

Outcomes of the Scleral Fixated Secondary Intraocular Lens Implantation in Aphakic Patients

Afakik Hastalarda Skleral Fiksasyonlu Sekonder Göz İçi Lens İmplantasyonu Sonuçları

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ABSTRACT

Purpose: To evaluate the secondary scleral fixated IOL implantation results in patients without adequate support of capsule for sulcus due to complications after cataract surgery.

Materials and Methods: In this retrospective study, 32 aphakic eyes of 32 patients following complications of cataract surgery were evaluated. Foldable three-piece acrylic intraocular lenses were fixed to the sclera at 3 and 9 o'clock, 1.5 mm from the limbus with 10-0 polypropylene suture by the suture technique of burying the knot through the scleral tunnel. Patients underwent a detailed ophthalmic examination. Visual acuity, intraocular pressure, anterior-posterior segment examination findings, complications were assessed preoperatively and in postoperative period of 1. day, 1. week, 1-3-6 and 12. months.

Results: The average age of the patients was 52.26. The mean of preoperative best corrected visual acuity was 0.24 logMAR, and at 12th month of the surgery the mean was calculated as 0.36 logMAR. Preoperative mean intraocular pressure was 16.26 mmHg, and the mean was 16.86 mmHg at month 12 following surgery. Prior to postoperative 1th month, the increase in intraocular pressure was observed mostly and it was followed by the anterior chamber hemorrhage as early complications. The most common observed late complication of surgery was cystic macular edema after postoperative 1th month and the second was irregular astigmatism.

Conclusion: Secondary scleral fixated intraocular lens implantation may be an effective surgical method in patients with an inadequate sulcus support complicated after cataract surgery. It might provide a significant increase in final visual acuity with minor complications.

Key Words: Scleral fixation, aphakia, cataract surgery.

ÖZ

Amaç: Katarakt cerrahisi sonrası gelişen komplikasyonlar nedeniyle afak kalmış, sulkus için yeterli kapsül desteği olmayan hastalarda skleral fiksasyonlu sekonder göz içi lens implantasyonu sonuçlarının değerlendirilmesi.

Gereç ve Yöntem: Retrospektif dizayn edilen çalışmada 32 erişkin hastanın komplike olmuş katarakt cerrahisi sonrası afak kalmış 32 gözü değerlendirildi. Saat 3 ve 9'da, limbustan 1,5 mm çıkışta 10-0 poliprolen suture ile skleral tünele gömülü düğüm sütür tekniğiyle üç parçalı katlanabilir akrilik intraoküler lens skleraya fiks edildi. Hastaların detaylı göz muayeneleri yapıldı. Preoperatif ve postoperatif 1. gün, 1. hafta, 1-3-6 ve 12. aylarda görme keskinliği, göz içi basıncı, ön-arka segment muayeneleri ve komplikasyonlar açısından değerlendirildi.

Bulgular: Hastaların yaş ortalaması 52,26 olarak hesaplandı. Ameliyat öncesi düzeltilmiş en iyi görme keskinliği ortalaması 0,24 logMAR, ameliyat sonrası 12. ayda ise ortalama 0,36 olarak hesaplandı. Ameliyat öncesi göz içi basıncı ortalaması 16,26 mmHg, ameliyat sonrası 12. ayda ise ortalama 16,9 mmHg olarak hesaplandı. Postoperatif 1. aydan önce erken komplikasyonlardan en çok göz içi basıncı artışı görüldü, bunu ön kamara hemorajisinin takip ettiği görüldü. Postoperatif 1. aydan sonra geç komplikasyonlardan en çok kistik makula ödeminin geliştiği görüldü, ikinci sırada düzensiz astigmatizmanın geliştiği gözlemlendi.

Sonuç: Katarakt cerrahisi sonrası komplike olmuş ve yeterli sulkus desteği olmayan hastalarda skleral fiksasyonlu sekonder göz içi lens implantasyonu etkili bir cerrahi yöntem olabilir. Final görme keskinliğinde anlamlı bir artış sağlayabilir.

Anahtar Sözcükler: Skleral fiksasyon, afaki, katarakt cerrahisi.

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INTRODUCTION

Cataract is the leading cause of blindness and loss of vision.^{1,2} By the world population gets older this prevalence will increase.³ The expectations of patients have been increased by the development of technique and materials in cataract surgery, so the tolerance of both patients and surgeons have been decreased in case of complications. This situation provides to find more solutions for complications.

