

The Management of Overhanging Filtering Blebs

BY LAMA A. AL-ASWAD, MD

CASE PRESENTATION

In 2004, a 65-year-old Hispanic male presented to the ophthalmology clinic with a complaint of discomfort and a foreign body sensation in his left eye for the past several weeks. His ocular history was significant for trabeculectomy with mitomycin C (MMC) in his right eye in 1998 and in his left eye in 1999. In 2002, an episode of mild blebitis in his left eye responded promptly to topical fortified vancomycin and tobramycin. A transient bleb leak occurred in the same eye in 2003.

On examination, the patient's BCVA measured 20/40 OD and 20/50 OS. His IOP was 10 mm Hg OD and 9 mm Hg OS. Pachymetry measured 470 μm OD and 505 μm OS. The patient's left eye had a cystic, thin-walled, translucent filtering bleb overhanging the cornea superiorly (Figure 1). The bleb was Seidel negative, and the optic discs had advanced glaucomatous cupping (Figure 2).

HOW WOULD YOU PROCEED?

1. Would you initiate topical lubrication therapy?
2. Would you graft with an autologous conjunctival patch?
3. Would you remodel or shrink the bleb with a laser procedure or cryotherapy?
4. Would you amputate the overhanging corneal section of the bleb and place a horizontal compression suture?

SURGICAL COURSE

The patient's symptoms were due to bleb dysesthesia in his left eye with an IOP at target level. I excised the extensive overhanging corneal component of the filtering bleb and placed a tight 9-0 nylon horizontal compression suture across the resulting limbal defect (Figure 3).



Figure 1. A slit-lamp photograph of the patient's left eye showed an overhanging, thin ischemic bleb.

OUTCOME

On the first postoperative day, visual acuity in the patient's left eye was 20/50 with an IOP of 11 mm Hg. The bleb had remained Seidel negative. At 1 week, his visual acuity was still 20/50, the IOP had decreased to 8 mm Hg, and the Seidel test was negative.

Two months after surgery, the visual acuity and Seidel test were unchanged, but the IOP had risen to 13 mm Hg. At that point, treatment with a prostaglandin analog was initiated to control the IOP and prevent further thinning of the bleb. One year after surgery, the patient's visual acuity had decreased to 20/60 due to the progression of a preexisting cataract, and the IOP had stabilized on prostaglandin-analog therapy to a range of 10 to 11 mm Hg. The bleb was still Seidel negative without a recurrence of the overhanging bleb (Figure 4).

The patient has done well. He has a Seidel negative, functioning filtering bleb and satisfactory IOP control.

LUMIGAN®

(bimatoprost ophthalmic solution) 0.03%

INDICATIONS AND USAGE

LUMIGAN® (bimatoprost ophthalmic solution) 0.03% is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension who are intolerant of other intraocular pressure lowering medications or insufficiently responsive (failed to achieve target IOP determined after multiple measurements over time) to another intraocular pressure lowering medication.

CONTRAINDICATIONS

LUMIGAN® (bimatoprost ophthalmic solution) 0.03% is contraindicated in patients with hypersensitivity to bimatoprost or any other ingredient in this product.

WARNINGS

LUMIGAN® (bimatoprost ophthalmic solution) 0.03% has been reported to cause changes to pigmented tissues. These reports include increased pigmentation and growth of eyelashes and increased pigmentation of the iris and periorbital tissue (eyelid). These changes may be permanent.

LUMIGAN® may gradually change eye color, increasing the amount of brown pigment in the iris by increasing the number of melanosomes (pigment granules) in melanocytes. The long-term effects on the melanocytes and the consequences of potential injury to the melanocytes and/or deposition of pigment granules to other areas of the eye are currently unknown. The change in iris color occurs slowly and may not be noticeable for several months to years. Patients should be informed of the possibility of iris color change.

Eyelid skin darkening has also been reported in association with the use of LUMIGAN®.

LUMIGAN® may gradually change eyelashes; these changes include increased length, thickness, pigmentation, and number of lashes.

Patients who are expected to receive treatment in only one eye should be informed about the potential for increased brown pigmentation of the iris, periorbital tissue, and eyelashes in the treated eye and thus, heterochromia between the eyes. They should also be advised of the potential for a disparity between the eyes in length, thickness, and/or number of eyelashes.

PRECAUTIONS

General:

There have been reports of bacterial keratitis associated with the use of multiple-dose containers of topical ophthalmic products. These containers had been inadvertently contaminated by patients who, in most cases, had a concurrent corneal disease or a disruption of the ocular epithelial surface (see Information for Patients).

