



PROSPECTIVE COMPARISON OF SUTURE-LESS GLUE-LESS INTRASCLERAL FIXATED INTRAOCULAR LENS (SFIOL) AND RETRO-PUPILLARY IRIS-CLAW LENS (RPICL) IMPLANTATION IN PATIENTS OF DEFICIENT POSTERIOR CAPSULAR SUPPORT

Ophthalmology

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ABSTRACT

Study Design: Prospective comparative, interventional study. **Methods:** 25 eyes (n=25) of 25 patients having deficient posterior capsular support were included and randomly divided into 2 group; group A (RPICL, n=15) and group B (suture-less glue-less SFIOL, n=10). The primary outcome was visual acuity and secondary outcomes were operating time, endothelial cell count (ECC), and complications. **Results:** There was marked improvement in best corrected visual acuity (BCVA) among both the groups. 60% patients of RPICL group and 50% patients of SFIOL group had final BCVA between 6/6- 6/12 followed by 6/18- 6/24 in 26.67% and 30% in RPICL and SFIOL group respectively. No statistically significant intergroup difference was found in postoperative BCVA ($p=0.607$). Surgical time was significantly lesser in RPICL implantation compared to sutureless SFIOL ($p<0.0001$). Ovalization in pupil shape and mild iritis were observed in 20% and 26.67% patients of RPICL group respectively while intra-operative slippage of haptic were observed in 40% patients of SFIOL group. There was significant loss of endothelial cells in both the groups ($p<0.05$) but no significant intergroup difference was observed ($p>0.05$). **Conclusion:** Both the technique were equally efficacious in correcting aphakia but SFIOL is technically demanding surgery whereas RPICL can have pupil and iris related issues.

KEYWORDS

Suture-lessglue-lessintra-scleral fixated intraocular lens, SFIOLs, RPICLs, Aphakia.

INTRODUCTION

Aim of cataract surgery in today's era is placing an appropriate IOL in the capsular bag in all cases. Circumstances, such as trauma, congenital aphakia, complications during cataract surgeries, zonular weakness etc. can lead to deficient posterior capsular support and consequently, in the bag IOL implantation is not possible. Alternatively, anterior chamber intraocular lens (ACIOLs) implantation, sulcus fixated IOLs, iris fixated lens and sutured and sutureless SFIOLs are available for such circumstances. ACIOLs are affiliated with corneal endothelial cell loss (ECL), peripheral anterior synechiae (PAS) and secondary glaucoma^(1,2) and hence they are obscured now. Iris claw lens (ICLs) is fixed in the iris, it may be associated with atrophy of iris, pigment dispersion and deposits, pupillary distortion, ECL etc.⁽³⁾. Sutured-SFIOLs can have problems of pseudophacodonesis and suture-associated issues such as suture knot exposure, IOL subluxation, suture breakage⁽⁴⁾. To avoid suture-related issues, various techniques as Schiøth's technique of intrascleral haptic fixation⁽⁵⁾, Glued IOL technique⁽⁶⁾, Yamane techniques⁽⁷⁾, XNIT technique⁽⁸⁾, simply modified intrascleral fixation using round flange (SMURF) technique⁽⁹⁾ MYX technique⁽¹⁰⁾ etc. were developed.

Our study aimed to assess the visual outcomes and complications of suturelessglueless SFIOLs and RPICL implantation prospectively.

METHODS

This study comprised of 25 eyes of 25 patients who presented in Manohar Das Eye Hospital (RIO), Prayagraj from August 2020 to July 2021. Patient age > 18 years having deficient capsular support were included. Patients having significant corneal and retinal pathology, glaucoma, vitreous hemorrhage, distorted anterior segment anatomy, significant iris defects, iris atrophy (contraindication for RPICL implantation) were excluded.

Surgical Procedures

RPICL Implantation: Under peribulbar anesthesia (5 ml of 2% lidocaine and 0.75% bupivacaine), a 6 mm conjunctival flap and a 5.5 mm superior sclero-corneal triplanar incision were created. Two paracenteses were made at 3 and 9 o'clock positions, followed by anterior vitrectomy. Intracameral pilocarpine 1% was used, and a single-piece ICL was introduced. Using ICL holding forceps, the optic was positioned, and the haptics were gently manipulated under the iris. The iris was enclaved into the haptic claw using a Sinskey hook. Viscoelastic was removed with a Simcoe cannula, and the conjunctival flap was repositioned.

