

# Algorithm approach for revision surgery following late-onset bleb complications after trabeculectomy: long-term follow-up

## *Algoritmo de abordagem para cirurgia de revisão nas complicações da bolha de início tardio após trabeculectomia: acompanhamento de longo prazo*

CLAUDIO I. PEREZ<sup>1</sup>, MARÍA J. OPORTUS<sup>1</sup>, FELIPE MELLADO<sup>1</sup>, FELIPE VALENZUELA<sup>1</sup>, CRISTIÁN CARTES<sup>1</sup>, DANIELA LÓPEZ-PONCE<sup>1</sup>, DANIELA SALINAS-TORO<sup>1</sup>, REMIGIO LÓPEZ-SOLÍS<sup>2</sup>, LEONIDAS TRAIPE<sup>1</sup>

### ABSTRACT

**Purpose:** The aim of this study was to introduce a reproducible algorithm for the surgical management of late-onset (>2 months) bleb complications after trabeculectomy with mitomycin C.

**Methods:** We performed a retrospective review of eyes treated using a reproducible algorithm approach by a single surgeon for the surgical management of late-onset bleb complications from July 2006 to April 2014. Exclusion criteria were bleb revision with less than 3 months of follow-up or bleb revision combined with other glaucoma procedures at the time of surgery. Success was evaluated using the Kaplan-Meier survival method and defined as achieving all of the following criteria: primary surgery indication resolved, no additional surgery required for decreasing the intraocular pressure (IOP), and IOP of  $\geq 6$  mmHg and  $\leq 18$  mmHg.

**Results:** Twenty-three eyes from 20 patients were evaluated. Indications for bleb revision were hypotonic maculopathy (47.8%), bleb leak (30.4%), and dysesthetic bleb (21.7%). The overall primary outcome success rate calculated using the Kaplan-Meier survival method was 65.2% at 48 months. When the IOP target was changed to  $\leq 15$  mmHg, the bleb survival rate was 47.8% at 48 months. At the most recent postoperative visit, 95.7% of eyes had an IOP of  $\leq 15$  mmHg and 56.5% were being treated with an average of one medication per eye. One eye (4.3%) required a second bleb revision for persistent hypotony and two eyes required glaucoma surgery to reduce IOP during follow-up.

**Conclusions:** An algorithm approach for the surgical management of late-onset bleb complications with a success rate similar to those reported in specialized literature is proposed. Randomized trials are needed to confirm the best surgical approach.

**Keywords:** Intraocular pressure; Glaucoma surgery; Trabeculectomy; Postoperative; Mitomycin C

### RESUMO

**Objetivo:** Descrever um algoritmo reprodutível para o tratamento cirúrgico das complicações da bolha de início tardio (>2 meses) após trabeculectomia com mitomicina-C.

**Métodos:** Revisão retrospectiva de olhos que foram submetidos a um algoritmo reprodutível para o tratamento cirúrgico das complicações da bolha de início tardio por um único cirurgião, de julho de 2006 a abril de 2014. Os critérios de exclusão foram revisão de bolha com menos de 3 meses de seguimento ou revisão de bolha combinado com outro procedimento antiglaucomatoso no momento da cirurgia. O sucesso foi avaliado pelo método de sobrevivência de Kaplan-Meier e definidos como ter atingido todos os seguintes critérios: indicação de cirurgia primária resolvida, nenhuma cirurgia adicional necessária para diminuir a pressão intraocular (IOP), IOP  $\geq 6$  mmHg e  $\leq 18$  mmHg.

**Resultados:** Vinte e três olhos de 20 pacientes foram incluídos. Indicações para revisão de bolha foram maculopatia hipotônica (47,8%), extravasamento da bolha (30,4%) e bolha elevada (21,7%). A taxa de sucesso do resultado primário global calculada pelo método de sobrevivência de Kaplan-Meier foi de 65,2% aos 48 meses. Quando a IOP foi diminuída para  $\leq 15$  mmHg, a taxa de sobrevivência de bolha foi de 47,8% em 48 meses. Na visita pós-operatória mais recente, 95,7% dos olhos apresentavam PIO  $\leq 15$  mmHg e 56,5% estavam sob tratamento com uma média de um medicamento por olho. Um olho (4,3%) necessitou de uma segunda revisão da bolha para hipotonia persistente e dois olhos necessitaram cirurgia de antiglaucomatosa para reduzir a IOP durante o seguimento.

