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Long-Term Outcomes from an Intraoperative Bleb Needling Procedure Augmented with Continuous Infusion

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Purpose: To investigate long-term outcomes of a modified bleb needling technique performed in the operating room in controlling intraocular pressure (IOP) and to report risk factors for procedure failure.

Design: Retrospective, observational cohort study.

Participants: One hundred six eyes of 98 consecutive patients undergoing intraoperative bleb needling with a continuous infusion of balanced salt solution at the Wilmer Eye Institute, Johns Hopkins Hospital, in the setting of a failed trabeculectomy or express shunt, between May 2011 and December 2015.

Methods: Postoperative data were collected between May 2011 and August 2019. Success was defined as achieving a previously determined target IOP regardless of (qualified success) or without (complete success) glaucoma medications. Patients who underwent additional glaucoma surgery were censored in the survival analysis.

Main Outcome Measures: Primary outcome measures included IOP, attainment of target IOP, and number of glaucoma medications used at different time points pre- and post-operatively.

Results: Needling was performed in 106 eyes at an average of 4.3 years from the time of trabeculectomy (standard deviation [SD], 6.5 years) and an average baseline IOP of 20.7 mmHg (SD, 7.2 mmHg). Further glaucoma surgery was required for 33 eyes. We observed a 70% qualified success rate with a mean IOP lowering of 25% (95% confidence interval [CI], 13.8%−36.4%) at 1 year after surgery and a 52% qualified success rate and 44.3% reduction in IOP (95% CI, 34.9%−53.6%) at 5 years after surgery. Nearly half and a third of the eyes did not require medications after 1 and 5 years, respectively. The average medication reduction was 0.8 at year 1 (95% CI, 0.5−1.1) and 0.4 at year 5 (95% CI, −0.2 to 1.0). Postoperative complications were uncommon. Poorer outcomes were not associated with the age of the bleb but were more likely in Black patients.

Conclusions: Reductions in IOP were maintained in most patients over the long term using a modified bleb needling technique, despite an average time from trabeculectomy of over 4 years. No significant adverse events were observed. Bleb needling may defer or avoid more invasive procedures such as tube-shunts or repeat trabeculectomy. *Ophthalmology Glaucoma 2021;4:244-250 © 2020 by the American Academy of Ophthalmology*

The only known treatment for glaucoma is lowering intraocular pressure (IOP) using medications, laser treatments, surgical procedures, or a combination thereof. Trabeculectomy is a common surgical method for reducing IOP in glaucoma patients and involves the creation of a filtration bleb to allow egress of aqueous humor from the eye.[1] Studies from around the world report a 40% to 75% success rate for the procedure after 3 to 5 years.[2−4] Approaches for managing failing filtration blebs, including bleb massage and scleral flap suture lysis, may be effective in the early postoperative period but do not seem to be effective in recovering bleb function in late bleb failure.[5−9] Management of late bleb failure may involve adding medications to lower IOP, but additional incisional surgery such as repeat trabeculectomy or glaucoma drainage device surgery often is performed, sacrificing healthy conjunctiva and subjecting the patient to additional surgical risks.

Another approach for failed trabeculectomies is to reestablish aqueous outflow through the original trabeculectomy using a needle to lyse the scar tissue that has formed. Bleb needling can be performed using a slit-lamp microscope in an office setting. However, such an approach has highly variable success rates, with some as low as 13%, possibly because of the technical challenges posed by positioning the patient at the slit lamp, limited mobility and maneuverability, and difficulty in directly visualizing successful lysis of adhesions.[10]

In a previous study, we found that a modified intraoperative bleb revision technique maintained IOP at or less than the target IOP in 64% of patients after 12 months, inclusive of those taking IOP-reduction medications.[11] To

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Table 1. Patient Characteristics of Eyes That Underwent the Modified Bleb Needling Procedure

Characteristics	Observations*	Mean	Standard Deviation
Patient age (yrs)	106	66.9	13.4
Gender, no. (%) female	54 (50.9)		
Ethnicity, no. (%)			
White	39 (36.8)		
Black	55 (51.9)		
Asian	7 (6.6)		
Native American /Pacific Islander	1 (0.9)		
Other	4 (3.8)		
Age of bleb (yrs)	103	4.3	6.5
Baseline IOP (mmHg)	106	20.7	7.2
Target IOP (mmHg)	106	14.3	3.0
Follow-up (yrs)†	106	2.9	1.9
Glaucoma medications before needling	106	2.0	1.0
Repeat needlings	19	1.4	1.0

