ORIGINAL ARTICLE

Long-term results of trabeculectomy surgery with Mitomycin-C and releasable suture

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ABSTRACT

Purpose: o evaluate the long-term results of trabeculectomy using Mitomycin-C (MMC) and releasable suture technique in various types of glaucoma.

Materials and Methods: Patients who underwent trabeculectomy by the same surgeon between May 2003 and June 2013 at Atatürk University Faculty of Medicine Department of Ophthalmology were retrospectively analyzed. Patients who were followed up for at least 6 months in the postoperative period and had regular follow-up for 10 years were included in the study. Intraocular pressure (IOP) of 18 mm Hg or less with or without medication was considered as success. IOP was measured with an applanation tonometry.

Results: In our study, 100 eyes of 87 patients, 60 males (68.96%) and 27 females (31.04%) were included. The mean age of the patients was 61.8±14 years. The follow-up period was between 6 months and 120 months with a mean of 30.5 months. During the follow-up period, IOP was maintained below 18 mmHg in a total of 87 eyes (87%), 63 eyes (63%) without medication and 24 eyes (24%) with medication, and no progression was observed. Postoperative complications were seen in 18 eyes (18%). Shallow anterior chamber and hypotonia in 7 eyes (7%), hyphema in 4 eyes (4%), hypotonia in 3 eyes (3%), fibrin reaction in 2 eyes (2%), choroidal detachment in 2 eyes (2%). Late complication was hypopyon keratitis in 1 eye (1%) 1 year after the operation.

Conclusion: Trabeculectomy using MMC and releasable sutures is an effective surgical method in reducing IOP and slowing progression. Releasable suture removal in case of postoperative hypertonia is easier, cheaper and does not require extra devices or equipment.

Keywords: Glaucoma, Mitomycin-C, Releasable suture.

INTRODUCTION

Glaucoma is the leading cause of irreversible blindness worldwide.[1] Since the intraocular pressure (IOP) is the only controllable risk factor, it comprises primary focus of both medical and surgical glaucoma management. Despite technical and pharmacological advances, surgery remains as an important option in the management of glaucoma.[2]Trabeculectomy is a filtration surgery technique with high success rate; thus, it is widely used to treat open-angle and angle-closure glaucoma; however, scar tissue formation arising from tenon's capsule and episclera is the most significant cause for failure in trabeculectomy.[3, 4] Fibroblasts are primary cell line responsible for scar tissue formation ; thus, mitomycin-C (MMC) that inhibits fibroblast activity by 90% is widely used in high-risk glaucoma cases.[5-8] The scleral flap is closed with tight sutures in order to improve the efficacy of trabeculectomy, reduce complications, and prevent excessive filtration; laser suturolysis is recommended in these sutures if the IOP increases at postoperative period.[9, 10] Releasable sutures have been proposed as an alternative due to the challenges and need for additional equipment in laser suture lysis.[11, 12] No special equipment is required in this method which cost-effective and safe and it can be applied in any case and at any time.[13] In our study, we aimed to investigate the long-term outcomes of trabeculectomy surgeries performed using MMC and releasable suture techniques in several glaucoma types.

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MATERIALS AND METHODS

The study was approved by Ethics Committee of Atatürk University, Medicine School. All patients gave informed consent before study. We retrospectively analyzed files of patients (100 eyes) who underwent trabeculectomy performed by same surgeon between May, 2003 and June, 2013. In all patients, visual acuity was determined using Snellen charts while IOP was measured using Goldmann applanation tonometry. In initial examination, iridocorneal angle was evaluated using three-mirror technique. Routine fundus examination was performed using 90 D lens. IOP values ≤18 mmHg (with or without medication) and lack of progression was defined as success. The study included patient who had postoperative follow-up of at least 6 months and regular follow-up visits over 10 years. Mean follow-up time was 30.5 months. There were 60 men (68.96%) and 27 women (31.04%) with a mean age of 61.8±14 years.

The trabeculectomy procedure: After placing a weight on the globe for 10 minutes under local or general anesthesia, a bridle suture was placed on the superior rectus using a 5/0 silk sutures. A fornix-based conjunctival flap (approximately 3 clock hours in width) was harvested from the superior temporal or superior nasal region, parallel to the limbus, and 0.5 mm away from the limbus. Wet cauterization was performed on the episcleral vessels exposed. Two MMC (0.3 mg/mL) - soaked cellulose sponges (approximately 4x4x1 mm^3 in size) were placed under the conjunctiva away from the limbus for 2.5 minutes; followed by irrigation with 30 cc of balanced salt solution (BSS) (Figure 1). A triangular scleral flap (4x4 mm in size; half the thickness of the sclera) was harvested using a 45° blade as its base being at the limbus. A side port was placed at the superior nasal quadrant using a 23-gauge MVR blade and paracentesis was performed.