**Conclusões:** Um algoritmo de abordagem para o tratamento cirúrgico das complicações tardias da bolha com uma taxa de sucesso semelhante aos relatados na literatura especializada é proposto. Ensaios clínicos randomizados são necessários para confirmar a melhor abordagem cirúrgica.

**Descritores:** Pressão intraocular; Glaucoma/cirurgia; Trabeculectomia/efeitos adversos; Cirurgia filtrante; Complicações pós-operatórias; Glaucoma/quimioterapia; Mitomicina/uso terapêutico

### INTRODUCTION

In the surgical management of glaucoma, trabeculectomy is commonly performed as the initial procedure for lowering the intraocular pressure (IOP). The introduction of antifibrotic agents as an adjunct to trabeculectomy has led to lower intraoperative pressures but higher long-term complications. These complications are more frequent in patients with thin-walled, avascular, or cystic blebs<sup>(1-4)</sup>, and a cumulative frequency of 26% at 20 years has been reported<sup>(5)</sup>. Some of these complications, such as late-onset bleb leak, can be managed

with bandage contact lenses, cyanoacrylate glue, or autologous blood injection. However, compared with conservative management, a surgical approach with conjunctival advancement is more likely to resolve bleb leaks and less likely to be accompanied with serious intraocular infections<sup>(5)</sup>. Therefore, late-onset bleb complications, such as hypotony, bleb dysesthesia, and bleb leak, are frequently managed with revision surgery<sup>(6)</sup>.

The literature contains reports on several surgical procedures for repairing bleb complications. However, these studies usually evaluate

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<sup>1</sup> Fundación Oftalmológica los Andes, Vitacura, Santiago de Chile.

<sup>2</sup> Program of Cellular and Molecular Biology, Faculty of Medicine-ICBM, University of Chile, Santiago, Chile.

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**Corresponding author:** Claudio I. Perez. Fundación Oftalmológica los Andes, Las Hualtatas 5951 - Santiago, Chile - E-mail: ciperezv@gmail.com.

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different surgeons using different techniques, which can lead to inconsistent comparisons. In this study, we report the outcomes of patients with various indications for bleb revision, including bleb leak, hypotony, and bleb dysesthesia, who were treated using a reproducible algorithm approach for surgical management by a single surgeon.

## METHODS

This study adhered to the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of Fundación Oftalmológica los Andes. Cases of bleb revision performed between July 2006 and April 2014 were retrospectively reviewed from an institutional database. The inclusion criteria included late-onset (>2 months) bleb complications after trabeculectomy with mitomycin C and treatment with bleb revision. The exclusion criteria were bleb revision with less than 3 months of follow-up or bleb revision combined with other glaucoma procedures at the time of surgery. The medical records of 24 patients were reviewed.

All surgical bleb revisions were performed by one surgeon (L.T.) using the following reproducible step-ladder approach. The condition of the conjunctiva was evaluated, and conjunctival dissection and excision were performed in cases of bleb leak or dysesthesia with oversized and thin-walled blebs. Then, the filtering state was evaluated by observing the amount of aqueous humor flowing outside the scleral flap. If no hyperfiltration was detected, the scleral flap was left untouched. If hyperfiltration was present, as in hypotony or certain bleb leaks, two options were considered. If the scleral flap was in good condition, it was secured using one or more adjustable 10.0 nylon sutures until the filtration state was adequate. If the scleral flap was in a poor condition, a scleral patch was secured over the flap using 10.0 nylon sutures. Finally, conjunctival advancement was performed, and the flap was secured to the superior corneal limbus using 9.0 nylon sutures.