IOP = intraocular pressure.
*Reported per eye among 98 total patients.
†Patients were followed up until they either underwent a revision procedure or were lost to follow-up. Patients with less than 3 months of follow-up were excluded from the study, unless an invasive glaucoma surgery was performed in that period.

control for patient movement and to visualize successful lysis better, this needling procedure is performed in the operating room with a continuous infusion of balanced salt solution into the anterior chamber. In the present study, we expanded on our previous work to study success rates of bleb needling by multiple surgeons in maintaining the IOP at or less than target over up to 5 years of follow-up. We also report needling-related complications and revision surgeries that occurred during this period.

Methods

Patient Selection

This retrospective chart review was approved by the Johns Hopkins Medical Institute Institutional Review Board, which provided a waiver of informed consent. The research complied with the Declarations of Helsinki. Participants for this study were individuals who underwent an intraoperative bleb needling procedure in the setting of a failed trabeculectomy or express shunt between May 2011 and December 2015 and had at least 6 months of follow-up between May 2011 and August 2019, regardless of bleb type. Patients who were younger than 18 years or underwent needling performed with a different technique were excluded. Preoperative and postoperative data collected include demographic information, target IOP, IOP at baseline and follow-up visits, glaucoma medications, postoperative complications, past ocular surgeries, and additional ocular conditions. For patients in whom target IOP was not clearly identified, the case notes from before the needling procedure (masked to the outcome of needling) were reviewed by the attending surgeon to determine the appropriate target IOP.

Surgical Technique

The surgical technique for the modified intraoperative bleb needling procedure with continuous infusion has been described previously in detail.[1] Briefly, the patient is brought to the operating room, administered sub-Tenon anesthesia or topical anesthesia, and draped in a sterile manner. A 25-gauge infusion cannula with balanced salt solution is placed in the anterior chamber to provide fluid pressure at a bottle height of approximately 100 cm. A stay suture is placed in the superior aspect of the corneal stroma to infraduct the eye and provide adequate exposure of the bleb. A 25-gauge needle then is used to enter the bleb from at least 3 mm away from the bleb site (usually posterior, but at times lateral) to lyse fibrotic adhesions within the bleb until a diffuse elevated bleb is noted. A subconjunctival injection of 5-fluorouracil or mitomycin C on a blunt 30-gauge canula is administered using the same conjunctival opening at the conclusion of each procedure. Rarely, a suture is placed through the conjunctival opening made by the needle.

Outcome Measures

Primary outcome measures included IOP measurements, attainment of target IOP, and number of glaucoma medications used at each time point (before the procedure and months 1, 3, and 6 and years 1, 2, 3, 4, and 5 after the procedure). Patients who were lost to follow-up within 6 months of needling were censored from the calculation. Eyes that had undergone further glaucoma surgery at any time point after needling, including those within 6 months, were included as treatment failures.

Secondary outcome measures included incidence of intraoperative and postoperative complications, including bleb leaks, bleb-related infections, hyphema, conjunctival buttonholes, blebitis, bleb-related endophthalmitis, and hypotony, as defined by an IOP of less than 6 mmHg in the presence of a shallow anterior chamber, choroidal folds or detachment, or all three. Any subsequent procedure was recorded, including further glaucoma operations, cataract extraction, intravitreal injections, or revision or repair of trabeculectomy.

Complete success was achieved when a patient maintained an IOP at or less than the predetermined target IOP and did not require glaucoma medications, whereas qualified success included those achieving an IOP at or less than the target with or without glaucoma medication. Failure was defined when a patient did not achieve an IOP at or less than the target IOP with medications, experienced a serious complication, or underwent additional trabeculectomy or glaucoma implant surgery. Repeat needling procedures were not considered failures.

Statistical Analysis

The paired Student *t* test was used to compare IOP and number of medications before and after the modified bleb needling procedure was performed at various time points. Kaplan-Meier plots were used to estimate the probability of success over time. Cox proportional hazards models were used to assess risk factors for failure.