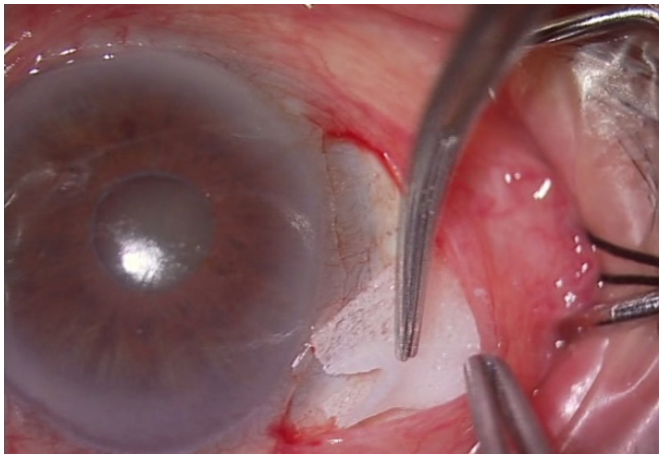


Figure 1: *Application of subconjunctival MMC.*

Two radial incisions using a 15° blade were made in the trabecular area beneath the scleral flap; then the posterior border of the trabecular block was dissected with the 15° blade and the anterior border was dissected with scissors, achieving trabecular block (1x3 mm) excision. A peripheral iridectomy was performed by grasping the iris which spontaneously prolapsed through the trabeculectomy opening with toothed forceps. The scleral flap was secured to the scleral bed at its apex with a 10/0 nylon suture (Figure 2). One edge of the flap was loosely sutured with a permanent 10/0 nylon suture, while the other edge was secured with a releasable suture formed by wrapping a 10/0 nylon suture four times around forceps, creating a loop suture. The other end of the releasable suture was passed lamellarly through the cornea, first 2 mm towards the center and then 2 mm parallel to the limbus, without exposing the suture end (Figure 3). Fluid was injected into the anterior chamber through paracentesis to check fluid passage through the trabeculectomy opening. Sutures were