The primary outcome of the procedure was considered successful if all of the following criteria were met: (a) the primary surgical indication was resolved, (b) no additional surgery was required to lower IOP, and (c) IOP of  $\geq 6$  mmHg and  $\leq 18$  mmHg was maintained with or without glaucoma medication (qualified IOP). Primary outcomes were also analyzed with qualified IOP targets of  $\leq 15$  mmHg and  $\leq 21$  mmHg to facilitate comparison with previous reports in the specialized literature. If any of the success criteria were not accomplished during the follow-up, the procedure was considered a failure even if the criteria were met in the future. Success rates using a qualified IOP of  $\leq 15$  mmHg and Kaplan-Meier analysis were also calculated for each indication of bleb revision (hypotony, bleb dysesthesia, and bleb leak). Secondary outcomes comprised IOP and glaucoma medication status at the last patient visit.

Statistical analysis was performed using SPSS 16.0 software (SPSS Inc, Chicago, IL). The Student *t*-test was used to evaluate differences between preoperative and postoperative best-corrected visual acuity (BCVA). Kaplan-Meier survival analysis was used to determine primary outcome success during the follow-up period. A *p* value of  $\leq 0.05$  was considered statistically significant.

## RESULTS

During the study period, 28 eyes of 24 patients underwent late-onset bleb revision for complications after trabeculectomy and met the inclusion criteria. One eye was excluded because the follow-up period was less than 3 months, and four eyes were excluded because an Ahmed valve was implanted simultaneously with bleb revision. Twenty patients (mean age  $46.7 \pm 25.5$  years, representing 23 eyes) were included in the final analysis. The glaucoma stages of the patients were severe, with a mean deviation of  $-17.1 (\pm 10.9)$  dB. The mean time between trabeculectomy and bleb revision was 61.4 months (range 2-300), and mean postoperative follow-up

time after bleb revision was 27.8 months (range 3-48). Mitomycin C (0.25 mg/mL) was used in all patients for 2.5-3 min during trabeculectomy. Table 1 summarizes the demographic and clinical characteristics of the patients included in the study as well as the indications for bleb revision, which included bleb hyperfiltration with hypotonic maculopathy (47.8%), bleb leak with or without blebitis (30.4%), and dysesthetic bleb (21.7%).

After the surgery algorithm was applied, 69.6% of eyes were treated with a scleral patch, 17.4% underwent scleral flap suturing, and 13% underwent bleb excision with conjunctival advancement as a unique procedure. Table 2 shows the preoperative and final postoperative BCVA and IOP values and glaucoma medication status. Postoperatively, the improvement in BCVA was not significant, whereas IOP increased significantly. After surgery, the mean number of glaucoma drops administered was one per eye, although the percentage of eyes needing glaucoma medication increased from 13% preoperatively to 56.5% postoperatively.

Figure 1 shows a Kaplan-Meier survival curve of primary outcome success after bleb revision, which required resolution of the primary surgical indication, no additional surgery to lower IOP, and maintenance of IOP of  $\leq 15$  mmHg and  $\leq 18$  mmHg. When the qualified IOP target of  $\leq 18$  mmHg was used, the success rate was 65.2% at 12 months after surgical revision. This percentage remained invariable at 48 months of follow-up. When the qualified IOP target of  $\leq 15$  mmHg was used, the success rate was 47.8% at 12 months after surgical revision and was also maintained at 48 months of follow-up. When the qualified IOP criterion of  $\leq 21$  mmHg was used, the success rate

