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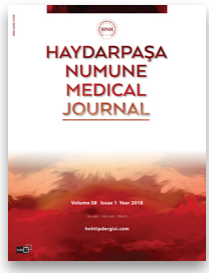

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ORIGINAL ARTICLE

Anatomic and Visual Outcomes Comparison of Two Different Scleral Fixation Techniques for the Patients without Capsule Support

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Abstract

Introduction: In this study, we described two different sutureless intrascleral fixation techniques performed by creating scleral tunnels in patients without capsular support. Additionally, we evaluated the complications, as well as the anatomic and visual outcomes of the two techniques.

Methods: This retrospective study included patients who underwent sutureless intrascleral intraocular lens (IOL) implantation using two different techniques. Patients who underwent sutureless intrascleral IOL implantation with the creation of a scleral tunnel at Kartal Dr. Lütfi Kırdar Training and Research Hospital between January 2016 and March 2017 were examined. The patients were compared in terms of (BCVA), intraocular pressure, mean keratometer values, refraction measurement, specular microscopy, corneal endothelial cell count, and anterior and posterior segment examination during the preoperative and postoperative periods. Complications occurring during and after the surgery were recorded.

Results: The study included 18 eyes of 18 patients who underwent technique 1 and 18 eyes of 17 patients who underwent technique 2 ($p>0.05$). The mean follow-up period for cases operated with technique 1 was 6.4 months, while for technique 2 it was 6.2 months. Postoperative BCVA was found to be 0.18 (range 0.00-0.40) logMAR in technique 1 and 0.22 (range 0.00-0.40) logMAR in technique 2 ($p>0.05$). Median spherical equivalent values of the patients postoperatively were myopic in both groups. Median corneal endothelial cell loss in the group operated with technique 1 was 10.19%, whereas it was 11.16% in the patients who were operated with technique 2. In 1 patient using technique 1 and in 2 patients using technique 2, the IOL haptic was broken.

Discussion and Conclusion: Anatomic and visual outcomes, as well as complications, are similar for both techniques. Acceptable short-term outcomes are obtained with the modified techniques used in the present study; however, studies with longer follow-up periods and larger patient series are needed to determine whether the techniques may be successful in the long term.

Keywords: Capsule support; intraocular lens; scleral tunnel; sutureless; two techniques.

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Some implantation techniques, such as transscleral-sutured IOL [1,2], iris-sutured IOL [3], anterior chamber lens [4], and intrascleral suture-free IOL [5,6], may be used when there is insufficient capsule support. Iris-sutured IOL and anterior chamber IOL may lead to chronic uveitis, inducing peripheral anterior synechiae and corneal decompensation due to endothelial cell loss [7,8]. Implantation of transscleral-sutured IOL may be associated with suture-dependent complications, such as inflammation, dislocation of the IOL due to suture degeneration, endophthalmitis, and retinal detachment [9-11].

Some surgeons have recently suggested different techniques for the intrascleral fixation of IOL without sutures in the posterior chamber [12]. These techniques were developed to eliminate suture-dependent complications of transscleral IOL implantation techniques [9,10,13,14]. Sutureless intrascleral fixation methods were developed for fixing IOL haptics within the sclera. IOL stability is provided by the scar tissue that forms around the haptics.

The aim of this study is to describe two different intrascleral fixation techniques through scleral tunnels in patients without capsular support and to compare the complications and visual outcomes of the two techniques.

Materials and Methods

The present retrospective study included 18 eyes of 18 patients who underwent sutureless intrascleral IOL implantation (technique 1) through scleral tunnels created by a 23G micro vitreoretinal (MVR) blade, and 18 eyes of 17 patients who underwent sutureless intrascleral IOL implantation (technique 2) through scleral tunnels created by a 27 gauge (G) needle between January 2016 and March 2017. Informed consent forms were signed by all patients. The present study was carried out in accordance with the Helsinki Declaration, and approval from the local ethical committee was obtained (decision no: 2017/514/108/11).

The BCVA (logMAR), intraocular pressure measured by Goldmann applanation tonometry, refraction measurement by autorefractokeratometer, corneal endothelial cell count, and findings of anterior and posterior segment examinations were recorded during the preoperative and postoperative periods. Complications during and after the surgery were also recorded.

Aphakic patients without sufficient posterior capsule support, as well as patients with traumatic or spontaneous subluxation of the lens or IOL, were included in the present study. Patients with preoperative corneal and retinal pathology, and those with any eye disease that may affect visual acuity, were excluded.