Suture-less, Glue-less SFIOL Implantation: Under peribulbar anesthesia, limbal marking was performed at two 180° apart meridians. After conjunctival peritomy and cauterization, an anterior chamber maintainer was used. Partial-thickness scleral tunnels (3 mm length) were created at 3 and 9 o'clock using a 26-gauge bent needle. A 5.5 mm sclero-corneal triplanar incision was made at 12 o'clock. The leading haptic of the IOL was externalized through the scleral tunnel using a bent needle and McPherson forceps. Both haptics were tucked into the scleral tunnels and the IOL centered. Anterior chamber wash and conjunctival suturing were performed to complete the procedure.

Data Collection

Data included age, gender, retinoscopy, fundus examination, keratometry, IOP, uncorrected distance visual acuity (UCDVA), previous medical and surgical history, etiologies behind deficient posterior capsular support of 25 patients were recorded.

Statistical Analysis

The results were expressed as mean $\pm$ standard deviation. Qualitative data were compared using chi-square and quantitative data by using t-test. Significance was evaluated at the level of $p<0.05$.

RESULTS

Table.1 Comparison of the Demographic and Baseline Characteristics Between RPICL Fixation and Suturelessglueless SFIOL Fixation Group.

Variables	GROUP A	GROUP B	P-value
Age, years (mean $\pm$ SD)	57.26 $\pm$ 11.13	57.30 $\pm$ 15.59	$p>0.05$
Gender, (Male/Female)	12/3	4/6	-
Implantation, n (primary/ secondary)	6/9	2/8	-
Etiologies, n (%)			
Surgical aphakia/ intraoperative posterior capsular rupture (PCR)	09(60%)	07 (70%)	—
Traumatic subluxated cataract	03(20%)	01(10%)	-
Spontaneously subluxated cataract	01(6.67%)	00	-
Dislocated IOLs	02(13.33%)	02 (20%)	-
Endothelial cell count (mean $\pm$ SD) in cells /mm ²	1683.13 $\pm$ 123.50	1689.80 $\pm$ 134.47	$p>0.05$

Mean IOP (mmHg)	14.76±3.28	15.29±2.79	p>0.05
Log MAR UCDDVA (mean ±SD)	1.23±0.29	0.93±0.17	p<0.05

In our study, maximum number of patients was between age 50-60 years. Of these cases, 64% diagnosed as surgical aphakia (intraoperative PCR / previously aphakic), 20% had subluxated cataract and 16% had dislocated IOLs. Most of the patients had previous history of SICS (64%), history of trauma (20%) etc. Most of the patients presented with 0 to 2 month (14 patients).

Table. 2 Comparison of the Postoperative Parameters Between both the Groups

Complications	Group A	Group B
Slippage of haptic (intraoperative)	00	04(40%)
Mild iris bleed (intraoperative)	02 (13.33%)	00
Mild Corneal edema	02(13.33%)	01(10%)
Raised IOP	01(6.67%)	01(10%)
Hypotony	00	01(10%)
Haptic exposure	00	01(10%)
Ovalization of pupil	03(20%)	00
Mild iritis	04(26.67%)	01(10%)
Lens decentration	00	01(10%)
Lens disencapsulation	01(6.67%)	00
CME	00	01(10%)

The RPICL group had a significantly shorter surgical time (22.55 ± 2.83 min) compared to the SFIOL group (35.12 ± 2.64 min, $p < 0.0001$). Endothelial cell loss was similar in both groups (7.68% vs. 7.97%, $p > 0.05$). Postoperative UCDDVA improved significantly in both groups ($p < 0.05$). At 6 weeks, BCVA of 6/6–6/12 was achieved by 60% (RPICL) and 50% (SFIOL) patients, with no significant intergroup difference in mean BCVA ($p > 0.05$).

Table-3 Comparison of the Complications Between both the Group

Parameters	Group A	Group B	p- value
Mean surgical time (minutes)	22.55±2.83	35.12±2.64	p<0.05
Mean Postoperative endothelial cell count (cells /mm ²)	1553.80 ±120.25	1555.10±119.98	p>0.05
Mean Postoperative IOP(mmHg)	16.34±4.11	15.47±4.57	p>0.05
Mean Postoperative logMAR UCDDVA (at 6 week)	0.58±0.22	0.60±0.22	p>0.05
Log MAR BCVA (at 6 week)	0.34±0.25	0.39±0.21	p>0.05

Intraoperatively, mild iris bleed occurred in 13.33% of RPICL patients (self-limiting), and haptic slippage was noted in 40% of SFIOL patients. Postoperatively, transient hypotony was observed in 10% of SFIOL patients due to wound leakage, managed by anterior chamber reformation. Mild corneal edema resolved within 2 weeks in 13.33% of RPICL and 10% of SFIOL patients. Mild iritis was observed in 26.67% of RPICL and 10% of SFIOL patients, attributed to mild inflammation.