Patients may slowly develop increased brown pigmentation of the iris. This change may not be noticeable for several months to years (see Warnings). Typically the brown pigmentation around the pupil is expected to spread concentrically towards the periphery in affected eyes, but the entire iris or parts of it may also become more brownish. Until more information about increased brown pigmentation is available, patients should be examined regularly and, depending on the clinical situation, treatment may be stopped if increased pigmentation ensues. The increase in brown iris pigment is not expected to progress further upon discontinuation of treatment, but the resultant color change may be permanent. Neither nevi nor freckles of the iris are expected to be affected by treatment.

LUMIGAN® (bimatoprost ophthalmic solution) 0.03% should be used with caution in patients with active intraocular inflammation (e.g., uveitis).

Macular edema, including cystoid macular edema, has been reported during treatment with bimatoprost ophthalmic solution. LUMIGAN® should be used with caution in aphakic patients, in pseudophakic patients with a torn posterior lens capsule, or in patients with known risk factors for macular edema.

LUMIGAN® has not been evaluated for the treatment of angle closure, inflammatory or neovascular glaucoma.

LUMIGAN® should not be administered while wearing contact lenses.

Information for Patients:

Patients should be informed that LUMIGAN® has been reported to cause increased growth and darkening of eyelashes and darkening of the skin around the eye in some patients. These changes may be permanent.

Some patients may slowly develop darkening of the iris, which may be permanent.

When only one eye is treated, patients should be informed of the potential for a cosmetic difference between the eyes in eyelash length, darkness or thickness, and/or color changes of the eyelid skin or iris.

Patients should be instructed to avoid allowing the tip of the dispensing container to contact the eye, surrounding structures, fingers, or any other surface in order to avoid contamination of the solution by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions.

Patients should also be advised that if they develop an intercurrent ocular condition (e.g., trauma or infection) or have ocular surgery, they should immediately seek their physician's advice concerning the continued use of the multidose container.

Patients should be advised that if they develop any ocular reactions, particularly conjunctivitis and eyelid reactions, they should immediately seek their physician's advice.

Contact lenses should be removed prior to instillation of LUMIGAN® and may be reinserted 15 minutes following its administration. Patients should be advised that LUMIGAN® contains benzalkonium chloride, which may be absorbed by soft contact lenses.

If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Carcinogenicity studies were not performed with bimatoprost.

Bimatoprost was not mutagenic or clastogenic in the Ames test, in the mouse lymphoma test, or in the *in vivo* mouse micronucleus tests.

Bimatoprost did not impair fertility in male or female rats up to doses of 0.6 mg/kg/day (approximately 103 times the recommended human exposure based on blood AUC levels).

Pregnancy: Teratogenic Effects: Pregnancy Category C.

In embryofetal developmental studies in pregnant mice and rats, abortion was observed at oral doses of bimatoprost which achieved at least 33 or 97 times, respectively, the intended human exposure based on blood AUC levels.

At doses 41 times the intended human exposure based on blood AUC levels, the gestation length was reduced in the dams, the incidence of dead fetuses, late resorptions, peri- and postnatal pup mortality was increased, and pup body weights were reduced.

There are no adequate and well-controlled studies of LUMIGAN® administration in pregnant women. Because animal reproductive studies are not always predictive of human response, LUMIGAN® should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether LUMIGAN® is excreted in human milk, although in animal studies, bimatoprost has been shown to be excreted in breast milk. Because many drugs are excreted in human milk, caution should be exercised when LUMIGAN® is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

ADVERSE REACTIONS

In clinical trials, the most frequent events associated with the use of LUMIGAN® (bimatoprost ophthalmic solution) 0.03% occurring in approximately 15% to 45% of patients, in descending order of incidence, included conjunctival hyperemia, growth of eyelashes, and ocular pruritus. Approximately 3% of patients discontinued therapy due to conjunctival hyperemia.

Ocular adverse events occurring in approximately 3 to 10% of patients, in descending order of incidence, included ocular dryness, visual disturbance, ocular burning, foreign body sensation, eye pain, pigmentation of the periorbital skin, blepharitis, cataract, superficial punctate keratitis, eyelid erythema, ocular irritation, and eyelash darkening. The following ocular adverse events reported in approximately 1 to 3% of patients, in descending order of incidence, included: eye discharge, tearing, photophobia, allergic conjunctivitis, asthenopia, increases in iris pigmentation, and conjunctival edema. In less than 1% of patients, intraocular inflammation was reported as iritis.

Systemic adverse events reported in approximately 10% of patients were infections (primarily colds and upper respiratory tract infections). The following systemic adverse events reported in approximately 1 to 5% of patients, in descending order of incidence, included headaches, abnormal liver function tests, asthenia and hirsutism.

