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# **OPHTHALMOLOGY**

# Fornix vs Limbus Based Flap in Phacotrabeculetomy with Mitomycin C: Prospective Study

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**Aim.** To compare the efficacy and safety of fornix-based and limbus-based conjunctival flaps of phacotrabeculectomy with mitomycin C in patients with primary open angle glaucoma and cataract.

**Methods.** The study included 16 patients (6 men and 10 women) with primary open angle glaucoma and bilateral cataract. In each patient, phacotrabeculectomy with mitomycin C was performed on both eyes: the eye first operated received a fornix-based conjunctival flap, whereas the fellow eye was assigned to the limbus-based group. We compared preoperative and postoperative visual acuity, intraocular pressure, number of antiglaucoma medications, and postoperative complications between flab-based and limbus-based groups.

**Results.** There was no difference in the decrease in the mean intraocular pressure between the fornix-based and limbus-based groups after phacotrabeculectomy: from  $22.1\pm4.4$  mm Hg to  $16.2\pm3.4$  mm Hg in the fornix-based group, and from  $22.4\pm4.5$  mm Hg to  $15.9\pm3.2$  mm Hg in the limbus-based group. The two groups also did not differ in the number of medications received either before or after the surgery. Early bleb leak was observed only in the fornix-based group (2 eyes).

**Conclusions.** Phacotrabeculectomy with intraoperative mitomycin C was successful in regard to both reduction of intraocular pressure and glaucoma medications. There was no difference in the safety or efficacy of the procedure between groups receiving either fornix- or limbus-based flap, except for the early bleb leak, which was observed only in the fornix flap group.

**Key words:** antimetabolites, antineoplastic; conjunctiva; glaucoma, open-angle; lens implantation, intraocular; phacoemulsification; trabecular meshwork; trabeculectomy

Cataract and glaucoma frequently coexist and many of these patients require an operation. Recently, combined cataract and glaucoma surgery has been advocated as a more efficient procedure that spares the patient from two sequential procedures, achieves better postoperative results, and also reduces the overall costs of surgery (1-3).

Phacoemulsification combined with trabeculectomy is widely used for the simultaneous treatment of cataract and glaucoma (3). However, the use of adjunctive antimetabolites such as mitomycin C is necessary in patients with risk factors for filtration failure (4,5). Several studies have shown that phacotrabeculectomy with mitomycin C is an effective method of treatment of glaucoma and cataract, leading to improved visual acuity and better long-term intraocular pressure control (2,6-15). The orientation of the conjunctival flap, fornix-based or limbus-based, has been in the focus of interest of several studies (7-10,16,17), which differed with respect to the type of glaucoma and previous surgical treatment of included patients.

The aim of our study was to compare the safety and efficacy of fornix-based and limbus-based conjunctival flaps in phacotrabeculectomy with mitomycin C in fellow eyes of the same patients with primary open angle glaucoma and cataract, with no previous laser or surgical treatment on either eye.

### **Patients and Methods**

Patients

There were 16 consecutive patients (6 men and 10 women) included in our prospective study conducted at the Eye Clinic, Sisters of Mercy University Hospital, between January 2001 and March 2003. Each patient had bilateral primary open-angle glaucoma on the maximum tolerated medical therapy, increased intraocular pressure, visual field defects due to glaucoma, and cataracts. We excluded patients with previous argon laser trabeculoplasty or other eye surgery (N=41). The mean age ( $\pm$  standard deviation) of our 16 patients was  $65\pm5.2$  years and a follow up ranged from 20 to 24 months.

Each patient underwent a one-site phacotrabeculectomy with the use of mitomycin C (0.4 mg/mL, exposure time 2.5 min) and implantation of a foldable posterior chamber intraocular lens (Allergan SI40, Allergan Inc, Irvine, CA, USA) in both eyes. All surgeries were performed by a single surgeon (ZM).

Methods

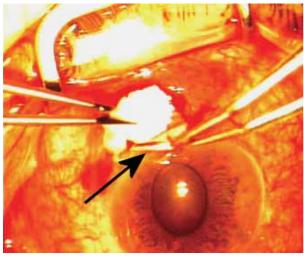
Visual acuity, biomicroscope examination, applanation tonometry, and fundus examination were performed preoperatively and at every follow-up visit in all patients.