One of these complications is the tear of posterior capsule and the absence of sufficient capsular support. The management options for an aphakic eye in case of inadequate capsular support are; aphakic glasses, contact lenses, and secondary intraocular lens (IOL) implantation.⁴ There are several surgical techniques for IOL implantation such as anterior chamber (AC) IOL, an iris-fixed IOL, and a transscleral-fixed (TSF) posterior chamber (PC) IOL through the ciliary sulcus or pars plana.^{5,6} AC-IOL have risk of postoperative complications like corneal endothelial damage, uveitis, glaucoma, hyphema and cystoid macular edema.^{7,8} Suturing the IOL to the iris may result in iris chafing, uveitis, and pupillary constriction.⁹ Furthermore, iris fixation is not applicable in cases of significant iris trauma.

Scleral fixated intraocular lens (SFIOL) has several advantages because it provides the most physiological placement of IOL as original lens position in case of bag or sulcus implantation is not possible and it also acts as a mechanical barrier between vitreous cavity and anterior chamber.^{10,11} It has no contact with corneal endothelium or trabecular meshwork.¹² Beside these it has disadvantages and complications.^{13,14} Suture erosion is a potential problem causing endophthalmitis and IOL dislocation. Scleral groove,¹⁵ burying the suture ends into scleral tunnel,¹⁶ covering the suture ends with fascia lata,¹⁷ tenon's capsule,¹⁸ scleral flap

or scleral pocket^{19,20} were described techniques to avoid the complications.

The aim of this study was to contribute to the literature by assessing the complications and results of TSF PC-IOL including visual outcomes in adult patients with no adequate capsular support due to complicated cataract surgery.

MATERIALS AND METHODS

This retrospective study obtained by a review of the medical records. The study was conducted in compliance with the tenets of the Declaration of Helsinki and was approved by the independent Ethics Committee of Okmeydani Training and Research Hospital. Informed written consent was obtained from all the patients prior to surgery. The study included 32 eyes of 32 adult patients, who had secondary IOL implantation between January 2012 and October 2014 in the Anterior Segment Division, Department of Ophthalmology.

Patients and Data Collection

Data collection was composed of demographic data, ocular history, indication for surgery, preoperative and postoperative detailed ophthalmic examination including best corrected visual acuity (BCVA), intraocular pressure, anterior segment and fundus evaluation using slit lamp biomicroscopy and indirect ophthalmoscopy. The preoperative power calculation of IOL was set using the Sanders-Retzlaff-Kraff II formula. All patients underwent ophthalmic examination before surgery and on the day 1, 3, 14 and at month 3, 12 postoperatively. The postoperative complications were also recorded. The position of IOL was assessed following pupil dilatation. Nonvisibility of the IOL optic edge was considered as a good centration in a mid-dilated pupil of 4 mm. BCVA of 12th month was accepted as the final and visual outcome indicator comparing with baseline BCVA of pre-

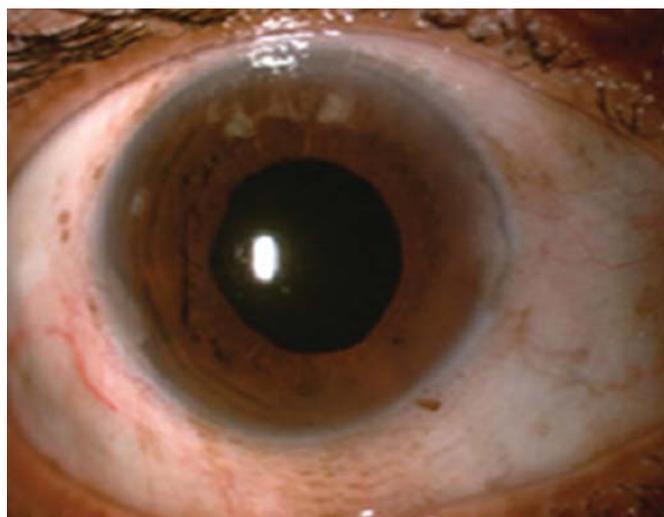


Figure 1. Preoperative anterior segment image of a 37 yo male aphakic patient due to traumatic cataract surgery