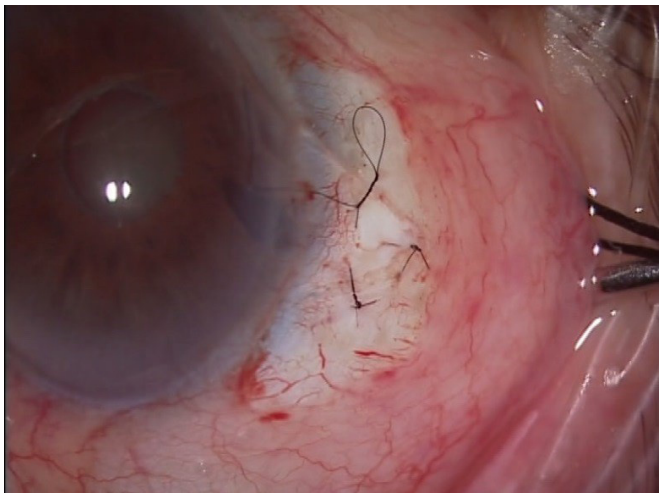


Figure 2: *Scleral flap closure with releasable suture.*

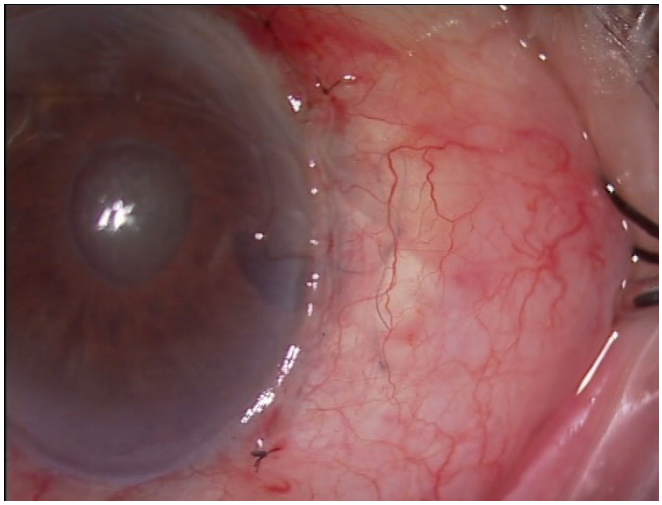


Figure 3: *Conjunctiva closure.*

added or removed as needed. The conjunctiva was sutured continuously along the cornea, parallel to the limbus, with 10/0 nylon, ensuring it was tight enough to prevent leakage. Subconjunctival antibiotics and steroids were administered from the lower half. The eye was closed by administering topical antibiotics, steroids, and 1% cyclopentolate. On the first postoperative day, all anti-glaucoma medications were discontinued. Patients were prescribed topical antibiotics and steroids for four weeks; the steroids were tapered by postoperative week 4. The 10/0 nylon conjunctival sutures were removed no earlier than four weeks postoperatively.

The follow-up visits were scheduled on postoperative day 1, at postoperative week 1, 2 and 3, at postoperative months 1, 3 and 6, and at year 1; annually thereafter. If the intraocular pressure (IOP) exceeded 18 mmHg, the releasable suture was removed. At each visit, visual acuity was assessed in patients using the Snellen chart, and biomicroscopic examinations were performed. In addition, IOP measurements by Goldmann applanation tonometry, and fundus examinations using a 90 D lens were also performed.

"P" value <0.05 was considered as statistically significant.

FINDINGS

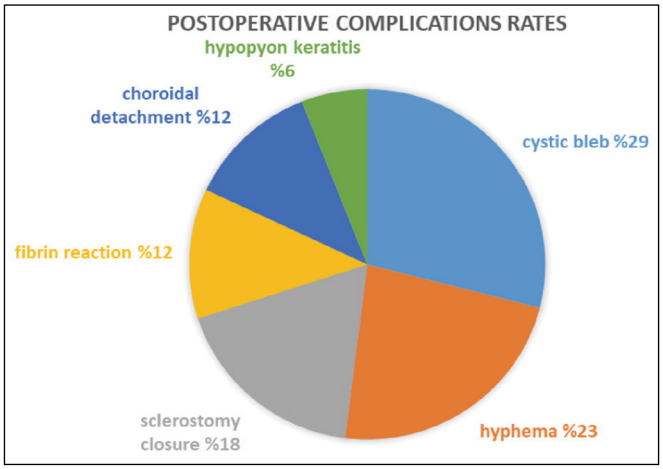
In the study, we reviewed 100 eyes from 87 patients including 60 men (68.96%) and 27 women (31.04%). Of the eyes examined, 38 were right eyes (38%) while 36 were left eyes (36%); both eyes were examined in 13 cases (13%). The mean age was of 61.8 ± 14 years ranging from 17 to 87 years. The mean follow-up duration was 30.5 months ranging from 6 to 120 months. The number of eyes followed up was 100 (100%) at month 6 , 95 (95%) at year 1, 65 (65%) at year 2, 45 (45%) at year 3 , 25 (25%) at year 4, 20 (20%) at year 5, 15 (15%) at year 6, 12 (12%) at year 7 , 10 (10%) at year 8, 3 (3%) at year 9, and 1 (1%) at year 10.

In our study, cases with a follow-up period of less than 6 months were excluded. Re-trabeculectomy was performed in only 3 patients. Thus, no statistical assessment was performed for factors that could influence the outcomes due to limited number of cases underwent re-trabeculectomy.. The cases were classified into3 groups according to the etiology: 72 eyes (72%) with primary open-angle glaucoma, 25 eyes (25%) with pseudo-exfoliative glaucoma, and 3 eyes (3%) with angle-closure glaucoma. The cases which had(IOP) below 18 mmHg, (with or without medication), and showed no progression, were considered "successful," while cases where IOP was ≥18 mmHg despite medication were considered "failure." The time to medication and time to treatment failure were recorded.

Of the 100 eyes (100%) analyzed, 63 (63%) maintained IOP below 18 mmHg without the need for medication, while 37 eyes (37%) required medication and mean time to medication was 15 months. Of the eyes required medication, IOP control was re-achieved in 24 (24%) while 13 (13%) were considered as failure despite medication. Treatment failure was noted in 2 eyes (2%) where IOP control was initially achieved with medication on average 36 months after starting the medication. Throughout the follow-up period, 87 eyes (87%) maintained IOP below 18 mmHg without progression, including 63 eyes (63%) that achieved IOP control without medication and 24 eyes (24%) with medication.