Results

Patient Characteristics

A total of 106 eyes of 98 consecutive patients meeting inclusion criteria were identified, with an average follow-up time of 2.9 years (standard deviation [SD] 1.9 years; Table 1). Half the patients were

Table 2. Reductions in Intraocular Pressure and Glaucoma Medications over Time

	No. of Eyes	Average Intraocular Pressure Percentage Reduction from Baseline (95% Confidence Interval), %	Average Glaucoma Medication Reduction from Baseline (95% Confidence Interval)
Month 1	98	26.0 (18.9–33.1)	1.1 (0.9–1.4)
Month 3	78	25.7 (17.3–34.1)	0.9 (0.6–1.1)
Month 6	80	31.3 (25.0–37.6)	0.8 (0.5–1.1)
Year 1	82	25.1 (13.8–36.4)	0.8 (0.5–1.1)
Year 2	68	31.0 (23.8–38.3)	0.6 (0.3–1.0)
Year 3	57	36.3 (27.5–45.1)	0.7 (0.3–1.1)
Year 4	53	37.8 (29.3–46.4)	0.6 (0.2–1.0)
Year 5	29	44.3 (34.9–53.6)	0.4 (−0.2 to 1.0)

women. The average age was 66.9 years (SD, 13.4 years), and the average time from the failed trabeculectomy to the needling procedure was 4.3 years (SD, 6.5 years). The mean target IOP was 14.3 mmHg (SD, 3.0 mmHg; range, 8–25 mmHg), and the average baseline IOP, which was measured at the visit before the procedure, was 20.7 mmHg (SD, 7.2 mmHg; range, 5–58 mmHg). Eight eyes underwent needling at IOPs lower than target because of simultaneous cataract extraction (measured, 5 mmHg, and target, 8 mmHg; measured, 10 mmHg, and target, 16 mmHg; and measured, 10 mmHg, and target, 12 mmHg), irritation from excessive eye drops (measured, 12 mmHg, and target, 15 mmHg), visual field loss (measured, 17 mmHg, and target, 21 mmHg; and measured, 16 mmHg, and target, 18 mmHg), progressive retinal damage on OCT (measured, 17 mmHg, and target, 20 mmHg), and for an undocumented reason (measured, 14 mmHg, and target, 20 mmHg). A sensitivity analysis excluding these eyes did not result in notable changes in the results of this study. Patients were using an average of 2.0 (SD, 1.0; range, 0–4) glaucoma medications before the procedure. Nineteen eyes (17.9%) required repeat needling, with a mean of 1.4 additional needlings (SD, 1.0) among them.

Reductions in Intraocular Pressure and Glaucoma Medications

Postoperative IOP was significantly lower than baseline IOP at all time points ($P < 0.05$) of follow-up. The mean IOP percent reduction among those whose treatment did not fail was 26% (95% confidence interval [CI], 18.9%–33.1%) at month 1, 25.1% (95% CI, 13.8%–36.4%) at 1 year, and 44.3% (95% CI, 34.9%–53.6%) at 5 years. The average reductions in glaucoma medications in this group were 1.1 (95% CI, 0.9–1.4) at month 1, 0.8 (95% CI, 0.5–1.1) at year 1, and 0.4 (95% CI, −0.2 to 1.0) at 5 years. Additional time points are listed in Table 2 and are displayed in Figure 1.

Needling Success Rates

A survival curve analysis analyzing the success rate of the procedure is shown in Figure 2. Patients were followed up until the end of their follow-up period. At 5 years after surgery, the complete success rate of the procedure was 27.5%, and the qualified success rate was 52.2%.

Procedure Failures

Among the 33 eyes that underwent more invasive glaucoma surgery, 30 were repeat trabeculectomies, and 3 were tube–shunt implantations. No patients experienced treatment failure because of postoperative complications.

