

Mitomycin C Primary Trabeculectomy with Releasable Sutures in Primary Glaucoma

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Purpose: To evaluate the effects of mitomycin C and a releasable suture technique on outcomes of primary trabeculectomy in primary glaucoma patients.

Methods: A prospective analysis of patients who underwent primary trabeculectomy with a mitomycin C concentration of 0.2 mg/mL for 2 minutes. For closing the scleral flap, releasable sutures were used in 18 patients (17 eyes), Group 1, or permanent sutures in 18 patients (20 eyes), Group 2. Clinical outcome factors including postoperative intraocular pressure (IOP), visual acuity, and incidence of complications were determined.

Results: The mean follow-up periods were 8.1 ± 1.3 months in Group 1 and 8.3 ± 1.3 months in Group 2. The postoperative reduction in IOP was highly significant ($P < .0001$) at all time intervals in both groups. In all measurement of IOP before the second week, mean IOP in Group 2 was found significantly lower than the mean IOP in Group 1 ($P = .01$). No statistically significant differences were found between the groups at later mean IOP measurements. At the last visit, the complete success rate was 88.8% in Group 1 and 85.0% in Group 2. No serious complications such as hypotonous maculopathy were observed in any patient.

Conclusion: Primary trabeculectomy with mitomycin C in eyes with primary glaucoma showed effective IOP pressure reduction. There were no cases of serious complications. In the early postoperative period IOP was controlled better in the releasable suture group. **Jpn J Ophthalmol 2000;44:524–529** © 2000 Japanese Ophthalmological Society

Key Words: Mitomycin C, primary trabeculectomy, releasable suture, uncomplicated glaucoma.

Introduction

After glaucoma filtration surgery, modulation of wound healing with the use of mitomycin C increases the success rate of the procedure in patients with high risk of flap failure.^{1,2} The use of this agent in primary trabeculectomy may be controversial because of the increase in the risk of postoperative complications; the risk-benefit ratio of this treatment is not well documented.^{1,3,4}

After trabeculectomy, overfiltration can lead to ocular hypotony, choroidal effusions, flat anterior

chamber, hypotensive maculopathy, and suprachoroidal hemorrhage. On the other hand, underfiltration can cause further optic nerve damage and progression of visual field defects. For this reason, a careful balance of filtration is essential. To reduce the problems associated with overfiltration, tight suture closure of the scleral flap with postoperative laser lysis of the sutures was advocated.^{5–7} However, this technique has some disadvantages; it requires access to a laser and the view may be obscured by hemorrhage or swollen Tenon's capsule. Tenonectomy for better visualization can lead to a thin-walled conjunctival flap. In addition, complications of laser suture lysis, such as conjunctival burns, flat anterior chamber, conjunctival flap leak, hypotonous maculopathy, malignant glaucoma, iris incarceration, and hyphema, were reported.^{5,7–11} An alternative to this technique is the use of releasable sutures.^{12–14}

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In this randomized, prospective study, the effects of mitomycin C and releasable suture in primary trabeculectomy patients with uncomplicated glaucoma are evaluated.

Materials and Methods

We prospectively followed up 35 consecutive patients (38 eyes) with advanced uncomplicated glaucoma (primary open-angle, low tension, chronic angle-closure or pigmentary glaucoma) who underwent primary trabeculectomy with mitomycin C. All patients were receiving medication for treatment of glaucoma and had demonstrated a progressive and pressure-related ocular disease process with variable combinations of cupping of the optic disc, visual field compromise, and increased intraocular pressure (IOP). Patients who had previous incisional ocular surgery or who were lost to follow-up were not included in this study (2 eyes were included that had been treated by argon laser trabeculoplasty).