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CHALLENGING CASES

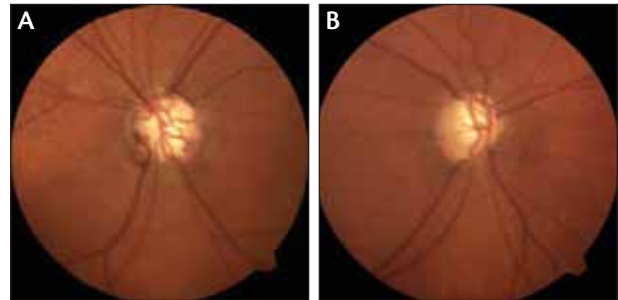


Figure 2. Disc photographs of the left (A) and right (B) eyes showed advanced glaucomatous cupping.

Bleb dysesthesia has not recurred, and the cataract's progression has been gradual. Nevertheless, he merits close monitoring because of the potential for further thinning of the bleb and recurrent growth of the bleb over the cornea, blebitis, and/or leakage as well as rising IOP with progression of his advanced glaucoma.

DISCUSSION

An overhanging bleb is a well-documented complication of trabeculectomy, especially when antimetabolites are used. The problem can be associated with hypotony due to overfiltration or external leakage, foreign body sensation due to an extremely large bleb, dysesthesia due to interference with lid function and closure leading to corneal drying with dellen formation, unacceptable cosmesis, and visual compromise due to astigmatism. Ophthalmologists are usually reluctant to relieve these symptoms through additional surgery if IOPs are well controlled.

Among the conservative measures that may avoid invasive surgical intervention are lubrication, aqueous suppressants, and compression sutures.¹ In general, these modalities tend to shrink the blebs gradually, and many patients do not require further intervention. The surgical revision of the bleb may be warranted, however, in patients who have intractable pain caused by dellen or fluctuating vision. Strategies include bleb excision with free conjunctival autologous patch graft,²⁻⁴ bleb excision with conjunctival advancement,⁵ laser bleb reduction,⁶⁻⁸ partial excision of the overhanging corneal portion,⁹ cryoapplication, and the application of trichloroacetic acid. Because these procedures may compromise the bleb's function, patients should understand they might require future medical and/or surgical intervention for IOP control.

In the case presented herein, medical management was not a realistic option because neither lubricants nor aqueous suppressants could relieve the symptoms caused by such a large overhanging bleb. Although

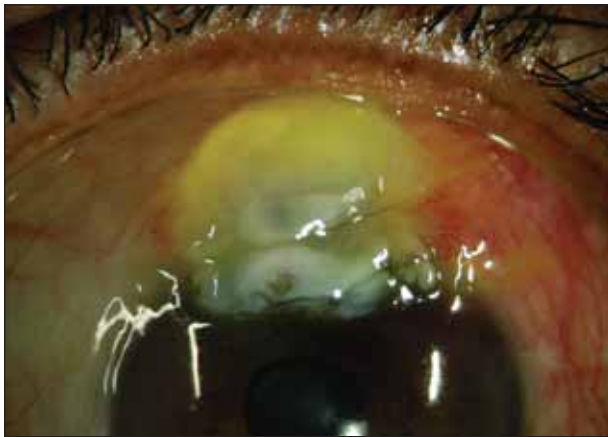


Figure 3. This slit-lamp photograph of the patient's left eye was taken 1 week after the partial excision of the section overhanging the cornea and the placement of a horizontal compression suture.

argon laser photocoagulation can remodel and reduce a bleb's size by means of protein denaturation and tissue shrinkage,¹⁰ my colleagues and I decided against this procedure due to the likelihood of penetrating the very thin ischemic bleb and thereby inducing a chronic leak. We considered cryoapplication and the application of trichloroacetic acid to be too potentially destructive to the corneal surface for the treatment of a bleb extending onto the cornea.

We were left with two options: either a partial excision of the overhanging corneal section of the bleb or a total excision of the bleb with conjunctival advancement or free autologous conjunctival patch graft. We thought the former was a simpler and yet precise method for relieving the patient's bothersome symptoms without significantly disrupting the bleb's function. These overhanging blebs are easily dissected off the corneal surface, but their partial excision does leave a limbal conjunctival dehiscence that may not seal rapidly in tissue previously treated with MMC. In addition to persistent leakage and hypotony, there would also be a risk of infection, especially in an eye with a prior history of blebitis. We therefore elected to place a tight horizontal compression suture at the limbus to tamponade the conjunctival incision to prevent oozing and facilitate healing (Figure 3).

If this procedure had failed to alleviate the problem, our next option would have been bleb excision with a free autologous conjunctival patch graft, a procedure that is frequently used to repair leaking blebs. For a large, intact, overhanging MMC bleb with satisfactory IOP control, however, the partial excision of the corneal component in conjunction with a horizontal compression



Figure 4. One year postoperatively, the slit-lamp photograph showed no recurrence of the overhanging section of the bleb.

sion suture appeared to be the simplest and most effective solution. □

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