Repeat Needling

A summary of the outcomes in the 19 eyes that underwent repeat needling is shown in Table 3. Among these eyes, most underwent 1 repeat needling. Those who underwent 1 needling only

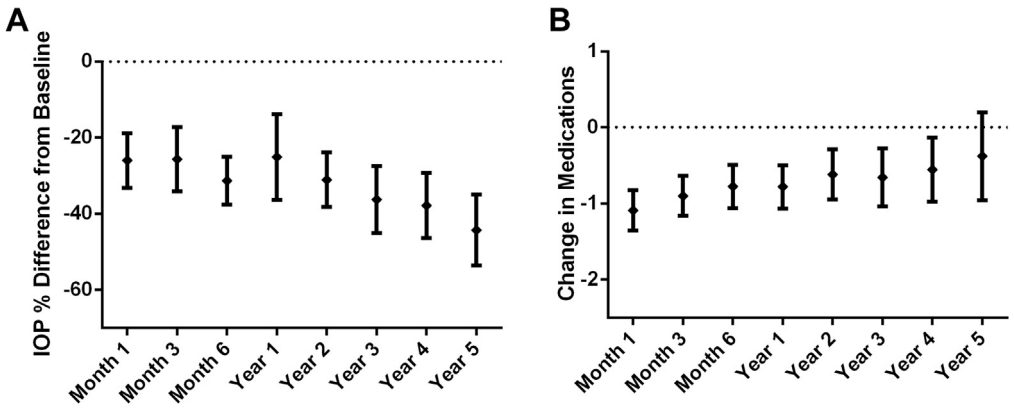

Figure 1. Graphs showing additional time points for postoperative intraocular pressure. **A**, Intraocular pressure (IOP) percentage difference from baseline. **B**, Change in medications.

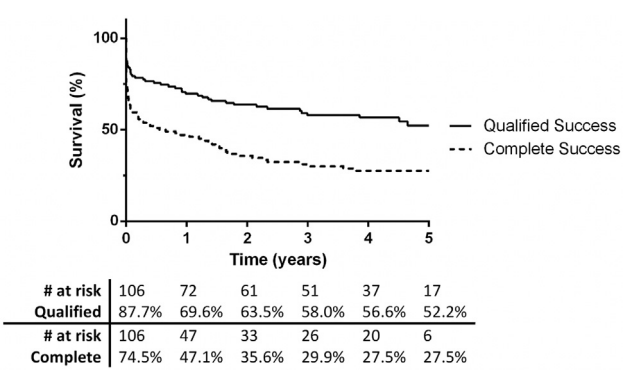

Figure 2. Survival curve for eyes that underwent the modified bleb needling procedure. The number at risk and success rates are provided at yearly time points. Qualified success included eyes that maintained intraocular pressure (IOP) at less than target regardless of glaucoma medications, whereas complete success included only eyes that maintained IOP at less than target without the use of glaucoma medications. Eyes also were considered to have experienced treatment failure when a repeat trabeculectomy or tube shunt implantation was performed. Values at zero represent those for postoperative day 1.

demonstrated a complete success rate of 21.4% and a qualified success rate of 42.9% after 5 years (n = 14). For the entire group of 19 patients, the complete success rate was 31.6%, whereas the qualified success rate was 52.6%, allowing for additional repeat needlings in the 5 patients who underwent more than 1 repeat needling. A survival analysis for eyes requiring repeat needling found that after 5 years, the qualified success rate was 58.7%, whereas the complete success rate was 34.0% (Fig 3).

Risk Factors for Needling Failure

The possible risk factors for failure are listed in Table 4. Under the qualified definition of success, patients who were Black showed a higher failure rate (hazard ratio [HR], 3.60; 95% CI, 1.50−8.66). Surgeon 4 demonstrated a higher risk of failure (HR, 8.75; 95% CI, 1.40−56.63) but operated on only 2 eyes that had both experienced treatment failure in the study. Other surgeons who operated on fewer than 10 patients were surgeons 2, 3, and 5, who saw failures in 2 of 6 patients, 1 of 4 patients, and 1 of 2 patients, respectively. Surgeons 1, 6, and 7 saw failures in 29 of 64 eyes, 8 of 17 eyes, and 6 of 11 eyes. Under the complete definition of success, failure was again higher in Black patients (HR, 2.31; 95% CI, 1.21−4.39), whereas no significant differences were found in failure rates among the surgeons. The time from original trabeculectomy was not a significant risk factor under either definition of qualified or complete success (HR, 1.00 [95% CI, 0.95−1.06] and 1.01 [95% CI, 0.97−1.05]).

Postoperative Complications

Eight eyes demonstrated hyphemas, all of which resolved without surgical intervention, 12 eyes experienced either shallow anterior chamber (n = 7) or iris−cornea touch (n = 5), with no cases of lens−cornea touch. All of these complications resolved spontaneously. A bleb leak occurred in 1 eye, requiring surgical intervention when the bleb was punctured during postoperative injection of 5-fluorouracil. No cases of blebitis, endophthalmitis, conjunctival buttonholes, choroidal hemorrhages, or permanent vision loss were associated with the procedure.