Intraoperative complications was observed in 2 eyes (2%), namely vitreous loss in both eyes. The first patient had history congenital cataract surgery with posterior capsulotomy 18 years ago while other patient had open-angle glaucoma. Anterior vitrectomy was intraoperatively performed for vitreous loss in these patients. No conjunctival tearing, scleral flap detachment, lens damage, or expulsive hemorrhage developed during trabeculectomy. In addition, no intraoperative complication was noted in the 3 eyes which underwent re-trabeculectomy.

At postoperative period, complications were observed in 18 eyes (18%), including transient shallow anterior chamber, hypotonia, and hyphema developed early postoperative period. The most common complication was hypotonia, observed in 3 eyes (3%). Hypotonia was defined as IOP below 5 mmHg. Since the anterior chamber was not shallow in these cases, no surgical intervention was required, and hypotonia resolved on postoperative week 1



Graphic 1: *Postoperative complication rates.*

at follow-up. A shallow anterior chamber and hypotonia were noted in 7 eyes (7%). In these cases, hypotonia and shallow anterior chamber were resolved with tight closure and medical treatment on postoperative week 1 at follow-up, no surgical intervention was required.

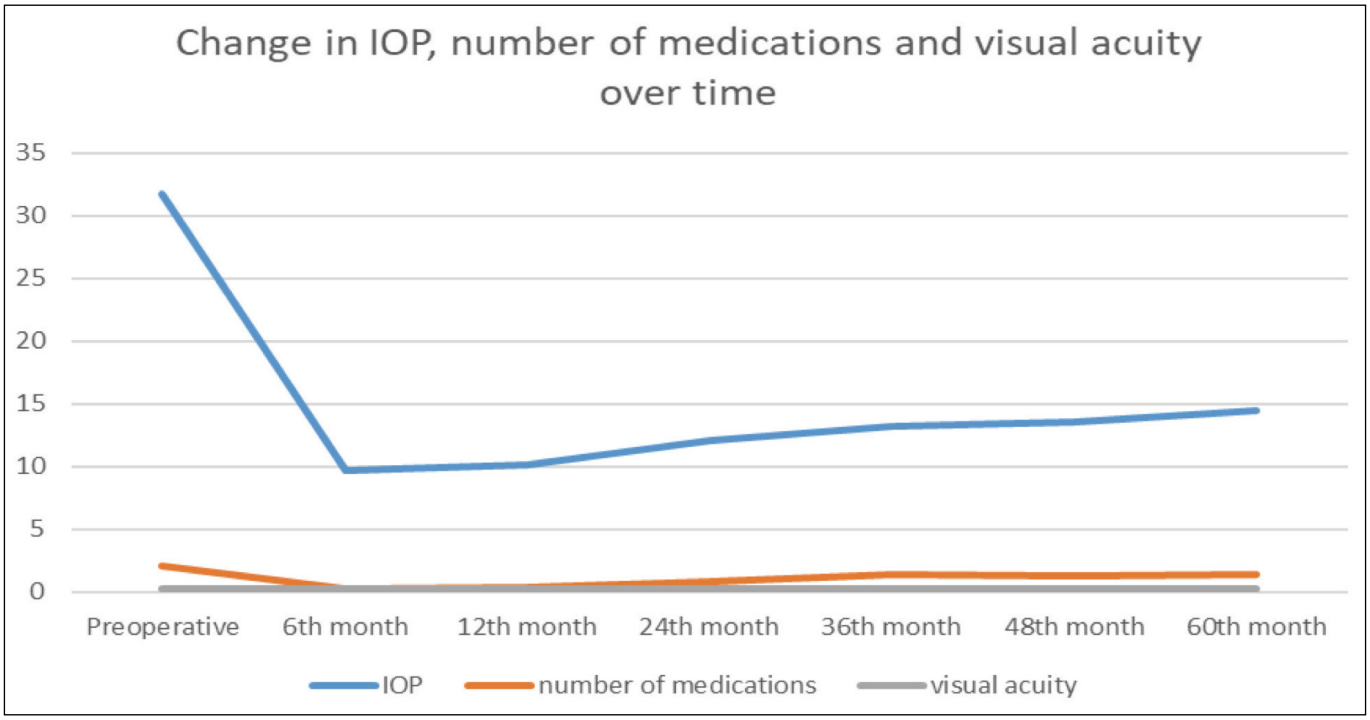
Early postoperative complications included hyphema in 4 eyes (4%), fibrin reaction in 2 eyes (2%), and choroidal detachment in 2 eyes (2%). No patient experienced a positive Seidel test, cataract development within a month, malignant glaucoma, retinal detachment, hypotonic maculopathy, blebitis, or endophthalmitis after trabeculectomy. In the late postoperative period, hypopyon keratitis was observed in 1 eye (1%) one year after surgery.

