent surgeon.
4. One-centred focus and short follow-up periods were also the limitations of this study.

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## Conflict of interest

The authors have no conflict of interest to declare.

## Ethical approval

This study was approved by the Institutional

Review Board of NIO & H (memo no. NIO/Aca./22/244, Date-26.06.22).

## Recommendations

1. A larger sample size and longer follow-up would be helpful to assess the long-term stability of the IOLs and give a better idea about the usefulness of the techniques and delayed complications.
2. Further study should be done comparing the outcomes of SFIOL implantation to alternative techniques, including ACIOL implantation.
3. Traumatic aphakic patients could be included in future studies.

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