Table 3. Absolute and Total Success Rates of the Eyes Requiring Repeat Needling

No. of Repeat Needlings	Observations	Qualified Success	Complete Success
1	14	6 (42.9%)	3 (21.4%)
2	4	3 (75.0%)	3 (75.0%)
5	1	1 (100%)	0 (0.0%)
Total	19	10 (52.6%)	6 (31.6%)

Discussion

Our surgical technique of performing bleb needling with a continuous infusion of balanced salt solution in the operating room was successful at achieving target IOP without medications in about 1 in 4 individuals over 5 years. When those requiring additional eye drops were included as successes, the success rate was 52% at 5 years, with a 44% average reduction in baseline IOP. No vision-impacting postoperative complications occurred.

Others have reported on bleb needling as a safer alternative to more invasive surgeries.[12−15] Although serious complications such as so-called kissing choroidal detachment requiring surgical drainage, suprachoroidal hemorrhage, malignant glaucoma, and endophthalmitis have been reported rarely after bleb needling, in this case series of more than 100 eyes, we did not encounter any.[14] In comparison, repeat trabeculectomy and implantation of a tube shunt have been shown to have postoperative complications ranging from 20% to 37% after 5 years of follow-up, with rates of failure ranging from 29% to 47%, with serious complications requiring reoperation, producing vision loss of at least 2 Snellen lines, or both.[16]

Publications describing other techniques to manage failing blebs are limited, although an ab interno bleb needling revision technique has been described.[17] The success rate was reported to be 58% after 3 years, comparable with results seen with our technique.[18] When comparing these procedures, needling with continuous infusion can be used for all failing blebs, whereas the ab interno procedure may make it more difficult to lyse the episcleral tissue binding down the scleral flap safely when the flap is scarred down and excessive scar tissue obscures the outline of the flap. However, concurrent gonioscopy may mitigate this risk and may demarcate better the plane for dissection. Suprachoroidal hemorrhages also were reported with the ab interno technique, although we did not encounter any major complications in our study.[18] Repeat revisions were also of limited benefit, with 5 of 10 failing by 6 months.[18]

One benefit of bleb needling is that it can be repeated, because fibrotic adhesions may reoccur despite apparent needling success, or existing fibrotic adhesions may not be lysed sufficiently with the initial procedure. Fifty-three percent of patients in this study who required a repeat

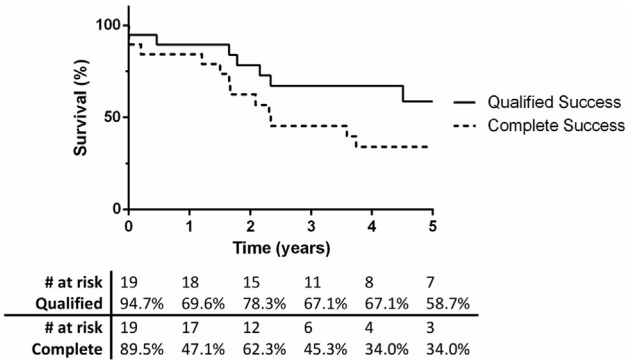

Figure 3. Survival curve for eyes that underwent repeat needlings using the modified bleb needling procedure. The number at risk and success rates are provided at yearly time points. Qualified success included eyes that maintained intraocular pressure (IOP) at less than target regardless of glaucoma medications, whereas complete success included only eyes that maintained IOP at less than target without the use of glaucoma medications. Eyes also were considered failures when a repeat trabeculectomy or tube shunt implantation was performed. Values at zero represent those for postoperative day 1.

needling achieved successful outcomes, whereas one third did not require medications measured at 5 years after surgery. Using a balanced salt solution infusion during the procedure provided the surgeon with intraoperative feedback and increased the likelihood of needling success, because it is obvious when the bleb needling has established flow. Surgeons who perform needling without concurrent continuous infusion do not have immediate feedback and may manipulate the tissue excessively, which may contribute to the higher rates of hypotony reported in the literature.[19,20] Thus, with a continuous infusion, the surgeon is more likely to conclude the procedure when a bleb has been re-established sufficiently. Furthermore, the fluid wave acts to dissect the tissue, further lysing adhesions and increasing the area of fluid outflow. In this series, less than 20% of eyes required a repeat needling procedure and experienced similar success rates as eyes that underwent needling only once. Although the extent to which an eye can be needled repeatedly is not explored thoroughly in this study, one atypical eye of a patient who did not want to undergo any additional major glaucoma surgeries underwent needling 5 times and experienced success with medications.