Axial length and keratometry measurements were calculated using the IOL Master (V.4.08; Carl Zeiss Meditec, Jena, Germany). The SRK/T II formula was used in the IOL Master to calculate the strength of the IOL. Three-piece foldable IOLs (TP 6130; Biotech Vision Care, India) were used in all cases.

Surgical Technique

All patients were operated under local anesthesia (retrobulbar block). The two techniques were performed by 2 surgeons (M.N.B, B.K) working in the same clinic with close professional experience and qualifications.

1. Technique 1:

Following routine surgical preparations, the conjunctiva is opened approximately 30 degrees at the 6 and 12 o'clock positions, and the sclera is cauterized (Fig. 1.a). Two corneal side incisions are made at the 3 and 9 o'clock positions using an MVR blade. An infusion cannula is inserted through the side incision at the 9 o'clock position, and anterior vitrectomy is performed if necessary. At the 12 and 6 o'clock positions, approximately 2 mm from the limbus, 2-3 mm scleral tunnels are created parallel to the limbus using a 23G MVR, and sclerotomies are performed at the ends of the tunnels (Fig. 1.b-e). The three-piece IOL is inserted into the anterior chamber using a cartridge through the corneal incision, and the trailing haptic is externalized through the corneal incision. The leading haptic is grasped with a 23-gauge forceps and externalized through the sclerotomy and scleral tunnel (Fig. 1.f). The same procedure is repeated for the trailing haptic through the upper sclerotomy and scleral tunnel (Fig. 1.g-i). The haptics are then buried in the tunnel using 8/0 vicryl and sutured externally. The corneal incision and conjunctiva are closed, and the operation is completed with a subconjunctival injection of gentamicin and dexamethasone (Fig. 1.i-k).

2. Technique 2:

The conjunctiva is opened at the 2 and 8 o'clock positions, and the sclera is cauterized (Fig. 2.a). Two corneal side incisions are made at the 3 and 9 o'clock positions using an MVR. An infusion cannula is inserted into the side incision at the 9 o'clock position, and anterior vitrectomy is performed through the other side incision if necessary. Sclerotomies are performed 1.5 mm away from the limbus at the 2 and 8 o'clock positions using a 23G MVR (Fig. 2.b-d). The three-piece IOL is inserted into the anterior chamber using a cartridge through the corneal incision,

