

Evaluation of the Postoperative Outcomes of Patients with Scleral-fixated Intraocular Lens Implantation

Dilek Özkaya¹, Umut Karaca¹, Gülşah Sofu¹, Mesut Avci², Alper Ertuğrul²

ABSTRACT

Purpose: To evaluate the visual outcomes and complications of scleral-fixated intraocular lens (IOL) implantation in patients without capsule and zonule support.

Materials and Methods: We retrospectively reviewed files of patients who underwent primary or secondary scleral-fixated intraocular lens (IOL) implantation between June 2018 and November 2020. Age, gender, preoperative surgery indications, and duration of follow-up were recorded in all patients. The preoperative best-corrected visual acuity (BCVA), intraocular pressure (IOP), refraction outcomes, central macular thickness (CMT), and macular segmentation measurements were compared with postoperative values.

Results: The study included 25 eyes of 25 patients. The median age was 72 (32-92) years. Surgical indication was aphakia in 11 patients (44%), IOL subluxation in 7 patients (28%), traumatic cataract in 3 patients (12%), lens dislocation in 2 patients (8%), senile cataract in 1 patient (4%) and anterior chamber IOL in 1 patient (4%). The median follow-up time was 6 months (3-24 months). A significant difference was found when preoperative BCVA and SE were compared with postoperative values ($p < 0.01$). There was no significant difference between preoperative and postoperative IOP, CMT, and macular segmentation measurements ($p > 0.05$). The postoperative complications included ocular hypertension in 4 patients (16%), choroidal detachment in 1 one patient (4%), retinal detachment in 1 patient (4%), macular edema in 1 patient (4%), and endophthalmitis in 1 patient (4%).

Conclusion: Scleral-fixated IOL implantation may be preferred in patients without capsule and zonule support for rehabilitation of aphakia and improvement of BCVA. However, low complication rates should not be ignored.

Keywords: Scleral fixated intraocular lens implantation, best-corrected visual acuity, complication.

INTRODUCTION

In the modern cataract surgery, primary goal is to implant an intraocular lens (IOL) into capsule by removing lens which lost its transparency. In case of posterior capsule tears during cataract surgery, IOL can be implanted into capsule, sulcus or anterior chamber based on extent of capsular tear, support status of capsule, eligibility and experience of surgeon.¹ The IOL implantation to anterior chamber can lead several complications including loss of corneal endothelial cells, pseudophakic bullous keratopathy, peripheral anterior synechia and ocular hypertension.² If the posterior capsule tear is large and capsule borders are vague, scleral-fixated IOL can be implanted to posterior chamber.³

If capsular support is insufficient during cataract surgery, scleral-fixated IOL implantation can be performed in the same session (primary) or after a certain period (secondary).⁴ The secondary IOL implantation is a standard method in both post-traumatic and postoperative aphakia. Due to their anatomic localizations, scleral-fixated posterior chamber IOLs have some advantages regarding complications in post-traumatic settings and young patients when compared to other IOLs. They allow avoiding complications related to anterior chamber IOLs in addition to ensuring better visual acuity and binocularity.⁵⁻⁸ In the literature, there are studies on positive outcomes of scleral-fixated IOL procedures. In previous studies, it was reported that visual outcomes were better while complication rates were lower in primary or secondary scleral-fixated IOL implantations.^{2,9-10}

1- Asist. Prof. Dr., Süleyman Demirel University, Faculty of Medicine, Department of Ophthalmology, Isparta, Türkiye

2- Asist. Dr., Süleyman Demirel University, Faculty of Medicine, Department of Ophthalmology, Isparta, Türkiye

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Correspondence Address:

Dilek Özkaya

Süleyman Demirel University, Faculty of Medicine, Department of Ophthalmology, Isparta, Türkiye

Phone: +90 246 211 9299

E-mail: drdilekozokaya@yahoo.com

The duration of surgery is longer in scleral-fixated IOL implantation where surgical technique is more demanding. In scleral-fixated IOL implantation, complications include IOL dislocation, ocular hypertension, suprachoroidal hemorrhage, retinal detachment, intravitreal hemorrhage and endophthalmitis.^{2,11} In our study, we aimed to assess visual outcomes and complications of primary and secondary scleral-fixated IOL implantations performed in patients without capsular or zonular support due to post-traumatic or postoperative causes.

MATERIALS AND METHODS

In this study, we retrospectively reviewed data from patients who underwent primary and secondary scleral-fixated IOL implantation at Ophthalmology Department of XXX University, Medicine School between July, 2018 and November, 2020. The study was conducted in accordance with tenets of Helsinki Declaration. The study was approved by Ethics Committee on Clinical Research of Suleyman Demirel University, Medicine School (No: 3/49-03.02.2021).