**Table 1. Demographic and clinical characteristics of patients undergoing bleb revision**

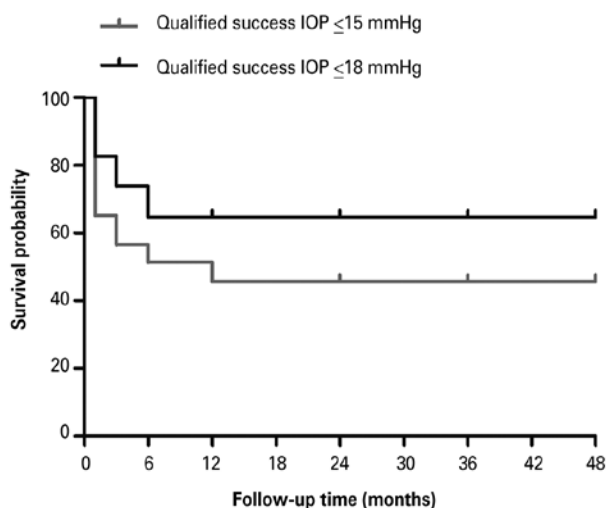
Characteristic	
Mean age $\pm$ SD (years)	46.7 $\pm$ 25.5
Male-to-female ratio	7:13
Glaucoma severity; mean deviation $\pm$ SD (dB)	-17.1 $\pm$ 10.9
Glaucoma type	N <sup>o</sup> of eyes (%)
Open-angle	11 (47.8)
Juvenile/childhood	4 (17.4)
Chronic angle closure	3 (13.0)
Congenital	2 ( 8.7)
Uveitic	1 ( 4.3)
Normal-tension	1 ( 4.3)
Post-keratoplasty	1 ( 4.3)
Indications for bleb revision	N <sup>o</sup> of eyes (%)
Hypotony	11 (47.8)
Bleb leak	7 (30.4)
Bleb dysesthesia	5 (21.7)

SD= standard deviation.

**Table 2. Preoperative and last postoperative visit BCVA, IOP values, and glaucoma medication status**

Variable	Preoperative	Postoperative	P value
BCVA (logMAR $\pm$ SD)	0.64 $\pm$ 0.7	0.48 $\pm$ 0.7	0.4500
IOP (mmHg $\pm$ SD)	7.70 $\pm$ 3.1	10.9 $\pm$ 2.6	0.0004
Glaucoma drops used (N <sup>o</sup> $\pm$ SD)	0.13 $\pm$ 0.3	1.04 $\pm$ 1.1	0.0003
Eyes with glaucoma drops (N <sup>o</sup> /%)	3 (13)	13 (56.5)	

BCVA= best-corrected visual acuity; IOP= intraocular pressure; N<sup>o</sup>= number; SD= standard deviation.



**Figure 1.** Kaplan-Meier curve for successful bleb revision in late-onset bleb complications after trabeculectomy. The criteria for a successful primary outcome included resolution of the primary surgical indication, no requirement for additional surgery to lower IOP, and maintenance of a qualified IOP of  $\leq 15$  or  $\leq 18$  mmHg.

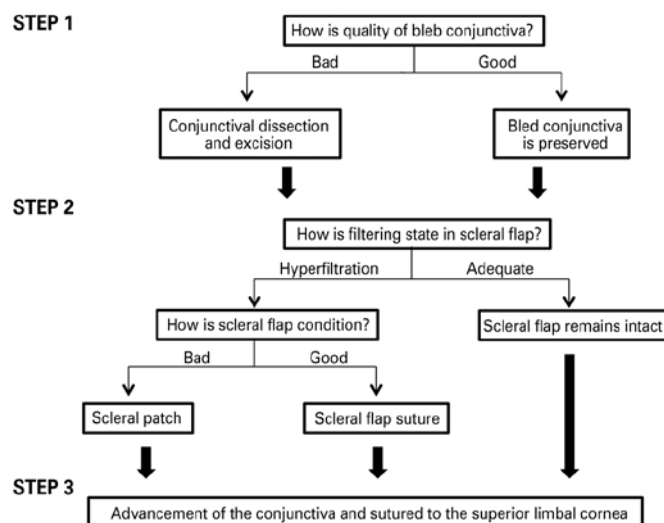
was 78% at 48 months of follow-up. When the success rate associated with each criterion was subjected to a separate Kaplan-Meier analysis, 96% of the primary indications for surgery resolved successfully, 91% of the eyes did not require surgery to lower IOP, 63% of the eyes had IOPs of  $\leq 15$  mmHg, 82% had IOPs of  $\leq 18$  mmHg, and 87% had IOPs of  $\leq 21$  mmHg throughout the follow-up period. The two eyes that required glaucoma surgery to lower IOP were eyes with dysesthetic blebs.