Before surgery, the patients were randomly assigned to a study group. All patients went through a complete preoperative ophthalmic examination, including corrected visual acuity measurement, tonometry with an applanation tonometer, biomicroscopy, direct and indirect ophthalmoscopy, gonioscopy, and automated perimetry. Written informed consent was obtained from each patient. A standard trabeculectomy procedure was performed for all patients. A limbal-based conjunctival flap was prepared 8.0-mm from the corneoscleral limbus. Hemostasis was achieved with monopolar or bipolar cautery. A triangular lamellar scleral flap, measuring 4 × 4 mm, was then dissected at a depth of one half the scleral thickness, until the entire corneoscleral limbus was exposed. A small (approximately 4.0 × 3.0 × 1.0 mm³) rectangular fragment cut from a commercially available triangular microsurgical sponge was saturated with mitomycin C (0.2 mg/mL) and placed in contact with the exposed scleral bed and overlying Tenon's capsule/conjunctival flap for 2 minutes. Subsequently, the sponge was removed and the area was copiously irrigated with 20 mL of balanced salt solution. Trabeculectomy was performed by removing a 1 × 3 mm block and a peripheral iridectomy was performed. The scleral flap was closed with 10.0 nylon sutures; in Group 1 (18 eyes of 17 patients) one permanent suture at the apex and two releasable sutures, one on each side of the triangle as described by Cohen et al,¹² and in Group 2 (20 eyes of 18 patients) three permanent sutures were used. In Group 1 the scleral flap was closed watertight and in Group

2 suture tension was adjusted so that the anterior chamber remained formed and a slow leak of aqueous humor was detected at the margins of the scleral flap. Tenon's capsule and the conjunctival layer were then closed in a single-layer closure with running 8.0 Vycril or 10.0 nylon suture. Following surgery, dexamethasone sodium phosphate 4 mg and gentamicin 20 mg were injected subconjunctivally.

Postoperative medications included 1% prednisolone acetate (every hour while awake), 1% atropine sulfate (two times daily) and 0.3% tobramycin (four times daily) eyedrops. Visual acuity and IOP measurements were made 1 day, 3 days, 1 week, 2 weeks, 1 month, 3 months, 6 months, and at the last available follow up. Visual acuity change was considered significant when a change of two or more Snellen lines or one low vision category (that is, hand motion to light perception) was observed compared to preoperative values. In the first 2 weeks, a releasable suture was removed when the anterior chamber was deep and IOP >16.0 mm Hg, if digital massage was ineffective at lowering IOP. Before the data collection a complete successful outcome was defined as an intraocular pressure <21.0 mm Hg without medication or a pressure reduction of 20% if the preoperative pressure was <21 mm Hg in the last examination. A qualified success was an IOP of <21 mm Hg with medication. Failure was defined as IOP ≥21 mm Hg with medication or when further glaucoma surgery was indicated. Shallow anterior chambers were graded according to the description of Costa et al 15 (Grade 1 = peripheral iridocorneal touch, Grade 2 = peripheral + central iridocorneal touch, Grade 3 = totally flat, including lens-corneal touch). For statistical analysis, Student *t*-test, chi-square, and Fisher's exact tests were performed.

Results

Preoperative data of the patients with at least 6 months of follow-up are displayed in Table 1. All patients were White. The two groups were similar with respect to most demographic and disease parameters. The mean (SD) preoperative IOP was 31.2 (10.3) mm Hg in Group 1 and 31.7 (8.2) mm Hg in Group 2; the difference between groups was not statistically significant ($P = .87$).

The mean follow-up periods were 8.1 ± 1.3 months in Group 1 and 8.3 ± 1.3 months in Group 2 ($P = .80$). Table 2 shows the mean IOPs at all time intervals by group. Postoperative reductions in IOP were highly significant ($P < .0001$) at all time intervals in both groups. In all measurement of IOP be-

Table 1. Preoperative Data

Variables	Group 1	Group 2
Age (yrs)		
Mean (SD)	61.4 (12.1)	60.9 (8.8)
Range	43-80	41-75
Sex (Female/Male)	9/8	9/9
IOP (mm Hg)		
Mean (SD)	31.2 (10.3)	31.7 (8.2)
Range	16-48	18-43
Diagnosis	n (%)	n (%)
POAG	11 (61.1)	13 (65.0)
CACG	5 (27.7)	5 (25.0)
Low tension	2 (11.1)	1 (5.0)
Pigmentary	-	1 (5.0)

SD: standard deviation; IOP, intraocular pressure; POAG: primary open angle glaucoma; CACG: chronic angle closure glaucoma.

fore the second week, the mean IOP in Group 2 was found to be significantly lower than the mean IOP in Group 1 ($P = .01$). No statistically significant differences were found between groups at later mean IOP measurement.