Figure 2. Intraoperative anterior segment image of the same patient

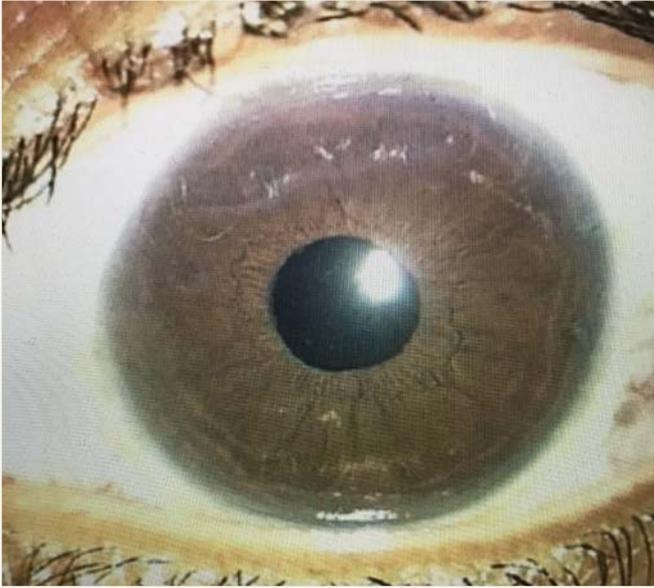


Figure 3. Postoperative anterior segment image of the same patient at 12th month

operative period. Inclusion criteria were as follows: (1) Pre-operative visual acuity of 0.1 or more with snellen chart (2) total absence of capsular bag and insufficient sulcus support (3) history of complicated cataract surgery causing aphakia, (4) regular 3 months follow-up. Exclusion criteria were as follows: (1) Central corneal opacities (2) Uncontrolled glaucoma (3) Active ocular inflammation (4) Macular edema or retinal detachment.

Surgical Technique

All patients were operated by one surgeon (NC) under local anesthesia (peribulbar injection of mixture of lignocaine, bupivacain and hyalase). Alcon MA60BM 3-piece, acrylic foldable IOLs (Alcon International, United States) were implanted. All eyes were performed anterior vitrectomy during the surgery. Postoperatively topical antibiotic/steroid drops were prescribed 5 times daily for 4 weeks.

Firstly two points 180° from each other around 2'o clock and 8'o clock positions were marked. A 2-mm-sized lamellar scleral tunnel was formed with a crescent blade without conjunctival dissection next to both incision points. A straight needle of 10-0 polypropylene suture was passed through one transconjunctivoscleral passage, which was located 1.5 mm posterior from the limbus (8 o'clock). The needle was inserted perpendicular to the sclera wall and then kept parallel to the iris until its tip appeared in the center of the pupil. A 27-Gauge hollow needle placed through the opposite side (1.5 mm behind the posterior surgical limbus at 2 o'clock) was used to retrieve the straight fine needle via its barrel. The straight fine needle was withdrawn from the eye guided by the hollow needle, leaving the 10-0 suture traversing the eye from one incision side to other. A 2.8-mm-sized corneoscleral incision was generated for IOL implantation. The

suture loop was pulled through this incision then cut and the ends were tied to the haptics of the IOL, respectively. An ophthalmic viscosurgical device (Alcon Laboratories, Inc. Fort Worth, TX, USA) was inserted into the anterior chamber to create a volume. The IOL was placed into posterior chamber through the superior incision, and the optics were centered in the ciliary sulcus by setting the sutures. The sutures were tied to themselves and the ends were left long (3-4 mm). The knot was laid flat into the prepared scleral tunnels. Finally the viscosurgical device was aspirated and the corneoscleral incision was closed.

Statistics

Continuous data were assessed as mean \pm standard deviation, and categorical variables were assessed as number (%). For statistical analyses, the decimal BCVA value was converted to the logarithm of the minimum angle of resolution (logMAR). All statistical analyses were carried out using IBM SPSS ver. 19.0 (IBM Co., Armonk, NY, USA) using the paired *t*-test and one-way ANOVA test. A *p*-value less than 0.05 was considered to indicate statistical significance.

RESULTS

The mean age of 32 patients was 56.26 ± 4.27 (40-70) years. The follow-up period was 12 months. The least interval time was 3 months after cataract surgery for scleral fixated IOL implantation. The operation time varied between patients. (Table 1)

There was a significant ($P < 0.05$) improvement in the mean of BCVA comparing preoperative baseline with final values at 12 month. 22 eyes had visual improvement while 7 eyes had decrease in visual acuity and 3 eyes had no visual changes. No statistical ($p=0.48$) change was observed between the means of baseline and final IOP values. (Table 2)

The recorded postoperative complications were divided into 2 groups of early (before 1 month) and late (after 1 month)