Success rates using the qualified IOP of  $\leq 15$  mmHg and Kaplan-Meier analysis were also calculated for each indication for bleb revision. The results showed that all criteria for primary outcome success were achieved in 54.5% of eyes in cases of hypotony, 42.9% in cases of bleb leak, and 40.0% in cases of dysesthetic bleb. In the patient groups with hypotony and bleb leak, failures occurred during the first month post-bleb revision, and the success rate subsequently remained unaltered. Eyes with dysesthetic bleb experienced failure during the 1st year, after which the success rate remained unmodified. At the last visit, IOP was  $\leq 15$  mmHg in 95.7% of the eyes and 56.5% of eyes were being treated with glaucoma medication with a mean of one drop per eye.

As an early complication, an IOP of  $>21$  mmHg was observed in 14 eyes (60.8%) at day 1 and in one eye (4.3%) at 1 week postoperatively. One eye with hypotonic maculopathy required a second bleb revision because the primary indication for surgery was not resolved. Three eyes (13%) with the primary indication of hypotony developed positive Seidel sign during the early postoperative period that resolved with medical management.

**DISCUSSION**

Despite an increasing number of drainage device surgeries and the emergence of new surgical options for treating glaucoma, trabeculectomy remains the most common glaucoma surgery<sup>(7,8)</sup>. Thus, glaucoma surgeons should familiarize themselves with the resolution of late-onset bleb complications, such as bleb leakage, hypotony, bleb dysesthesia, and bleb-related infections. In this study, we propose a reproducible step-ladder approach for the surgical management of late-onset bleb complications of trabeculectomy (Figure 2). All patients in the study were treated by a single surgeon, thereby eliminating the technical variations that naturally occur in studies that include multiple surgeons. Another strength of the study was the long-term (48 months) follow-up using Kaplan-Meier analysis.



**Figure 2.** Algorithm approach for the surgical management of late-onset bleb complications after trabeculectomy. This approach was used for all eyes in the study.

Potential sources of bias related to the observed success rates after bleb revision were the retrospective nature of the study, exclusion of one patient with less than 3 months of follow-up, and exclusion of patients who underwent another glaucoma procedure at the time of revision surgery (glaucoma surgery with simultaneous bleb revision alone). Such potential sources of bias may partly account for success rate differences between the present and previous studies<sup>(9-18)</sup>.

The literature contains several studies that review the surgical outcomes of late-onset bleb complication repair, but the use of different definitions for overall success precludes direct comparisons with the results of our study<sup>(9-18)</sup>. Furthermore, although some of these studies, similar to the present study, have analyzed bleb revision outcomes for multiple indications<sup>(9-15)</sup>, others have performed separate reviews of the outcomes management of late complications, such as hypotony, bleb dysesthesia, or bleb leak<sup>(16-18)</sup>. Compared with other reports, our study has stricter success criteria<sup>(9-18)</sup>, including resolution of the surgical indication, no need for additional IOP-lowering glaucoma surgery, and qualified IOP targets measured using Kaplan-Meier survival analysis.

Our primary outcome success rate for all criteria was 47.8% with a qualified IOP of  $\leq 15$  mmHg and 65.2% with a qualified IOP of  $\leq 18$  mmHg. The largest study on this subject by Radhakrishnan et al.<sup>(9)</sup> used a similar set of success criteria, including resolution of primary indication, no development of new bleb-related complication, and no requirement for further IOP-lowering surgery. However, no specific IOP target was included<sup>(9)</sup>. The study, which evaluated 177 eyes that underwent bleb revision for multiple indications, showed an overall success rate of 63%<sup>(9)</sup>, which is similar to our rate of 65.2% with a qualified IOP of  $\leq 18$  mmHg. In another study with 49 eyes treated with bleb excision and conjunctival advancement for leaking or hypotonous eyes, Tannenbaum et al.<sup>(10)</sup> reported a success rate of 83%. In this report, success criteria included the resolution of the primary surgical indication, no requirement for further IOP-lowering surgery, and the maintenance of a qualified IOP between  $\geq 6$  mmHg and  $\leq 21$  mmHg. Accordingly, the success rate in this study is similar to the 78% success rate in our study using a qualified IOP of  $\leq 21$  mmHg. On the contrary, Catoira et al.<sup>(11)</sup> and van de Geijn et al.<sup>(12)</sup> used the success criteria implemented by Tannenbaum et al.<sup>(10)</sup> in studies with 30 and 36 eyes, respectively, that underwent bleb revision for hypotony, bleb dysesthesia, or bleb leak. They reported