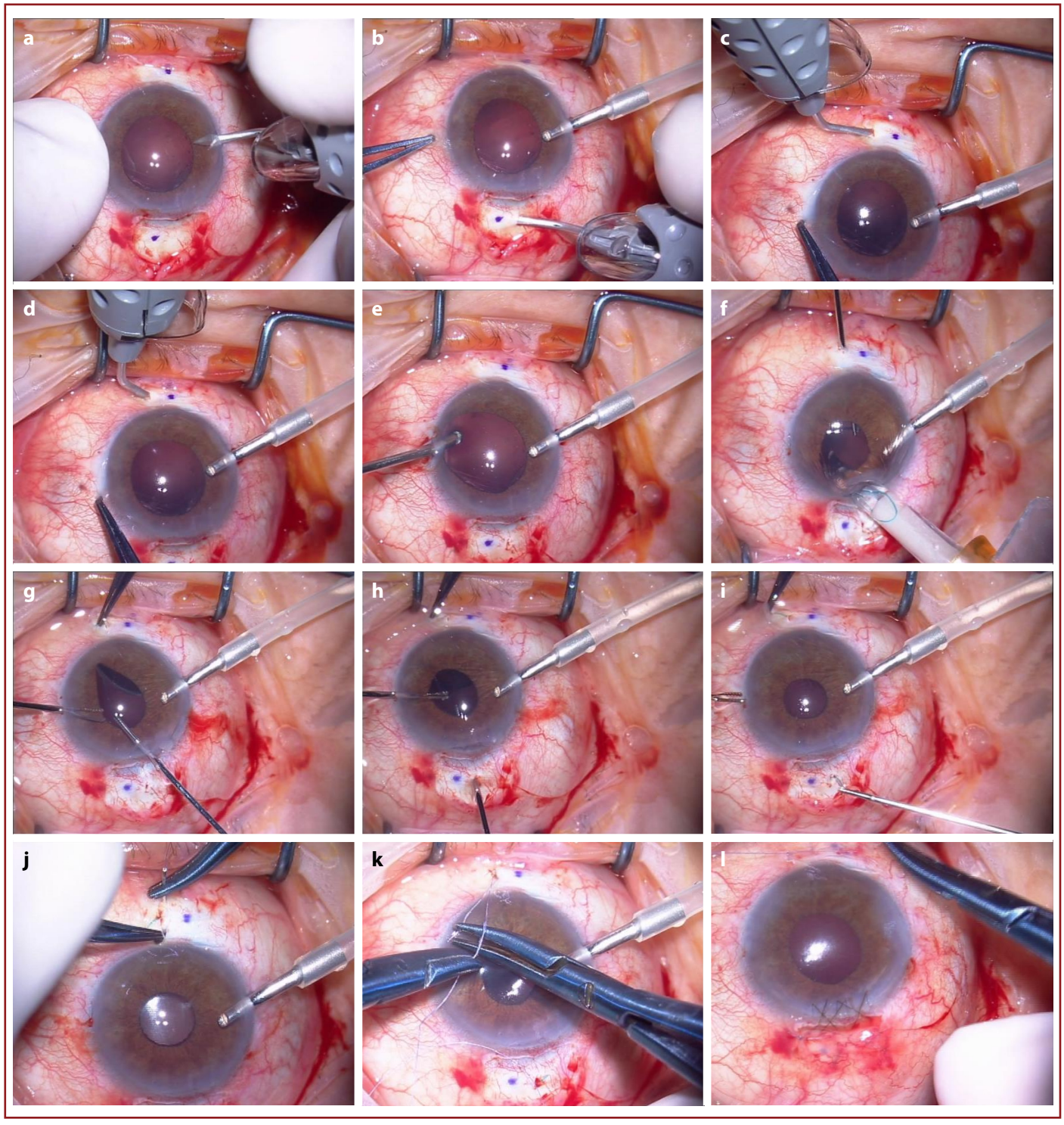

Figure 1. (a) Opening of the conjunctiva and cauterization of the sclera. **(b-d)** Creation of a 2 mm scleral tunnel parallel to the iris plane using a 23-G MVR and performance of a sclerotomy at the termination point. **(e)** Anterior vitrectomy. **(f)** Implantation of a 3-piece foldable IOL into the anterior chamber and extraction of the haptic using a 23-gauge forceps inserted via the sclerotomy. **(g-i)** Extraction of the other haptic using forceps inserted into the side orifice and 23-gauge forceps inserted into the sclerotomy. **(j, k)** Covering and suturing of the haptic in the tunnel using 8/0 vicryl. **(l)** Closure of the cornea and conjunctiva.

and the trailing haptic is externalized through the corneal incision. The leading haptic is grasped with a 23G forceps and externalized through the sclerotomy. The same procedure is repeated for the trailing haptic through the upper sclerotomy using the side incision (Fig. 2.e-g). Scleral tunnels of 2 to 3 mm are created using a 27G needle,