Cystic blebs were observed in 5 eyes (5%); however, no intervention was needed since there was no leakage. Sclerostomy closure occurred in 3 eyes (3%), requiring bleb revision. An encapsulated bleb developed in 1 eye (1%), which was treated with needling. Of the 3 eyes that underwent re-trabeculectomy, hypotonia occurred in 1 eye (33.3%), but no surgical intervention was performed.

Interventions including digital massage, releasable suture removal, bleb needling, and surgical bleb revision were attempted in 134 eyes with bleb failure. Digital massage was performed in 10 eyes (71.42%) while bleb needling in 1 eye (7.15%), and bleb revision in 3 eyes (21.42%). At the final follow-up, releasable sutures were in place in 55 eyes (55%). No releasable suture removal was performed in the early postoperative period. 45 eyes without sutures were removed due to IOP exceeding 18 mmHg in 12and due to irritation or suture loosening in 33. The mean time to suture removal was 1 month.

Changes in IOP, optic nerve head cup-to-disc ratio, visual acuity, and the number of medications used were evaluated to assess the course of glaucomatous damage following trabeculectomy. The mean ± SD IOP values over time were: 31.7 ± 8.76 mmHg at baseline and 9.78 ± 1.89 mmHg at month 6 after surgery, indicating a statistically significant reduction ($P<0.05$). The IOP increased from 9.78 ± 1.89 mmHg at month 6 to 10.1 ± 1.45 mmHg at month 12, but the difference did not reach statistical significance ($P>0.05$). It was found that IOP increased from 10.1 ± 1.45 mmHg in the first year to 12.1 ± 1.97 mmHg in the second year , indicating statistically significant increase ($P<0.05$). In the subsequent years (years 3, 4 an 5), the IOP elevated progressively; however, the increase did not reach statistical significance ($P>0.05$).

The medications used during short-term fluctuations in IOP were not considered when analyzing the medications used before and after trabeculectomy. Only medications used for more than 6 months that provided stable IOP control were included. The average number of medications used preoperatively was 2.1, which decreased to 0.4 in the postoperative year 1($P<0.05$); then increased to 0.8 in the year 2, 1.4 in the year 3, 1.3 in the year 4, and 1.4



Graphic 2: *Changes in IOP, number of medications and visual acuity over time.*

in the year 5, however, the increase was not statistically significant (P>0.05).

The optic nerve head cup-to-disc ratio was 0.77 at baseline and remained stable at postoperative years1, 2, 3, 4, and 5, without significant change (P>0.05). No significant changes were detected in the visual field at postoperative period (P>0.05).

The mean visual acuity, as measured by the Snellen chart, was 0.27 at baseline and 0.24 at year 1, 0.25 at year 2, 0.28 at year 3, 0.30 at year4, and 0.30 at year5 after surgery. There was no statistically significant difference in visual acuity between baseline and postoperative years 1-to-5 (P>0.05).

DISCUSSION

Glaucoma is an insidious disease often progressing without any clinical symptoms, which may result in blindness if left untreated, although lowering IOP, improving ocular blood flow, and directly protecting neurons could be effective in preventing glaucoma damage in theory, the only approach currently proven to protect visual function is reducing IOP to a target level that varies individually.[14, 15] There are three treatment options for glaucoma: medical, laser, and surgical. The surgical methods are considered when medical and laser treatments fail or are insufficient to control glaucoma; trabeculectomy is the most commonly performed surgical and currently considered as gold standard.[16]

In filtration surgeries, the most common cause for failure is secondary fibrosis and the closure of the fistula due scar tissue formation. MMC is the most frequently used anti-fibrotic agent in order to inhibit fibroblast activity. However, MMC increases the risk for complications associated with excessive filtration at the postoperative period.[17, 18] To mitigate this risk, it is widely used technique to close the scleral flap tightly closed standard sutures.[19] It is preferred to cut the tight sutures using an argon laser or a 27-gauge needle in case of hypertonia after surgery.[17] However, this approach may require special equipment or could potentially damage the bleb. The releasable suture technique facilitates suture removal in hypertonia by burying one end in the cornea without using permanent knot, resulting in accessible the tight suture in the scleral flap, with , thereby reducing conjunctival damage.[21]