Table 3 shows the success rates of IOP control in each group. After a follow-up of approximately 8 months, 2 eyes in Group 1 and 3 eyes in Group 2 required treatment with a beta-blocker. There was no statistically significant difference in success rate between the two groups ($P > .05$).

Three patients (16.6%) in Group 1 and 8 patients (40.0%) in Group 2 had transient ocular hypotony (defined as IOP of ≤ 5 mm Hg, lasting < 1 month) not associated with leakage of aqueous through a conjunctival defect except for one who had one releasable suture removal 3 days postoperatively. This difference between groups in the incidence of hypotony was not statistically significant ($P > .05$). The hypotony resolved spontaneously in these patients.

Postoperative complications are shown in Table 4. One eye (5.0%) in Group 2 with choroidal detach-

Table 2. Intraocular Pressure After Surgery (mm Hg)

Follow-up Time	Group 1	Group 2	<i>P</i>
	Mean (SD)	Mean (SD)	
1 day	9.55 (3.94)	6.66 (2.70)	.01
3 days	9.72 (3.78)	7.20 (2.14)	.01
1 week	10.16 (2.99)	7.90 (2.10)	.01
2 weeks	10.61 (2.45)	10.15 (1.34)	.48
1 month	11.33 (2.19)	11.55 (1.43)	.72
3 months	12.44 (2.74)	12.15 (2.45)	.73
6 months	13.11 (2.63)	13.25 (2.46)	.86
Last visit	13.27 (2.32)	13.45 (1.87)	.80

Table 3. Success Rates of Intraocular Pressure Control

Success	Group 1	Group 2
	No. of Eyes (%)	No. of Eyes (%)
Complete	16 (88.8)	17 (85.0)
Qualified	2 (11.1)	3 (15.0)
Failure	-	-

ment showed concomitant shallow anterior chamber, which resolved spontaneously after a duration of 1 month. Three eyes (16.6%) in Group 1 and 8 eyes (40.0%) in Group 2 showed shallow anterior chamber; this difference was not statistically significant ($P > .05$). Surgical reformation of the anterior chamber was not required in any case as all resolved with conservative measures. Cataract formation was observed in 2 eyes in each group. One eye in Group 2 (5.0%) developed a noticeable hyphema and the blood cleared within 24 hours. One eye had a small conjunctival wound leak after a suture was removed 3 days postoperatively. The leak healed spontaneously within 3 days.

In 16 eyes (88.8%) in Group 1 and 17 eyes (85.0%) in Group 2, visual acuity improved or did not change from preoperative values ($P = .55$). Two eyes in each group had visual reduction from cataract formation.

In the first 2 weeks postoperatively, one releasable suture was removed in 6 eyes (33.3%) in which the IOPs were > 16.0 mm Hg (one suture at 3 days, five sutures at 1 week) despite digital massage. The mean change in IOP from before to 1 hour after suture release was 8.20 ± 2.74 mm Hg in these eyes. Remaining releasable sutures were removed at 2nd (16 sutures) and 4th week (14 sutures, 1 suture broke) postoperatively. The mean change in IOP was $5.12 \pm$

Table 4. Postoperative Complications

Complication	Group 1	Group 2
	No. of Eyes (%)	No. of Eyes (%)
Choroidal detachment	-	1 (5.0)
Shallow anterior chamber		
Grade 1	2 (11.1)	5 (25.0)
Grade 2	1 (5.5)	2 (10.0)
Grade 3	-	1 (5.0)
Total	3 (16.6)	8 (40.0)
HypHEMA	-	1 (5.0)
Cataract	2 (11.1)	2 (10.0)
Conjunctival wound leak	1 (5.5)	-
Suture breakage	1 (5.5)	-

1.65 mm Hg when sutures were released at the 2nd week. Suture removal at 4th week had no noticeable effect on bleb size or IOP (change in IOP was 2.21 ± 1.17 mm Hg).