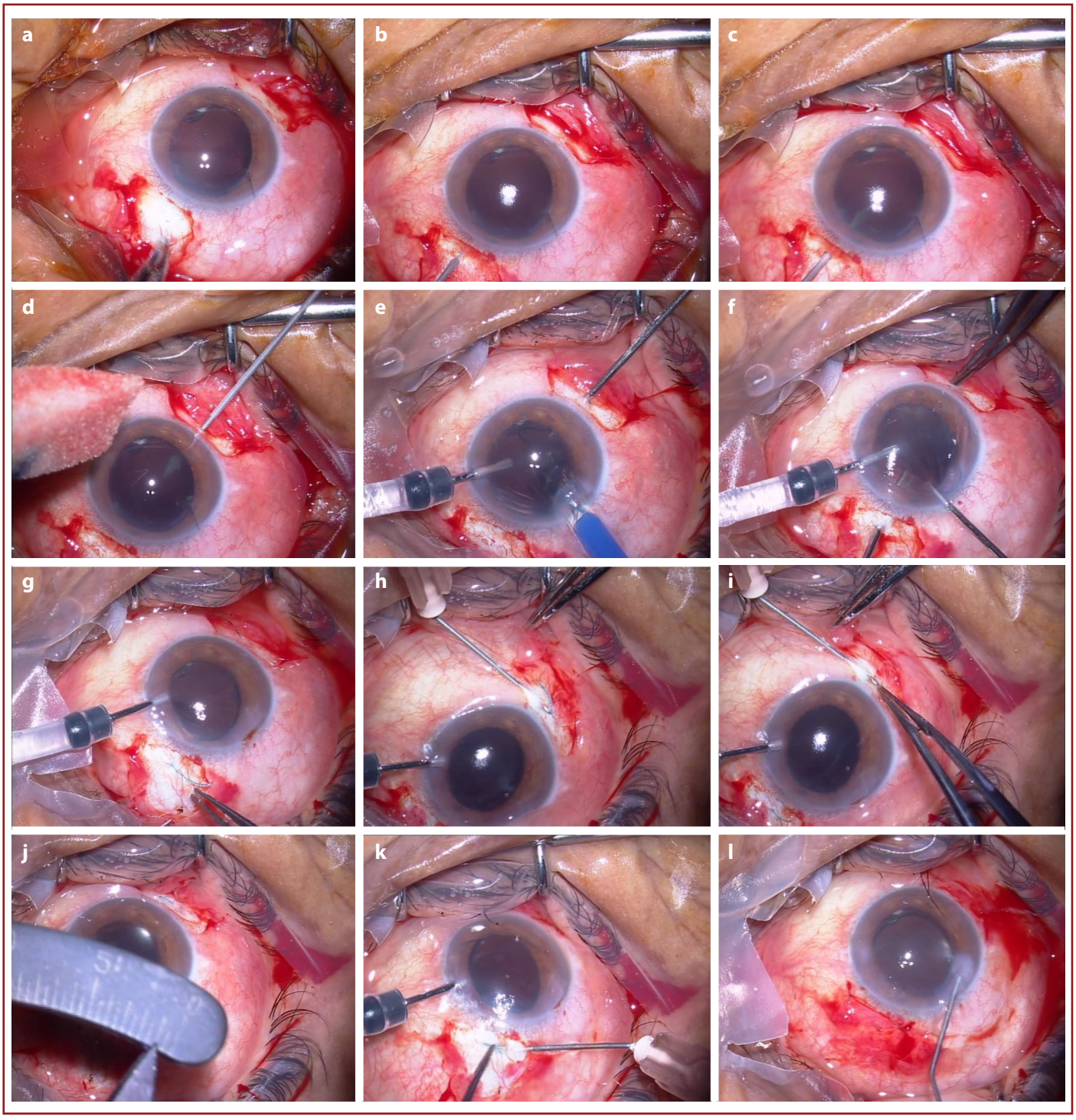

Figure 2. (a) Opening of the conjunctiva and cauterization of the sclera. **(b-d)** Sclerotomy, with two sclerotomy procedures performed 1.5 mm away from the limbus and parallel to the iris plane using a 23-G MVR. **(e)** Implantation of the standard 3-piece foldable IOL into the anterior chamber and extraction of the haptic using a 23-G forceps inserted via sclerotomy. **(f)** Extraction of the haptic using a 23-G forceps inserted via sclerotomy. **(g)** Image of the haptics following externalization. **(h-j)** Creation of scleral tunnel by 27 G needle and insertion of the haptic through the needle 1 mm away from the sclerotomy. **(k)** Insertion of the other haptic using the same procedure. (l) Closure of the conjunctiva by suturing and closure of the corneal incision site by hydration.

1 mm away from the sclerotomy zones and parallel to the limbus. The haptics are placed into the 23G needle and implanted into the scleral tunnels (Fig. 2.h-j). The conjunctiva and corneal incision are closed with sutures if needed, and subconjunctival injections of gentamicin and dexamethasone are administered (Fig. 2.k).

Statistical Analysis

The data obtained in the present study were analyzed using the SPSS 17 for Windows package program. Patient characteristics were reviewed through descriptive statistics. The differences between nominal measures were assessed by the chi-square test. Compliance of the numeric variables with normal distribution was analyzed by the Kolmogorov-Smirnov test; the difference between independent numeric variables without normal distribution was evaluated by the Mann-Whitney U test. The limit for statistical significance was taken as $p<0.05$.

Results

The present study included the evaluation of 18 eyes (11 right, 7 left eyes) of 18 patients (9 males, 9 females) operated on with technique 1 and 18 eyes (12 right, 6 left eyes) of 17 patients (8 males, 9 females) operated on with technique 2. The median age of the patients was 75 years (range: 41-85) in the technique 1 group and 67 years (range: 21-84) in the technique 2 group (Table 1).