One patient in each group required re-surgery: haptic disencapsulation in RPICL (1st week) and haptic exposure in SFIOL (2nd week). Cystoid macular edema occurred in one patient, resolving within 3 months. Slight IOL decentration was noted in 10% of SFIOL patients at 3 months, which did not affect vision.

DISCUSSION

In our study the mean age in RPICL group was 57.26±11.13 years and 57.30±15.59 years in Sutureless-SFIOL group ($p > 0.05$) while in Kelkar et. al⁽¹¹⁾ study, mean age in ICL group was 62.0±23 years and 57.06±16.9 years in sutureless-SFIOL group. In Madhivanan et al⁽¹²⁾ study, the mean age of the patients was 63.6±12.2 years and 63.6±9.7 years in ICL and sutureless-SFIOLs respectively. In our study, the most common etiology was surgical aphakia (64%) followed by traumatic subluxated cataract (16%) and dislocated IOLs (16%) while 4% had spontaneous subluxated cataract. 60% patients of RPICL group and 70 % patients of sutureless-SFIOL group were surgically aphakic while 20% patients of group A and 10% patients of group B had traumatic subluxated cataract. Most of patients had history of previous SICS (60%) and this may be because SICS is more prevalent

in our tertiary care centre and other peripheral centers of the city. In Kaczmarek et. al. study⁽¹³⁾, most common presentation was post-operative aphakia with insufficient posterior capsular support. In Mahajan et. al.⁽¹⁴⁾ study, post- complicated cataract surgery was the most common cause of aphakia and secondary implantation (65%) was more common than primary implantation. In Madhivanan et al.⁽¹²⁾ study, 56 % patients of RPICL group and 14% of SFIOL group undergone primary implantation suggesting that primary RPICL implantation was more common than primary SFIOL implantation ($p < 0.001$). In our study, primary implantation was done in 6 patients of RPICL group and 2 patients of sutureless-SFIOL group suggesting that primary RPICL implantation was more commonly performed than primary SFIOL implantation. In our study, mean surgical time was 22.55±2.83 minutes and 35.12±2.64 minutes in RPICL and SFIOL group respectively and difference among them was statistically significant ($p < 0.0001$) suggested that RPICL implantation takes lesser time than SFIOL. In Mahajan et. al⁽¹⁴⁾ study, mean surgical time required for ICIOL group was 12±4.21 minutes while 30.9±5.81 minutes for SFIOL group compared to Maher Saleh et. al⁽¹⁵⁾ in which mean surgical time for ICL group was 32.5±4.97 minutes and 50.5±10.2 minutes in SFIOL group ($p < 0.001$). The final BCVA was compared at 6-week follow-up. 60% of RPICL group and 50% SFIOLs group patients had final BCVA 6/6-6/12 while 26.67% RPICLs and 30% SFIOLs patients had final BCVA 6/18-6/24. Only 13.33% and 20% patients of RPICLs and SFIOLs group respectively had BCVA < 6/24. The mean postoperative BCVA in Navya et al⁽¹⁶⁾ study was 0.34±0.3 for ICIOL and 0.36±0.24 for SFIOL group. In our study, the final log MAR BCVA was 0.34±0.25 and 0.39±0.21 in RPICL and SFIOL group respectively at 6 week. There was no statistically significant difference in BCVA at 6 week among both the groups (unpaired t-test, $p > 0.05$).

CONCLUSIONS

No significant intergroup difference in visual outcomes was observed but RPICL needs less surgical time, lesser instrumentation as compared to SFIOL implantation. SFIOL requires more surgical dexterity. Learning curve for SFIOL is more steep as compared to RPICL for the surgeon.

Both techniques are adequately safe with good visual outcomes. RPICL should be avoided in patients with inadequate iris support. Likewise SFIOL should be done with caution in myopic patients. Surgical time can be a biasing factor for surgeon to choose between the two implantation techniques. Cost wise RPICL are available at less cost as compared to SFIOLs and can be deciding factor for choosing between the IOLs.

LIMITATIONS

This study was conducted over a small size sample within a limited period of time. We excluded complicated cases from our study, which may affect the outcomes in day to day surgeries. IOL decentration and tilt could not be measured accurately because of lack of suitable instruments.

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