Among similar studies involving the use of MMC and releasable sutures, Beckers et al. reported a success rate of 80% in achieving IOP below 15 mmHg at the end of the year1, which decreased to 60% by the end of the year 6.[22] In the study by Unlu et al. it was reported that the success rate was 88.8% trabeculectomy.[23] It is difficult to directly compare our results with literature due to the variability in outcomes reported. However, the success rate in our study was consistent with studies using same success criterion defined as maintaining IOP below 18 mmHg. This may be due to the facts that the majority of our patients was ≥ 40 years of age (89.6%), that the groups with poor trabeculectomy outcomes (e.g., those with neovascular, uveitic, and surgically induced secondary glaucoma) were excluded, the use of MMC during trabeculectomy, and early intervention in case of bleb failure.

In the literature, a wide range of complications have been reported after trabeculectomy with MMC, particularly in the early postoperative period including hypotonia, shallow anterior chamber, hyphema, anterior synechia, posterior synechia, and in the late postoperative period such as hypotonic maculopathy, endophthalmitis, blebitis, cataracts, macular edema, central retinal vein occlusion, suprachoroidal hemorrhage, and effusion.

In our study, the most common complications in the postoperative period were hypotonia and shallow anterior chamber. In a study on trabeculectomy using MMC with both permanent and releasable sutures, Unlu et al. reported that the releasable suture group experienced more hypotonia and shallow anterior chamber, although this difference did not reach statistical significant.[23] Authors concluded that the releasable suture is as effective as a standard suture. In another study by Dubey et al., no intraoperative complications were reported while postoperative complications were noted in 7% of cases, 4% of which was shallow anterior chamber.[24] Cohen and Burchfield reported cases with endophthalmitis following trabeculectomy with releasable sutures. Authors emphasized that releasable sutures could be a potential risk for bacterial entry, suggesting that burying the suture tip in the cornea and using topical antibiotic therapy mitigated such risk.[25, 26] Due to variability of results in the literature, it is challenging to directly compare our results with others. However, it seems that surgery using releasable sutures and MMC has a similar complication rate to surgery using standard sutures and MMC. In our study, the absence of postoperative endophthalmitis may be due to burying the tip of the releasable suture in the cornea and the use of postoperative topical antibiotics.

We evaluated changes in IOP, optic nerve head cupping, visual acuity, and the number of medications used to

assess the progression of glaucomatous damage following trabeculectomy, In their study, Kurnaz et al. assigned patients into two groups—one with MMC and releasable sutures (Group 1) and the other with MMC and permanent sutures (Group 2. In the study, the mean follow-up was 20 months and authors reported that IOP was 34.8 mmHg in Group 1 and 35.5 mmHg in Group 2 at baseline while 12.4 mmHg and 12.6 mmHg at month1, 13.2 mmHg and at month 6, and 17.4 mmHg and 20.3 mmHg at year 1 in Group 1, and in Group 2, respectively, with statistically significant changes in IOP between preoperative and postoperative periods in both groups.[27] Consistent with previous studies, a statistically significant reduction in postoperative IOP was observed in our study.

In the study on 29 patients with a mean follow-up of 20 months, Kurnaz et al. reported that the mean number of medications decreased from a 2.75 ± 0.98 at baseline to 1.14 ± 1.42 at postoperative period, indicating a significant reduction.[27]

There are inconsistent results regarding optic nerve head findings in the literature. Katz et al. reported a 21% improvement in optic nerve head cupping using stereoscopic photographs after trabeculectomy.[28] In the glaucoma, central vision and visual acuity are affected in the advanced stages of the disease; following trabeculectomy, the visual acuity may decline due to cataract formation or macular degeneration. There was no significant changes in visual acuity and the cup-to-disc ratio between preoperative and postoperative periods in our study and literature. However, there was significant changes in IOP and the number of medications used, showing a reduction in the early postoperative period and remaining significant over time.

Given these findings, it can be suggested that trabeculectomy using MMC and releasable sutures is an effective surgical method for lowering IOP and slowing the progression of glaucoma. The use of releasable sutures makes it easier and more cost-effective to address postoperative hypertension, while MMC reduces fibrosis and improves surgical success.

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