For sutureless intrascleral IOL implantation, the most common reason for patients to be aphakic was complicated cataract surgery in both groups. In eyes operated with technique 1, the cause of aphakia was complicated cataract surgery in 12 (67%) eyes and dislocated crystalline lens in 6 (33%) eyes. In eyes operated with technique 2, the cause of aphakia was complicated cataract surgery in 8 (44%) eyes, dislocated crystalline lens in 5 (28%) eyes, and dislocated IOL in 5 (28%) eyes.

The BCVA of the patients preoperatively was 0.22 (range 0.00-0.7) logMAR in technique 1 and 0.26 (range 0.05-0.50) logMAR in technique 2. Postoperative BCVA was 0.18 (range 0.00-0.40) logMAR in technique 1 and 0.22 (range 0.00-0.40) logMAR in technique 2. Visual acuity of 0.5 or better according to the Snellen chart (0.3 and below logMAR) was achieved in 16 (88%) cases operated with technique 1 and 17 (94%) cases operated with technique 2. Final postoperative visual acuity levels according to the Snellen chart were found to be 0.5 or better (0.3 and below logMAR) in 88% of the group operated with technique 1 and 94% of the group operated with technique 2.

The median spherical equivalent values of the patients preoperatively were 11.56 diopters (D) (range: 10.75-13.75 D) in the group operated with technique 1 and 12.28 D (range: 10.50-13.75 D) in the group operated with technique 2. The median spherical equivalent values of the patients postoperatively at the end of the 6th month were myopic (-1.5 D in technique 1 and -1.31 D in technique 2) in both groups.

The median endothelial cell loss in the group operated with the first technique was 10.19%, whereas it was 11.16% in the patients who were operated with the second technique at the postoperative 6th month.

There was no statistically significant difference between the two groups in terms of preoperative and postoperative 6th-month intraocular pressure (IOP) measurements ($p>0.05$) (Table 2).

Complications

The 3-piece foldable IOL was broken in 1 patient who underwent surgery with technique 1. The IOL haptics were broken in 2 patients who underwent surgery with technique 2 during the procedure. The broken IOLs were replaced with new IOLs, and the surgeries were completed successfully.

Minimal bleeding into the vitreous space was observed in 4 patients, including 2 patients from each group, during the procedure. Intravitreous hemorrhage regressed spontaneously within 2 weeks during postoperative follow-up.

Tilt of the IOL was observed in 2 patients, including 1 patient from each group, during the postoperative period. No intervention was required since there were no serious vision problems in these patients, and they were followed up. Haptic exposure occurred in 1 patient who underwent surgery with technique 2 in the first week postoperatively.

Table 1. Demographic characteristics of the patients

Characteristics	Technique 1 (%)	Technique 2 (%)	p
Gender male/female	9 (50)/9 (50)	8 (47)/9 (53)	0.74*
Age (median)	75 (41-85)	67 (21-84)	0.1**
Eye (right/left)	11 (61)/7 (39)	12(66)/6(34)	0.72*
IOL Dioptrics (median)	21.5 (17.5-24)	22 (19.5-23)	0.79**
Follow-up period (month) (mean)	6.4 (range 6-9 months)	6.2 (range 6-8 months)	

* From chi-squared tests; ** From Mann Whitney U tests.

Table 2. Preoperative and postoperative findings of the patients

	Technique 1	Technique 2	p
Median preoperative BCVA (LogMAR)	0.22	0.26	0.85*
Min/max	0.00/0.07	0.05/0.50	
Median postoperative BCVA (LogMAR)	0.18	0.22	0.74*
Min/max	0.00 / 0.40	0.00/0.40	
Median preoperative spheric equivalent (D)	11.56	13.25	0.22*
Min/max	10.75/13.75	12/14.5	
Median postoperative spheric equivalent at 6th month (D)	-1.50	-1.31	0.87*
Min/max	-3.00/1.25	-2.87/1.37	
Median Preoperative ECC (h/mm^2)	2151	2150	0.88*
Min/max	1243\2725	1285\2560	
Median Postoperative ECC at 6th month (h/mm^2)	1960	1950	0.89*
Min/max	1023\2506	1068\2300	
Median Preoperative IOP (mmHg)	15.5	16	0.48*
Min/max	11/19	11/18	
Median Postoperative IOP at 6th month (mmHg)	16	16	0.82*
Min/max	12\19	12\20	

*From Mann Whitney U tests.