Table 1. Patient demographic information and follow-up periods

| | |
|--|--------------------------|
| Gender(%) | |
| Male | 37.50 |
| Female | 62.50 |
| Mean Age (SD, y) | |
| Male | 52.66 ± 3.76 |
| Female | 57.82 ± 4.48 |
| Mean Interval from primary to TSF-PCIOL (mo) | 3.4 ± 0.8 (3-5) |
| Mean operation time (min) | 18.55 ± 3.22 (14-28) |
| TSF-PCIOL: Transscleral-fixed posterior chamber intraocular lens; SD, y: Standard Deviation, years; mo: months; min: minutes | |

Table 2. BCVA and IOP mean changes during follow-up periods in preoperative and postoperative 1, 3, 6 and 12 months.

| | preop | 1 month | 3 month | 6 month | 12 month |
|------|-------|---------|---------|---------|----------|
| BCVA | 0.24 | 0.32 | 0.36 | 0.38 | 0.36 |
| IOP | 16.26 | 19.34 | 17.14 | 15.32 | 16.86 |

BCVA: Best corrected visual acuity, IOP: Intraocular pressure

surgery complications. The most common seen early complication was transient increase in IOP. The most common late complication was cystic macular edema (CME). (Table 3)

DISCUSSION

Secondary IOL implantation is a common treatment method for aphakic patients with insufficient capsular support. TSF-IOL is one of the surgery widely performed by surgeons in addition to AC-IOL and iris-claw lens implantation.²¹ Iris-claw IOL is also a promising technique however with the risk of more complications.⁹ Forlini M et al.²² presented a retrospective study reporting long-term evaluation of the use of retropupillary implantation of the Artisan iris-claw intraocular lens (RPICOL) in several aphakic conditions without capsular support. They concluded RPICOL for secondary implantations is a valid alternative strategy to scleral-fixated or angle-supported IOL implantation. They noted disenclavation in 3 eyes, retinal detachment in 1 eye, macular edema in 1 eye, chronic dull pain in 8 eyes and severe iridodonesis in 5 eyes in their study.

Table 3. Early and late postoperative complications

| Postoperative complications | N (%) |
|-----------------------------|----------|
| Early | |
| Transient IOP increase | 4 (12.5) |
| Anterior chamber hemorrhage | 3 (9.34) |
| Postoperative inflammation | 2 (6.3) |
| Vitreous hemorrhage | 1 (3.1) |
| Late | |
| CME | 4 (12.5) |
| Irregular astigmatism | 3 (9.34) |
| Glaucoma | 2 (6.3) |
| IOL decentralization | 2 (6.3) |
| Retinal detachment | 1 (3.1) |
| Bullous keratopathy | 1 (3.1) |
| Endophthalmitis | 1 (3.1) |

CME: Cystic macular edema, IOP: Intraocular pressure, IOL: intraocular lens

TSF of sutured PC-IOL was first introduced by Malbran et al.²¹ in 1986 in aphakic patients previously performed intracapsular cataract extraction. Following the improvements in medical technology, many TSF modification techniques have been developed.⁵ Although this, however complications; such as IOL dislocation due to suture lysis or endophthalmitis as a result of knot exposure are sometimes unavoidable.^{11,23,24} Although the atrophic tendency of the flap by time, placing the knot with a triangular scleral flap is one of the most common technique applied by surgeons.^{13,25} Intrasceral pocket technique ensure more long-term IOL stability via providing a greater coverage surface area for suture ends.²⁶ Beside being unlikely to be loosen and easier to be laid flat, an adequate 4 mm length of suture yields a better knot integrity. So there is low risk of suture breakage and spreading out the covering scleral roof.²⁷

TSF performed with intrasceral pocket technique is especially useful for patients who had vitrectomy since the conjunctiva and Tenon's space maintain their original integrity. The risk of corneal nerve injury is low in the intrasceral pocket technique because the corneal limbus is intact. This technique can be performed with topical anesthesia because it is associated with less pain compared with techniques. Less astigmatism and irritation is observed because the knots are placed in the intrasceral pocket without a wound gap.

Techniques of TSF without suture are also frequently performed in aphakic patients. In a retrospectively reviewed study from the medical records, Kawaji T et al.²⁹ reported the results of sutureless scleral fixation of PCIOL by using a modified technique described as fixing the haptic of the IOL into the limbus-parallel and lamellar dissected scleral tunnel. The IOLs were fixed and centered well. Postoperative complications included smooth vitreous hemorrhage in 4 eyes (8.3%), CME in 2 eyes (4.2%), and iris capture of the IOL in 2 eyes (4.2%) during the 26.7 months mean follow-up period. Narang P et al.³² retrospectively analyzed the visual outcome of patients undergoing glue-assisted intrasceral fixation of PCIOL in the absence of posterior capsular support. Postoperatively, they noted improvement in visual acuity and observed promising results after 1 year follow-up. Postoperative complications included decentralization in 1 case and vitritis with chronic macular edema in another case.