The first eye of each patient received a fornix-based conjunctival flap, while the fellow eye was assigned to the limbus-based group. The mean time between the surgery of the first eye and the surgery of the second eye was  $25\pm7.2$  days.

Before the procedure, the pupils were dilated with a combination of 0.5% tropicamide and 5% phenylephrine. Retrobulbar anesthesia with 3 mL of 2% lydocaine hydrochloride and pressure patch was performed in all eyes.

After a standard preparation, surgery began with the preparation of the conjunctiva. In a fornix-based group, the conjunctiva was opened at the corneoscleral limbus, whereas in the limbus-based group an opening was placed at 10 mm from the limbus-Hemostasis was cautiously done with bipolar diathermy. We used the one-site technique: the filtering bleb and phacoemusification were performed on the 12 o'clock position.

After outlining and creating a superficial scleral flap, a cellulose sponge soaked in 0.4 mg/mL of mitomycin C was applied under the scleral flap and covered with the conjunctiva (Fig. 1). The sponge was applied for 2.5 minutes and then removed. The area covered by the sponge was copiously irrigated with a balanced salt solution.



**Figure 1.** A cellulose sponge soaked in mitomycin C prior to the application under the scleral flap (arrow).

After that, a scleral tunnel was created and continuous curvilinear capsulorhexis and hydrodissection were performed through a clear cornea temporal paracentesis. Pupil stretching was performed in 6 eyes before the capsulorhexis. Sodium hyaluronate (Healon GV, Pharmacia, Uppsala, Sweden) was injected in the anterior chamber. Phacoemulsification was done in the capsular bag, followed by the irrigation/aspiration of the remaining cortical lens material. More sodium hyaluronate (Healon GV) was injected in the anterior chamber to deepen the capsular bag.

A foldable silicone IOL (SI-40, Allergan, Inc.) was implanted in the capsular bag. Sodium hyaluronate (Healon GV) was aspirated from the anterior chamber and a sclerectomy was performed with a Kelly Descemet punch (Katena Products, Inc., Denville, NJ, USA). A peripheral iridectomy was performed through the opening.

The superficial scleral flap was closed with two 10-0 nylon sutures placed at the superior angles of the flap. The conjunctiva was closed with two 9-0 polyglactin sutures (Vicryl, Johnson& Johnson, New Brunswick, NJ, USA) placed at each corner of the conjunctival flap in the fornix-based group, whereas a running 9-0 polyglactin suture (Vicryl, Johnson&Johnson) was used in the limbus-based group.

Each eye received a subconjunctival injection of dexamethasone 0.4% in the lower fornix. Combined dexamethasone 0.1% and neomycin ointment was applied and the eye was patched.

Postoperatively, combined dexamethasone 0.1% and neomycin drops were used for 2 months, with gradual tapering. Patients were seen weekly for the first month after surgery and then once a month during the whole follow-up period.

We compared preoperative and postoperative visual acuity, intraocular pressure, number of antiglaucoma medications, and postoperative complications.

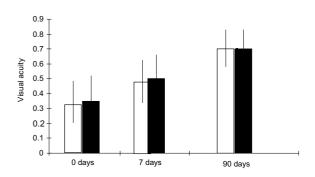
Statistical Analysis

Statistical analysis was performed with SPSS 8.0 statistical package for Windows (SPSS Inc. Chicago, IL, USA), and data were compared with Student t-test. P-value of < 0.05 was considered statistically significant.

#### **Results**

We analyzed 16 patients and 32 eyes. The patients were followed up for 20-24 months.

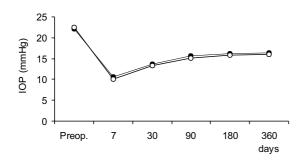
Best corrected visual acuity improved equally in both groups after the operation. However, a slightly faster improvement was observed in the limbus-based group (Fig. 2).