Table 3. Intraoperative and postoperative complications

	Technique 1	%	Technique 2	%
Haptic breaking	1	5	2	10
Transient intravitreous hemorrhage	2	10	2	10
Tilt on the IOL	1	5	1	5
Extraction of IOL haptic	--	--	1	5
Transient hypotonia	--	--	1	5
Optic capture IOL	--	--	1	5
Cystoid macular edema	1	5	--	--

The haptic was successfully repositioned into the scleral tunnel.

Hypotonia developed in 1 case that was operated on using technique 2 during the early postoperative period. The patient was followed up, and he became normotonic by postoperative day 1. No complications due to hypotonia were detected.

Replacement of the IOL optic towards the anterior chamber (iris capture) was detected in 1 patient who underwent surgery with technique 2 during the early postoperative period. In this patient, iris capture recovered spontaneously during follow-up.

Cystoid macular edema (CME) occurred in a patient operated on with technique 1 and resolved with topical treatment. Retinal detachment and endophthalmitis were not detected in any of the patients during postoperative follow-up. The distribution of complications is presented in Table 3.

Discussion

Since 2007, surgeons have introduced sutureless intrascleral fixation techniques with various modifications for use in aphakic patients with insufficient capsule support. These techniques have their own advantages and disadvantages. The primary goal of all these techniques is to achieve anatomical and visual outcomes while eliminating suture-dependent complications associated with sutured scleral fixation methods. The current study compared the visual outcomes and complications of sutureless scleral fixation IOL surgery using two different techniques.

The most common cause for the lack of capsule support was previous cataract surgery, reported by 67% in the group operated with technique 1 and 44% in the group operated with technique 2. Previous cataract surgery was reported by Sindal et al. [15] and Gabor et al. [5] as the most common cause by 72% and 25%, respectively, whereas

Takayama et al. [16] reported the most common cause as dislocation of the IOL by 44%. The higher rates detected in the present study may be due to the referral of patients from other medical centers when the lack of capsule support was noted.

Final postoperative visual acuity levels according to the Snellen chart were found to be 0.5 or better (0.3 and below logMAR) in 88% of the group operated with technique 1 and 94% of the group operated with technique 2. Khatri et al. [17] reported BCVA as 6/12 or better in 94% of their cases. Kawaji et al. [12] reported postoperative BCVA as 0.3 logMAR or better in all patients, whereas Sindal et al. [15] reported that they detected BCVA according to the Snellen chart as 6/12 or better in 86% of their patients who underwent sutureless intrascleral IOL implantation.

The median spherical equivalent values of our patients at the end of the 6th month postoperatively were myopic (technique 1: -1.33 D and technique 2: -1.25 D) in both groups. Scharioth et al. [18] reported a postoperative median spherical equivalent of -0.98 D in their study, while Sindal et al. [15] detected a median spherical equivalent of -0.90±0.74 D in the group that underwent sutureless intrascleral IOL implantation. The visual and refractive outcomes of the present study appear to be consistent with the final visual acuity and spherical equivalent values reported in the literature.

The average endothelial cell loss was 10.19% in the group operated with technique 1 and 11.16% in the group operated with technique 2. Takayama et al. [16] reported a median corneal endothelial cell loss of 12.80%, while Kawaji et al. [12] reported a rate of 12.50% after sutureless scleral fixation IOL procedures. We believe that proper placement of the haptics and IOL into the cartridge would prevent uncontrolled movement of the IOL in the anterior chamber and contact with the peripheral corneal endothelium, thereby reducing endothelial cell loss.

Hypotonia is also one of the possible complications after sutureless scleral fixation procedures. Hypotonia did not appear in the patients operated with technique 1, and we may associate this with suturing around the scleral tunnel. One (5%) patient who underwent surgery with technique 2 developed hypotonia. The number of patients who developed hypotonia was reported as 1 (1.59%) by Scharioth et al. [18], 1 (4%) by Wilgucki et al. [19], 2 (13.3%) by Abbey et al. [20], and 1 (2.5%) by Nb et al. [21]. Totan and Karadag concluded that the reason for the lack of hypotonia in their patients would be the transconjunctival security suture [22,23]. Yamane et al. [24] reported in their study that leaks appeared when they used 22, 24, and 25G needles, but there was no leak with a 27G needle. We also believe that leaks and postoperative hypotonia may be prevented by reducing the difference between the sclerotomy and haptic diameter. Therefore, we want to stress that using an MVR blade with a diameter similar to that of the IOL haptic would be more appropriate than using a 23G MVR during the sclerotomy procedure.