Several studies have been reported considering the efficiency and complications TSF-IOL implantation. We aimed to assess the efficiency and complications of TSF-IOL in this study which 32 aphakic eyes of 32 adult patients enrolled in. So we planned to provide additional contributions to the literature.

Hoffman et al.³¹ reported a study considering TSF technique in which the scleral pockets were formed from peripheral clear corneal incisions. However, their technique required two suture passes through the sclera for each haptic, which means more risk of vitreous hemorrhage compared with single suturing technique. Compared with this we performed a single transscleral pass for IOL haptic fixation, and we did not use any suture for closure of scleral flap.

In a retrospective designed study (n=42), Haszcz D et al.³² evaluated functional outcomes and safety of posterior chamber IOL implantation using Hoffman scleral haptic fixation and sutureless Sharioth technique in patients with posttraumatic and postoperative aphakia after 1-year follow-up. They concluded both techniques are feasible with low incidence of complications and no significant differences in BCVA were found between groups. While no complication was observed in Hoffman group, 2 IOL dislocation was observed in Sharioth group. In our study we did not observe any IOL dislocation. Overall, they recorded; the final BCVA improved in 26 eyes, did not change in 5 eyes, and worsened in 11 eyes. In our study; 22 eyes had improvement in BCVA, 3 eyes had no change and 7 eyes had deterioration.

Yalnız-Akkaya Z et al.³³ designed a retrospective study with the purpose of evaluation and comparison of the results of primary and secondary scleral-fixated PCIOL implantations in adult patients. They concluded both primary and secondary scleral-fixated PCIOL implantations can provide favorable visual outcomes with lower complication rates. They divided the complications into 2 subgroups as early and late complications similar to our study. Anterior chamber hemorrhage (13.5%, 6.8%), transient elevated intraocular pressure (8.1%, 18.6%) were of the early complications. Glaucoma (2.7%, 11.9%), irregular astigmatism (2.7%, 5.0%), CME (5.4%, 6.8%), bullous keratopathy (2.7%, 1.7%), IOL decentralization (2.7%, 1.7%) were of the late complications.

Yong-Wun Cho et al.³⁴ retrospectively compared short-term 6 month clinical effects of the two transscleral fixation (TSF) techniques of intrascleral pocket and conventional scleral flap with conjunctival division techniques in 40 consecutive patients with aphakia. They did not find significant difference in endothelial cell count (ECC) at 6 months after surgery. However, they observed a significant difference of BCVA in intrascleral pocket group at 1 day and 6 months after surgery compared to the conventional-flap group. No postoperative complications were noted in the intrascleral pocket group., while 5 of the 20 patients experienced irrita-

tion in the conventional-flap group.

Long C et al.²⁸ reported a modified technique allowing stability of PCIOLs in post-traumatic aphakic eyes with a wide range of follow-up (32.3±10.8 months; 3–67 months) to minimize the risk of suture exposure for the TSF of PCIOL. They recorded mild IOL tilt (5–10°) in 5 eyes, and slight IOL decentralization (0.5–1.0 mm) in 3 eyes. They did not observe any suture exposure, suture breakage, IOL dislocation, or endophthalmitis during the follow up period. They noted vitreous hemorrhage in 4 (8.3%) eyes, CME in 5 (10.4%) eyes, suprachoroidal hemorrhage in 2 (4.2%) eyes and retinal detachment in 2 (4.2%) eyes.

Yang CS et al.³⁵ designed a study with the purpose to determine the long-term safety, efficacy and refractive status of combined vitrectomy and transscleral suture fixation of posterior chamber (PC) IOLs in the management of posteriorly dislocated lenses in Taiwan. They demonstrated good long-term visual outcome with only minor complications such as erosion of prolene suture through conjunctiva in 3 patients. No suture breakage or IOL dislocation and no retinal detachment, corneal compromise, or endophthalmitis was noted in any of the patients.

The limitations of this study are retrospective nature, absence of comparing group, small population and one pre-operative indication. Our technique might be modified and used for other kinds of IOL or intraocular devices that requires transscleral suture fixation.

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