The inclusion criteria included rupture in posterior capsule during cataract surgery which may hamper posterior chamber lens implantation; luxation, subluxation or passage of crystal lens or IOL into vitreal space due to trauma or other reasons; aphakia previously left to secondary IOL implantation and bullous keratopathy due to anterior chamber lens. The cases with follow-up duration < 3 months or incomplete data were excluded. The decision for primary or secondary IOL implantation was made based on anesthesia employed, general health status and surgeon's preference. In all patients, age, gender, surgical indication and duration of follow-up were recorded. The patients were assessed before surgery and on day 1, week 1 and at months 1 and 3. All patients underwent a comprehensive ophthalmological examination including measurement of best-corrected visual acuity (BCVA, decimal), intraocular pressure (IOP), refraction values (spherical equivalent; SE), central macular thickness (CMT) and macular segmentation as measured by optical coherence tomography (OCT). Using OCT, the CMT measurements were performed at areas of central 1 mm (central subfield, [CSF]), 3 mm (superior inner macula [SIM]; temporal inner macula [TIM]; inferior inner macula [IIM]; nasal inner macula [NIM]) and 6 mm (superior outer macula, [SOM]; temporal outer macula [TOM]); inferior outer macula [IOM]; nasal outer macula [NOM]) in reference to thinnest macular region. These measurements were performed before and after surgery. The preoperative IOP values were compared to those obtained on postoperative week 1 while other parameters were compared with those

obtained at postoperative month 3. The complications due to scleral-fixated IOL implantation were also recorded.

The surgery was performed under general or local anesthesia. Conjunctival periotomy was performed at 3 and 9 o'clock directions in patients with posterior capsule rupture during cataract surgery who scheduled to scleral-fixation IOL implantation based on preoperative surgical indication. In phakic patients, intra-capsular lens extraction was performed following corneoscleral incision. In all cases, vitreous, residual lens and capsule fractions were removed via anterior vitrectomy. Viscoelastic was given to anterior chamber; followed by IOL implantation. The needles of a double-armed, 10-0 polypropylene suture (PC-9, Alcon Surgical, Fort Worth, TX) were passed through holes in the haptics of monoblock PMMA posterior chamber lens and tied. After passing sutures from sclera, IOL was placed into eye through corneoscleral incision. The IOL was fixed to sclera and centralized via balanced tension on corresponding sutures. The corneoscleral incision was closed using 10/0 nylon sutures. The scleral sutures were locked and scleral tunnel was formed and embedded. Viscoelastic and vitreous was removed using vitrectomy probe; tone was achieved and conjunctival gap was closed using 8/0 vicryl sutures.

All statistical analyses were performed using SPSS version 22.0. The normal distribution of data was assessed with Kolmogorov-Smirnov test. The skewed data are presented as median (min-max). The Wilcoxon test was used to compare preoperative and postoperative data. Mann-Whitney U test was performed to compare skewed data between independent groups. A p value < 0.05 was considered as statistically significant.

RESULTS

The study included 25 eyes of 25 patients. The median age was 72 years (32-92 years). The female: male ratio was 9:16 (36:64%). In the study, surgery was performed at right eye in 9 patients (36%) and left eye in 16 eyes (64%). Mean follow-up duration was 6 months (3-24 months). Secondary implantation was performed in 11 of 25 patients included. Table 1 presents surgical indications. At postoperative follow-up, BCVA improved in 20 cases while it remained stable in 3 cases and decreased in 2 cases. Of the patients with decreased BCVA, postoperative retinal detachment developed in one patient while there was history of corneoscleral perforation in the other patient. The median preoperative BCVA was 0.03 (0.001-0.4) while median postoperative BCVA was 0.4 (0.001-1.0). A significant difference was observed between preoperative and postoperative BCVA values (p < 0.01). Anti-glaucomatous treatment was initiated in 4 patients

Table 1: Surgical indications of the patients.

Indications	n	%
Aphakia	11	44
IOL subluxation	7	28
Traumatic cataract	3	12
Lens dislocation	2	8
Senile cataract	1	4
Anterior chamber IOL	1	4

IOL: Intraocular lens

(16%) with postoperative high IOP. The IOP was decreased to normal limits by medical treatment. Table 2 presents preoperative and postoperative BCVA, IOP and refraction values (SE) and p values.

No significant difference was observed between preoperative and postoperative CMT and macular segmentation values (p>0.05). Table 3 presents preoperative and postoperative measurements of CMT and macular segmentation analysis and p values.