One important strength of this retrospective study is the inclusion of data from 7 surgeons. We do not have a standardized protocol at Wilmer for how to perform bleb needlings, but all use the same basic approach including an infusion canula. Although 1 surgeon seemed to achieve slightly lower qualified success, this surgeon operated on only 2 patients for this study. Overall, all surgeons were able

Table 4. Hazard Ratios for Risk of Failure after Modified Bleb Needling

	Failure (Qualified)		Failure (Complete)	
	Hazard Ratio (95% Confidence Interval)	P *Value*	*Hazard Ratio (95% Confidence Interval)*	P *Value*
Patient age	1.01 (0.98–1.03)	0.54	1.00 (0.98–1.02)	0.75
Race				
White	Reference	Reference	Reference	Reference
Black	3.60 (1.50–8.66)	**0.004**	2.31 (1.21–4.39)	**0.01**
Asian	3.53 (0.95–13.22)	0.06	1.88 (0.69–5.13)	0.22
Native American	3.33 (0.32–34.59)	0.31	8.47 (0.88–81.23)	0.06
Other	4.56 (0.69–30.38)	0.12	3.74 (0.83–16.80)	0.09
Gender				
Male	Reference	Reference	Reference	Reference
Female	1.09 (0.54–2.18)	0.81	0.63 (0.36–1.11)	0.11
Diagnosis				
Open-angle glaucoma	Reference	Reference	Reference	Reference
Closed-angle glaucoma	0.55 (0.06–4.86)	0.59	1.86 (0.54–6.39)	0.33
Glaucoma (unspecified)	1.71 (0.27–10.67)	0.57	1.07 (0.19–5.90)	0.94
PXF glaucoma	3.94 (0.70–22.04)	0.12	2.02 (0.41–9.91)	0.39
Uveitic glaucoma	0.95 (0.20–4.48)	0.95	0.49 (0.07–3.62)	0.48
Age of bleb (yrs)	1.00 (0.95–1.06)	0.94	1.01 (0.97–1.05)	0.77
Baseline IOP (mmHg)	0.99 (0.94–1.05)	0.72	1.03 (0.99–1.07)	0.12
Target IOP (mmHg)	1.01 (0.89–1.14)	0.84	0.94 (0.85–1.03)	0.18
Surgeon (failures/cases)				
1	Reference	Reference	Reference	Reference
2	0.84 (0.15–4.69)	0.85	0.69 (0.20–2.36)	0.55
3	0.73 (0.06–8.30)	0.80	0.21 (0.02–2.00)	0.17
4	8.75 (1.40–54.63)	**0.02**	2.12 (0.39–11.67)	0.39
5	1.13 (0.11–11.81)	0.92	5.03 (0.90–28.06)	0.07
6	2.01 (0.79–5.09)	0.14	1.48 (0.69–3.18)	0.31
7	1.73 (0.58–5.14)	0.32	0.85 (0.32–2.26)	0.75

IOP = intraocular pressure; PXF = pseudoexfoliation.
Hazard ratios for failure under the definitions of qualified and complete success are provided for patient and clinical characteristics, as well as the operating surgeon for the modified needling technique. Boldface indicates statistical significance.

to achieve the results reported here, indicating that this procedure can be used more widely. The contribution of patient race to the success of bleb needling is consistent with a previous study using a slit-lamp needling procedure[2] and with the many publications showing that success rates of trabeculectomy are substantially lower among Black patients.[21–24]

This was a retrospective analysis of procedures performed at Wilmer, and by definition, data collection did not occur at uniform time points and was collected for clinical care and therefore, was not always complete. The study also had variable follow-up: 19 eyes had at least 5 years of follow-up, whereas 33 eyes that had required either a repeat trabeculectomy or shunt placement ended the follow-up for the study. Among the 54 remaining eyes, 38 eyes had needling dates after October 2014, which limited their follow-up period to less than 5 years. Despite this limitation, 39 eyes had at least 4 years of follow-up, 54 eyes had at least 3 years of follow-up, and 19 eyes had less than 3 years of follow-up. We also may have missed some complications that were not documented. Also, we devised no standardized criteria for when patients would undergo additional surgeries or repeat needlings, which likely affected the success rate of the procedure.