Discussion

The use of mitomycin C in primary trabeculectomy may be controversial because of the increase in the number of postoperative complications.^{1,3,4} The first study that presents the results of intraoperative mitomycin C in a large series of patients undergoing intraocular surgery for the first time was reported by Costa et al.¹⁵ In this study, the success rate of IOP control in patients who underwent primary trabeculectomy with mitomycin C (0.4 mg/mL, 1.5–2.5 minutes) and closure of scleral flap with 2–4 permanent sutures was high (97.4%) after a mean follow-up of 6.7 months. However, the authors suggested that the indications of mitomycin C should be limited to eyes in which surgical prognosis is poor because of probable unacceptable risks of vision-threatening complications related to excessive filtration. Nuijts et al¹ reported no serious complication, such as persistent hypotonous maculopathy, in patients who had primary trabeculectomy with adjunctive mitomycin C (0.2 mg/mL, 5 minutes) and laser suture lysis postoperatively.

To reduce the complications that related to excessive filtration, the closure of the scleral flap with 5–8 tight sutures with postoperative laser suture lysis was advocated.^{5–7} However, this technique has some limitations. Not all ophthalmologists have ready access to an argon laser; the view may be obscured by hemorrhage or edema, and, in addition, complica-

tions may be observed in up to 30% of eyes undergoing this procedure.¹¹ Closing the scleral flap with releasable sutures is an alternative method to this technique.^{12–14}

To our knowledge, this is the first study that compares the effect of using releasable sutures for scleral flap closure on the outcome of primary trabeculectomy with mitomycin C in White patients who had uncomplicated glaucoma with the effect of using permanent sutures for the same purpose. The success rate and postoperative intraocular pressure of some groups consisting solely of uncomplicated cases who underwent primary trabeculectomy with mitomycin C are summarized in Table 5. The success rates varied from 64% to 100% in this series. Application time and concentration of mitomycin C can effect success and complication rates.^{16–18} As shown in the table, the shortest application time and one of the lowest concentrations of mitomycin C (0.2 mg/mL, 2 minutes) was used in our study. Although the mean IOP at the last visit seem to be higher than in other reports, the success rate was 100% in both our groups. Use of releasable sutures did not affect the ultimate outcome of the filtering operation in terms of rate of success. Postoperative reductions in IOP were highly significant at all time intervals in both groups. In the early postoperative period (before 2nd week), the mean IOPs were significantly different between groups and this finding indicates that the permanent scleral-flap sutures were not tied as tightly as the releasable sutures. A similar result was reported by Kolker et al.¹⁹

Despite the higher frequency of prominent transient ocular hypotony in Group 2, the difference between groups was not statistically significant. Tight

Table 5. Summary of Primary Trabeculectomies with Mitomycin C

Author	No. of Eyes	MMC (Concentration/min)*	Follow-up (mo)	IOP† (mm Hg) mean ± SD	Complete Success‡ (%)	Total Success§ (%)
Costa et al ¹⁵	39	0.4/1.5–2.5	6	9.7 ± 3.9	95	97
Kitazawa et al ¹⁷	11	0.2/5	11	8.8 ± 3.0	82	100
	11	0.02/5	11	10.0 ± 1.8	46	64
Kupin et al ¹⁶	33¶	0.5/3	6	10.3 ± 7.1	88	91
Nuijts et al ¹	25	0.2/5	12	12.5 ± 3.9	92	100
Unlü						
RS	18	0.2/2	8	13.2 ± 2.3	89	100
PS	18	0.2/2	8	13.4 ± 1.8	85	100

MMC: mitomycin C; IOP: intraocular pressure; RS: releasable suture; PS: permanent suture.

*Concentration (mg/mL)/minute.

† Intraocular pressure at last follow-up examination.

‡ Complete success = IOP < 21 mm Hg without medication.

§ Total success = IOP < 21 mm Hg with/without medication.

¶ 73% of cases from Black race.