Table 2: Preoperative and postoperative BCVA, IOP, refraction values (SE) and p values.

	Preoperative	Postoperative	p*
BCVA	0,03 (0,001-0,4)	0,4 (0,001-1,0)	<0,01
IOP (mmHg)	15 (7-30)	15 (8-40)	0,793
SE (diopter)	10,25 (3,50-14)	-0,75 (-5,50-1,50)	<0,01

BCVA: Best-corrected visual acuity; IOP: Intraocular pressure, SE: Spherical equivalent, *: Wilcoxon test

Table 3: Preoperative and postoperative CMT and macular segmentation analyses and p values.

(µ)	Preoperative Median (Min-Max)	Postoperativ Median (Min-Max)	p*
CMT	245 (175-290)	233 (193-478)	0.532
CSF	302 (213-357)	300 (242-568)	0.959
SIM	347 (220-374)	352 (317-432)	0.191
TIM	332 (237-390)	344 (292-434)	0.173
IIM	340 (229-382)	342 (277-488)	0.171
NIM	358 (222-391)	354 (293-599)	0.877
SOM	299 (226-341)	309 (273-347)	0.222
TOM	200 (252-368)	294 (256-333)	0.532
IOM	287 (243-319)	295 (228-375)	0.167
NOM	320 (209-352)	336 (267-398)	0.154

CMT: central macular thickness, CSF: central subfield, SIM: superior inner macula, TIM: temporal inner macula, IIM: inferior inner macula, NIM: nasal inner macula, SDM: superior outer macula, TDM: temporal outer macula, IDM: inferior outer macula, NDM: nasal outer macula, *: Wilcoxon test

Table 4 presents postoperative BCVA and CMT measurements and comparisons in primary and secondary IOL implantation groups. The median BCVA was 0.4 in primary IOL implantation group while it was 0.1 in secondary IOL implantation group (p=0.042). The significantly lower BCVA in secondary IOL implantation group is attributed to the fact that the patients with complications (retinal detachment, cystoid macular edema) and corneoscleral perforation underwent secondary IOL implantation.

The postoperative complications included ocular hypertension in 4 patients (16%), choroidal detachment in 1 one patient (4%), retinal detachment in 1 patient (4%), macular edema in 1 patient (4%), and endophthalmitis in 1 patient (4%). In all patients, IOL centralization was confirmed. Table 5 presents postoperative complications of patients.

Table 4: Postoperative BCVA and CMT measurements and p values in patients underwent primary and secondary IOL implantation.

	Primary implantation (n=14) Median (Min-Max)	Secondary implantation (n=11) Median (Min-Max)	p*
BCVA	0.4 (0.25-1.0)	0.1 (0.001-1.0)	0.042
CMT	215 (210-330)	255 (193-478)	0.529

BCVA: Best-corrected visual acuity, CMT: central macular thickness, *: Mann-Whitney U test

Table 5: Postoperative complications of patients.

Complication	n	%
Ocular hypertension	4	16
Choroidal detachment	1	4
Retinal detachment	1	4
Cystoid macular edema	1	4
Endophthalmitis	1	4

DISCUSSION

In cataract surgery, the most common complication is posterior capsule rupture with or without loss of vitreous. When sufficient capsule support is lacking, the surgeon should decide whether he/she will perform primary or secondary IOL implantation. The type of anesthesia, general health status and patient’s compliance, time required to correct complications and surgeon’s experience influence the decision process.

Since scleral-fixated IOL implantation requires better surgical experience and meticulous intraocular maneuvers, it should not be performed under stressful conditions or when the patient shows poor compliance. The surgical time is longer in scleral-fixated IOL implantation since more time is required for scleral flap preparation, IOL haptics sutures, vitrectomy and IOL implantation. In complicated cataract surgery, addition of time required for scleral-fixated IOL implantation to lens extraction increases the risk of postoperative implantation related cystoid macular edema in primary implantation.^{3,12,13} In addition, it has been suggested that visual outcomes are better, and inflammation and sequels are less common in patients undergoing secondary scleral-fixated IOL implantation.¹⁰ In our study, secondary IOL implantation was performed in 11 of 25 patients (44%) due to above-mentioned reasons.