similar success rates of 77% and 86.1%, respectively. Moreover, Wadhvani et al.<sup>(13)</sup> analyzed bleb revision in 22 eyes with various surgical indications and reported a success rate of 86% at the last patient visit (defined as the resolution of surgical indication with one or more bleb revisions with adequate IOP control on two or fewer glaucoma medications without a specific target IOP) with a mean follow-up of 21 months. In this study, if the second bleb revision had been scored as a failure, the surgical success rate would have been 68%. Altogether, Wadhvani et al.<sup>(13)</sup> reported a mean IOP of 11 mmHg with an average of 0.6 glaucoma medications per eye after bleb revision and two or more bleb revisions in 18% of eyes. Kaplan-Meier survival analysis was not used.

In contrast, in our study involving a mean follow up of 27.8 months, the mean postoperative IOP was 10.9 mmHg with an average of one glaucoma medication per eye and only one patient (4.3%) requiring a second bleb revision. Au et al.<sup>(14)</sup> studied bleb revision using a scleral patch technique in 18 eyes and reported that 72% of patients had a qualified IOP of  $\leq 15$  mmHg at the last postoperative visit with a mean follow-up of 23.7 months. At the last patient visit in our study, IOP was  $\leq 15$  mmHg in 95.7% of eyes with a similar follow-up. Au et al.<sup>(14)</sup> and Budenz et al.<sup>(15)</sup> found similar results with a mean postoperative IOP of 13.1 mmHg and 14.2 mmHg, respectively, and a mean of 1.1 glaucoma medications per eye at the last visit.

Some studies have analyzed bleb revision results only in eyes with bleb leaks. Lin et al.<sup>(16)</sup> and Al-Shahwan et al.<sup>(17)</sup> reported overall success rates of 71% in 78 eyes and 73% in 34 eyes, respectively. Both studies used success criteria including a qualified IOP of  $\leq 21$  mmHg, no additional glaucoma surgery, and bleb leak resolution. Their results are slightly worse than those observed in our study, which showed a 78% success rate using the same success criteria. Lin et al.<sup>(16)</sup> also reported a success rate of 48% at 36 months using a qualified IOP of  $\leq 15$  mmHg, which is similar to the rate of 47.8% of our study in the survival analysis at 48 months. Al-Shahwan et al.<sup>(17)</sup> reported a lower success rate of 5% when using a qualified IOP of  $\leq 15$  mmHg as the success criterion with a longer follow-up of 60 months in the Kaplan-Meier analysis. Radhakrishnan et al.<sup>(9)</sup> performed separate analyses for the success rates of various indications for bleb revision and observed an overall success rate of 65%, 63%, and 57% for patients with bleb leak, hypotony, and bleb dysesthesia, respectively<sup>(9)</sup>. However, as noted above, these authors used similar success criteria without a specific IOP target. In our study, the success rates with a qualified IOP of  $\leq 15$  mmHg and the other success criteria were 54.5%, 42.9%, and 40.0% in cases of hypotony, bleb leak, and dysesthetic bleb, respectively. However, because of the small number of eyes in each group, caution is needed in the interpretation of these rates.