wound closure is obviously one measure to avoid hypotony. However, this alone does not appear to insure protection from the complication.²⁰ It is known that the toxic effects of mitomycin C on the ciliary epithelium may play a role in the development of ocular hypotony.²¹ This toxic effect may explain the reason of why there was no statistically significant difference between Group 1 in which the tighter sutures were used and Group 2. No hypotonous maculopathy or persistent ocular hypotony in any patient was noted. Shields et al²⁰ confirmed that hypotony after trabeculectomy with mitomycin C occurred in patients who were at low surgical risk and in those who received a longer exposure to mitomycin. Chen et al²² demonstrated in a series of mitomycin C trabeculectomies that patients who received a mitomycin C concentration of 0.4 mg/mL for 5 minutes were more likely to develop complications of long-term hypotony, whereas none of the patients who received mitomycin C at a concentration lower than 0.4 mg/mL for the same application time developed hypotony. Kitazawa et al¹⁷ demonstrated a high success rate with only transient hypotonous maculopathy after a 5-minute application of a 0.2 mg/mL concentration of mitomycin C in trabeculectomy in primary glaucoma patients. Zacharia et al¹⁸ reported a statistically significant association with longer application time of mitomycin C in patients who underwent trabeculectomy with 0.4 mg/mL concentration of mitomycin C and a trend toward increased incidence of hypotony in primary filtration. Palmer²³ reported no ocular hypotony in patients (all with either previous filtering procedures or at high risk for procedure failure) who received a mitomycin C concentration of 0.2 mg/mL for 5 minutes. Costa et al¹⁵ reported ocular hypotony in 17.9% of the patients who underwent primary trabeculectomy with a mitomycin C concentration of 0.4 mg/mL for 1.5–2.5 minutes. A significantly higher incidence of prolonged hypotony was seen in the mitomycin C group (primary trabeculectomies with 0.5 mg/mL mitomycin C for a 3-minute exposure in patients with primary open-angle glaucoma) compared with the control group (primary trabeculectomies without an adjunctive antifibrotic agent in patients with primary open-angle glaucoma) in a study of Kupin et al.¹⁶ Nuijts et al¹ reported no cases of persistent hypotonous maculopathy after application of mitomycin C (0.2 mg/mL for a 5-minute exposure) in patients who underwent primary trabeculectomy.

There were no statistically significant differences in postoperative complications between the releasable and permanent suture groups in our study.

Complications associated with the use of releasable sutures were few and relatively minor. Corneal abrasions, corneal infection, or endophthalmitis that had been reported previously^{12,13,24} were not encountered in our releasable suture cases. The cause of the decreased visual acuity in four cases was cataract formation.

Raina et al²⁵ observed minimal or no change in IOP when sutures were released between days 11 and 15 in the postoperative period in eyes that had primary trabeculectomy without antifibrotics. Tezel et al²⁶ concluded that intraoperative pharmacologic modulation of wound healing in trabeculectomy extends the period for which releasable suture removal is clinically effective. In our study, we observed an effective IOP reduction in eyes that had suture release before the 4th week in the postoperative period. We think that factors such as type of glaucoma, race, previous ocular surgery, type of surgery, concentration and application time of antifibrotics not only influence the surgical outcome, they may also be effective in determining the extension of this period. Generally, to reduce the development of postoperative hypotony it was advised to postpone suture removal or suture lysis until 2–3 weeks after surgery.²⁷ In a study of Geijssen and Greve²⁸ they reported frequent (38%) occurrence of hypotony in the first 3 months after surgery when suture lysis after trabeculectomies with mitomycin was applied in a similar way as in trabeculectomies without mitomycin. In another study,⁸ they concluded that delayed and controlled suture lysis can reduce severe hypotony with reduced visual acuity. Morinelli et al²⁷ reported that a shorter interval between surgery and laser suture lysis (particularly within the first 2–3 weeks postoperatively) correlated with a higher incidence of subsequent hypotony in patients who had trabeculectomy with mitomycin C. Kupin et al¹⁶ advised temporary resumption of medical therapy and institution of home digital massage before the release or laser lysis of scleral flap sutures to decrease the incidence of hypotony. In our study, 6 eyes in the releasable suture group had one suture removal within the first 2 postoperative weeks because of increased pressure (>16.0 mm Hg) despite digital massage. Of these patients, 1 had transient ocular hypotony.

In conclusion, success rates of primary trabeculectomy with a mitomycin C concentration of 0.2 mg/mL for 2 minutes in patients with uncomplicated glaucoma were high in both groups in our study. No serious complication was seen with this concentration and application time of mitomycin C in both groups, and the complications associated with the use of mi-

tomycin C and releasable sutures were few and relatively minor. Because of the better control of IOP in the early postoperative period, we believe that the releasable suture technique should be preferred to permanent sutures for closing scleral flaps in primary trabeculectomy with mitomycin C in patients with uncomplicated glaucoma.

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