In one patient using technique 1 and in two patients using technique 2, the lens haptic was broken. Holding the end of the haptic while it is being extracted from the sclerotomy and carefully performed intraocular manipulations reduce the risk of haptic breakage. Kumar et al. [25] reported haptic breakage in 1 (0.4%) patient and haptic deformation in 2 (0.9%) patients during the implementation of their technique. Since a single-piece polymethyl methacrylate (PMMA) IOL was used in the aforementioned study, haptic breakage was associated with this type of lens. In our study, we used an IOL with polyvinylidene fluoride (PVDF) haptics. The use of haptics made from this material could reduce the surgeon's stress during scleral fixation IOL surgery due to their resistance to breaking and detachment.

Furthermore, we detected tilt on the IOL, similar to other studies in the literature. As reported by Kumar et al., [25] the cause for this may be the discordance between the scleral tunnel and haptic diameter in technique 1. An unequal distance between the haptic diameter and scleral tunnel diameter, despite compliant diameters, and not creating scleral tunnels 180° opposingly may cause tilt of the IOL. Therefore, tilt of the IOL may be reduced by measuring and marking. Another cause for tilting of the IOL may be deformation of the haptics during intraocular manipulations and the placement of such deformed haptics into the scleral tunnels.

In the present study, minimal intravitreous hemorrhage occurred from the sclerotomy insertion site intraoperatively in 1 (5%) patient who underwent technique 1. Scharioth et al. [18] reported 2 (3.17%), Akimoto et al. [26] reported 2 (8%), Wilgucki et al. [19] reported 1 (4%), and Totan and Karadağ [27] reported 1 (8.3%) patient with transient intravitreous hemorrhage. The cause of intravitreous hemorrhage in the first technique may be traumatization of the ciliary body during the scleral tunnel and sclerotomy. Sclerotomies are usually opened close to the 3-9 o'clock axis in other techniques reported in the literature. In cases where the sclerotomy site is close to the 3-9 axis, the risk of hemorrhage may increase due to injury of the ciliary artery extending over the area.

In one patient who underwent surgery with technique 1, we observed CME at the 4th week postoperatively. This patient was successfully treated with a subtenon corticosteroid injection. In the literature, the most common postoperative complication was reported as CME [11,28], but the most common complication was observed as optic capture by Yamane et al. [24]. In our study, we observed IOL optic capture after dilation at 6 months postoperatively. On the next day, the pupil was miotic, and the IOL optic was located behind the iris. Wilgucki et al. [19], Akimoto et al. [22], and Abbey et al. [20] reported optic capture in 1 (4%) patient, 1 (4%) patient, and in 2 (13.3%) patients, respectively.

No endophthalmitis or retinal detachment were detected postoperatively in any of the cases during our follow-up. Our techniques have some advantages over transscleral suturing, which can cause suture-induced inflammation and endophthalmitis. Additionally, fibrin glue techniques are likely to transmit infectious agents due to the use of some forms of fibrin adhesives, which may increase the risk of endophthalmitis [29]. However, endophthalmitis has not been reported in any of the sutureless and glueless scleral fixation articles in the literature. Retinal detachment was detected by Ohta et al. [29] in 3% of their patients who were followed for 6 months postoperatively following scleral fixation IOL implantation through the Y-fixation technique. Previous studies suggest maximum care for patients requiring anterior vitrectomy to prevent retinal complications.

Limitations of the present study include its retrospective design, limited number of cases, and shorter follow-up periods. However, anatomical and visual outcomes, as well as complications, were similar for both techniques. Placement of the haptics into the scleral tunnels is feasible and safe in the hands of surgeons experienced in these two techniques. Advantages of these techniques include not requiring specific tools and having a lower risk of endophthalmitis and hypotonia compared to techniques using fibrin adhesive.

Conclusion

Anatomic and visual outcomes, as well as complications, are similar for both techniques. Acceptable short-term outcomes are obtained with the modified techniques used in the present study; however, studies with longer follow-up periods and larger patient series are needed to determine whether the techniques may be successful in the long term.

Ethics Committee Approval: The study was approved by Kartal Lütfi Kırdar Training and Research Hospital Clinical Research Ethics Committee (No: 2017/514/108/11, Date: 30/05/2017).

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Conflict of Interest: The authors declare that there is no conflict of interest.

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