In this study, we expanded on our previous study of a modified bleb needling procedure performed in the operating room for revision of failed filtering blebs. Unlike bleb needling performed at the slit lamp, our procedure provides visual, real-time feedback of when aqueous flow to the bleb is re-established. A high success rate for achieving target IOP was maintained with minimal complications in the long term, despite an average of 4.3 years since the original trabeculectomy. Although our findings were limited by the number of eyes remaining in the study after 5 years, the modified needling procedure described in this article may delay or avoid the need for further glaucoma surgery in patients with failed filtering blebs and should be considered as an alternative to office-based or traditional needling methods.

Footnotes and Disclosures

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No animal subjects were included in this study.

Author Contributions:

Conception and design: Kim, Iyer, Aziz, Friedman

Analysis and interpretation: Kim, Iyer, Aziz, Friedman

Data collection: Kim, Iyer, Aziz, Friedman

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Overall responsibility: Kim, Iyer, Aziz, Friedman

Abbreviations and Acronyms:
HR = hazard ratio; **IOP** = intraocular pressure; **SD** = standard deviation.

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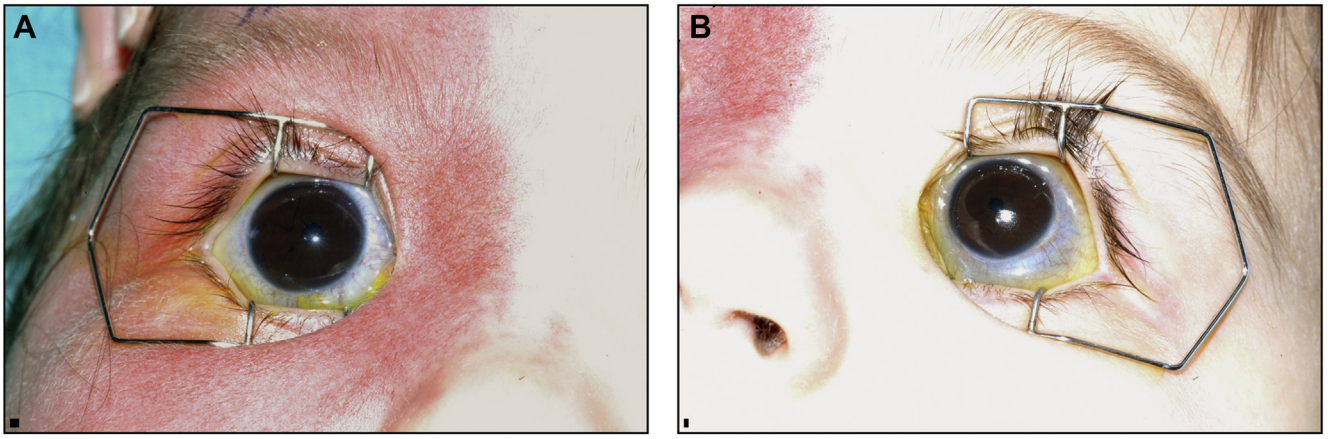
Pictures & Perspectives



Phakomatosis Pigmentovascularis

A 38-day-old Asian-White girl was diagnosed with phakomatosis pigmentovascularis (PPV) given the combination of Sturge-Weber syndrome in her right eye (OD) (Fig **A**) and ocular melanosis in both eyes (Figs **A**, **B**). Phakomatosis pigmentovascularis is a rare neural crest disorder with both pigmentary and vascular congenital lesions. Usually found in Asian individuals, PPV typically occurs sporadically but can be caused by somatic mutations in the *GNA11* or *GNAQ* genes. These patients can have neurologic and musculoskeletal disorders, as well as glaucoma. This patient developed seizures at age 2 weeks and had a goniotomy in her OD at age 3 months for uncontrolled glaucoma (Magnified version of Fig **A**-**B** is available online at www.ophthalmologyglaucoma.org/).

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