**Figure 2.** Mean preoperative and postoperative best corrected visual acuity in the fornix flap (open bars) and the limbus flap (closed bars) group. Vertical lines denote standard deviations.

Preoperative mean intraocular pressure in the fornix-based flap group was 22.1 ± 4.4 mmHg, and the mean number of antiglaucoma medications was  $2.4\pm0.8$ . In the limbus-based flap group, the values for the mean intraocular pressure were  $22.4 \pm 4.5$  mm Hg, and the mean number of antiglaucoma medications was  $2.6\pm0.7$  before the surgery. After a mean follow up of 22 months, the mean intraocular pressure fell to 16.2±3.4 mmHg in the fornix-based group, and to  $15.9\pm3.2$  in the limbus-based group. The mean number of antiglaucoma medication fell to  $0.3\pm0.3$  in the fornix-based group and  $0.3\pm0.4$  in the limbus-based group. The decrease in intraocular pressure level between the preoperative and postoperative period was statistically significant (p = 0.001), but there was no statistically significant difference in intraocular pressure decrease between the fornix and limbus-based group (p = 0.810, Fig. 3).

The decrease in the number of medications between preoperative and postoperative period was



**Figure 3.** Preoperative and postoperative intraocular pressure (IOP) in the fornix-based (closed circles) and the limbus-based flap (open circles) group.

also statistically significant (p < 0.001), with no statistical significance between the tested groups (p = 0.950).

Early postoperative complications occurred more frequently in the fornix-based group. Early onset bleb leak occurred only in the fornix-based group. Late postoperative complications were comparable between the two groups (Table 1).

**Table 1.** Early and late postoperative complications in 16 patients

Complications	Group of patients (n)	
	fornix-based	limbus-based
Early:		
hyphema	1	0
shallow anterior chamber	1	0
leakage	2	0
iritis	3	2
total	7	2
Late:		
bleb leak	1	0
intraocular lens capture	2	3
capsule opacification	7	8
posterior synechiae	5	6
cystic bleb or bleb fibrosis	3	2
total	18	19

## **Discussion**

Phacotrabeculectomy is often used in the treatment of coexisting cataract and glaucoma. There is a choice between two conjunctival flaps in phacotrabeculectomy with mitomycin C: a fornix-based and a limbus-based flap. The results of our study showed a significant increase in visual acuity and a significant decrease in intraocular pressure and the number of antiglaucoma medications in both groups. There was no significant difference between the two groups, though. These results are comparable with those obtained by Shingleton et al (17) and Tezel et al (8) who used a one-site technique as we did. Kozobolis et al (16) published similar results using a two-site technique.

Several studies have studied visual acuity, postoperative intraocular pressure control, and postoperative complications in regard to the flap orientation (7,8,16,17). However, these studies included patients with different types of glaucoma, as well as those with previous laser or surgical procedures. Compared with other studies, the uniqueness of our study is in the strict criteria for patient selection.

We tried to minimize the variability between the groups and therefore studied the effects of the flap orientation on the fellow eyes of same patients with cataract and primary open angle glaucoma and no previous laser or surgical procedures. All eyes were operated on by the same surgeon, which limited the variability even further.

The importance of correct choice of the orientation of a conjunctival flap is in the occurrence of post-operative complications. Early postoperative complications were more frequent in the fornix-based group, but, except for the bleb leak, they were transitory and subsided after medical therapy.

We encountered two cases with early bleb leakage in the fornix-based group and none in the limbus-based group. This corresponds to the results by other authors (8,16,17). In the late postoperative period we encountered a single case of late bleb leak, again in the fornix-based group. Shingleton et al (17) also reported one patient with a late bleb leak in the fornix-based group. Kozobolis et al (16) and Tezel et al (8) reported no late bleb leak in either group.

The fornix-based flap orientation allows better surgical view and is less time consuming, whereas the limbus-based flap reduces the possible exposure of cornea to mitomycin C.

In conclusion, even though the fornix-based group had more frequent bleb leakage, phacotrabeculectomy with mitomycin C was equally effective in both groups in terms of postoperative visual acuity and long-term intraocular pressure.

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