The goal of scleral-fixated IOL implantation is to improve visual acuity in eyes without sufficient capsule support by correcting refractive error without need for aphakic glasses or contact lenses. In previous studies, it was reported that there is significant improvement in postoperative visual acuity by scleral-fixated IOL implantation.^{2,9,14} In a study, McAllister et al. reported long-term visual outcomes and complications after scleral-fixated IOL implantation and found that mean BCVA was 6/18 (light perception - 6/5) before surgery and 6/12 (light perception - 6/4.5) after surgery. In the study, mean increase in postoperative BCVA was 1.6 orders in Snellen chart and was significantly different.² In a retrospective study, Luk et al. reviewed outcomes of 104 patients underwent primary or secondary scleral-fixated IOL during 11 years period and reported that mean BCVA was 0.8 ± 0.58 logMAR before surgery and 0.5 ± 0.44 logMAR after surgery, indicating a significant improvement after surgery.¹⁴ In a study about outcomes of transscleral-fixated posterior chamber IOLs, Kjecha et al. reported that mean BCVA was 0.37 (finger counting-1.0) before surgery, increased to 0.5 (light perception-1.0) after surgery. It was reported that BCVA improved or remained stable in 89% of patients while it decreased by 2 orders in 4.4% and remained between light perception and finger counting in 4.4% of patients.⁹ In a study by Kutucu et al., the BCVA was between hand movement and 0.3 before surgery, while it was between hand movement and 0.6 after surgery.¹⁵ In our study, we found that BCVA was 0.03 before surgery and 0.4 after surgery, indicating a significant difference.

Several complications have been reported due to longer surgical time in scleral-fixated IOL implantation and challenges in surgical procedure. These include suture-related complications, ocular hypertension, choroid detachment, suprachoroidal hemorrhage, IOL dislocation,

endophthalmitis, retinal detachment and cystoid macular edema in scleral-fixated IOL implantation.^{2,16-18} In our study, no suture-related complication was observed in any patient. We think that formation of scleral tunnel after scleral suture placement and embedding scleral sutures in the tunnel reduced suture erosion. In our study, we observed IOP elevation at early postoperative period in 4 cases (16%). The IOP elevation was controlled by anti-glaucomatous treatment in these cases. In a study, Yu et al. assessed long-term outcomes and complications of sutured, scleral-fixated foldable IOL implantations and reported temporary IOP elevation in 9.62% of patients.¹⁹ In our study, choroidal detachment developed in one patient (4%). No suprachoroidal hemorrhage or IOL dislocation was observed in any patient. Endophthalmitis was observed in one patient (4%) on postoperative day 10, which was treated with intravitreal plus topical antibiotic therapy.

Retinal detachment is one of the most important complications in scleral-fixated IOL implantation. Postoperative retinal detachment can develop due to impaired integrity of anterior hyaloid surface, vitreal traction at sclerotomy areas and prolonged surgery. To minimize retinal detachment, sufficient anterior vitrectomy should be performed before IOL implantation in traumatic patients and young patients with attached posterior hyaloid.^{2,20,21} The retinal detachment incidence has been reported as 1-5% after scleral-fixated IOL implantation. The incidence is higher in patients with history of trauma, those with high myopia > -1.0 diopter and those with vitreous hemorrhage.²² In a previous study from our clinic, retinal detachment was observed in 3% of cases underwent scleral-fixated IOL implantation to posterior chamber.²³ In our study, the retinal detachment rate was found as 4% similar with literature.

The cystoid macular edema occurs due to loss of vitreous at trauma or beginning or during scleral-fixated IOL implantation procedure. In current studies, it has been reported that the cystoid macular edema incidence is 1% after standard cataract surgery and 5.5-7.3% after scleral-fixated IOL implantation. Particularly in young patients, sufficient vitrectomy should be performed during surgery in order to minimize the risk for disintegration of anterior hyaloid surface and vitreal traction. Cystoid macular edema occurs approximately 1-3 months after scleral-fixated IOL implantation and shows good response to topical non-steroidal anti-inflammatory drugs (NSAIDs) and peribulbar steroid injections.^{2,18,24,25} In our study, we compared preoperative and postoperative CMT and macular segmentation analyses (as measured by OCT) to evaluate cystoid macular edema and found no significant difference. In our study, clinically significant cystoid macular edema

was observed in one patient (4%) 1.5 months after surgery and the patient was treated with topical NSAID drops and peribulbar steroid injection.

This study has some limitations including small sample size, retrospective feature and single-center design, short and variable follow-up. Thus, there is need for prospective, multi-center studies with longer follow-up evaluating effectiveness and complications of scleral-fixated IOL implantation.

In conclusion, scleral-fixated is an effective treatment method to ensure rehabilitation of aphakia and improvement of visual acuity in cases without capsular and zonular support. One should be careful about complications which may occur due to long and challenging surgery. Complications such as retinal detachment and cystoid macular edema which may threaten vision can be minimized by preventing vitreal tractions through sufficient anterior vitrectomy during surgery.

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