According to the Kaplan-Meier plot in this study and that published by Au et al.<sup>(14)</sup>, bleb revision failures occurred only in the 1<sup>st</sup> year of follow-up, after which the success rate remained stable. In the present study, failures in the patient groups with hypotony and bleb leak occurred during the 1st month after bleb revision, after which the percentage of success was maintained. Eyes with dysesthetic bleb failed during the 1st year, after which the success rate remained unmodified. The two eyes that required glaucoma surgery for decreasing IOP were part of the group with dysesthetic bleb. One patient required a second trabeculectomy, and the other received an Ahmed valve implant. These observations are consistent with the slightly lower success rate observed in patients with dysesthetic bleb<sup>(9)</sup> and could be considered a warning sign for glaucoma surgeons. In our view, patients must have critical dysesthetic blebs to justify bleb revision, which can destabilize a previously functioning bleb.

Dietlein et al.<sup>(18)</sup> reported success in 11 of 12 eyes treated for late macular hypotony after trabeculectomy with the subconjunctival implantation of Ologen just above the scleral flap to exert counter-pressure on the flap. One patient in this study required secondary conjunctival advancement because of localized implant exposure postoperatively, and another patient required medical treatment for postoperative corneal dellen. Only 16.6% of patients

required antiglaucomatous topical medication at 6 months of follow-up. These results suggest that the scleral patch included in our surgical approach (Figure 2) may eventually be replaced by the use of a matrix (Ologen).

In this study, the percentage of eyes requiring treatment with glaucoma medication after bleb revision increased from 13% to 56.5%, a postoperative outcome that agrees with increase from 41.2% to 62% reported in the literature<sup>(12-17,19)</sup>. Although the percentage of patients requiring hypotensive drops was significant, an average of one drop per eye was sufficient to achieve a mean IOP of 10.9 mmHg, which is appropriate for patients with advanced glaucoma. Two independent studies on bleb revision with short mean follow-up periods (10 and 6 months) reported low percentages (6% and 16.6%, respectively) of patients requiring glaucoma medication<sup>(18,20)</sup>.

With respect to the complications in our study, only one patient (4.3%) required a second bleb revision to resolve persistent hypotony. Two other eyes (8.6%) required glaucoma surgery to lower IOP. These fractions are similar to those of independent reports in the literature (4%-10%)<sup>(9,10,16)</sup>. We also observed that 13% of eyes developed Seidel or bleb leak in the early postoperative period that resolved with medical management. Other studies in the literature have reported rates between 0% and 20% for bleb leaks requiring surgical management<sup>(9-11,13,15,21)</sup>. Au et al.<sup>(14)</sup> reported a rate of 33% for early postoperative Seidel that resolved spontaneously. Finally, 60.8% of the eyes in our study showed IOPs of  $>21$  mmHg on postoperative day 1, a parameter that was reduced to one eye (4.3%) at 1 week after surgery.

In summary, our results on bleb revision are similar to those reported in the literature. Bleb revision is a useful procedure for resolving late complications of trabeculectomy and preventing potentially devastating complications, such as endophthalmitis<sup>(22)</sup>. Using a strict outcome criteria, we observed a success rate of 47.8% with a qualified IOP of  $\leq 15$  mmHg and 65.2% with a qualified IOP of  $\leq 18$  mmHg in a survival analysis. Nevertheless, a patient with an IOP of  $>15$  mmHg during the follow-up may have an IOP of  $\leq 15$  mmHg at the last visit was considered a failure. Therefore, it was clinically quite promising, particularly in patients with severe-stage glaucoma, to observe that IOP was  $\leq 15$  mmHg in 95.7% of eyes at the last postoperative visit and that only 56.5% of eyes required glaucoma medication with a mean of one drop per eye. Notably, almost all of the reports in the specialized literature have evaluated surgical procedures performed by more than one surgeon using different techniques, thereby making the results less reproducible for other glaucoma surgeons<sup>(9,11-18)</sup>. On these grounds, we propose herein a reproducible algorithm approach for the surgical management of late-onset bleb complications that has results similar to those reported in the literature. Such an approach can be particularly useful for less experienced surgeons. Thus, we now advise the development of new prospective randomized trials to define the best management and surgical procedures for late-onset bleb complications.

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