Clinical Evaluation of Intra-Bleb Pigmentation after Trabeculectomy: A Case-Control Study

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Objective: *To evaluate the clinical status of a filtering bleb with visible pigment (intra-bleb pigmentation, IBP), in a case-controlled manner.*
Material and Method: *Forty-one patients with IBP and 40 patients without visible pigment in blebs (controls) were enrolled from the authors' clinic. All patients underwent either trabeculectomy alone or combined cataract extraction with intraocular lens implantation and trabeculectomy.*
Results: *Mean follow-up period was 22.8 months. Complete success (final IOP < 22 mmHg without additional treatment) was achieved more often in IBP patients (82.9%) than in controls (60%, p = 0.022). Median survival time was greater in IBP patients (49.9 $\pm$ 0 months) than in controls (35.5 $\pm$ 4.9 months, p = 0.013). Regression analysis revealed that IBP was associated with thin and cystic blebs (p = 0.023). Sex, age, eye, diagnosis, procedure, and mitomycin C had no effect on IBP development. IBP grading, location, and appearance did not relate to the success rate or bleb characteristics.*
Conclusion: *IBP appears to be a favorable sign in filtering blebs, in terms of complete success and survival time, because IBP is associated with thin-walled blebs. Clinicians should carefully observe patients for IBP when evaluating filtering blebs.*

Keywords: *Asian continental ancestry group, Glaucoma, Pigmentation disorders, Trabeculectomy, Treatment outcome*

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Evaluation of filtering blebs is necessary because bleb characteristics relate to function. Kronfeld classified blebs into three types[1]. Type I blebs are thin and polycystic and are considered to be functional blebs because the aqueous humor can flow across the conjunctival epithelium into the tear film. Type II blebs are moderately thicker than Type I and are functional. Type III blebs are flat and scarred and are considered to be non-functional blebs because the scarred conjunctiva adheres to the episcleral tissue, obstructing fluid from the anterior chamber (AC). In addition, encapsulated blebs (Type IV), dome-shaped, and thick-walled blebs are represented by Tenon's capsule with entrapped aqueous, another type of non- functional bleb[2].

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In addition to the bleb characteristics mentioned above, many filtering blebs have visible pigment underneath the conjunctival epithelium after trabeculectomy. A few case reports have mentioned the pigment in filtering blebs. In full-thickness filtering surgery, the sclerectomy site provides a fistula to view uveal structures transconjunctivally. Ticho and Ivry[3] reported a case of argon laser reopening of the sclerectomy site after Scheie's procedure and reported pigment dispersion within the bleb. Ulrich et al[4] reported a histopathologic study of an excised overhanging bleb following full-thickness filtering surgery. The tissue revealed numerous melanin granules at the peripheral cornea. Some reports mentioned a pigmented membrane at the sclerectomy site[5,6]. In guarded filtering surgery, unlike full-thickness filtering surgery, a scleral flap covers the internal sclerectomy site. The underlying uveal structures cannot be seen through the conjunctiva.

In addition, Shields et al[7] reported focal pigment aggregation in subepithelial tissues in a histopathologic study of filtering blebs with trabeculectomy and adjunctive mitomycin C (MMC). The authors did not mention the pigment in the clinical examination. In a preliminary study, the authors examined 10 eyes from eight patients with filtering bleb with intra-bleb pigmentation (IBP), and reported that the success rate was 90% for the 11-month follow-up period[8].

The present study examined whether or not IBP in trabeculectomy is a favorable sign. A case-control study of IBP was conducted to evaluate the success rate of the IBP group compared to controls. Other clinical aspects were also investigated.

Material and Method

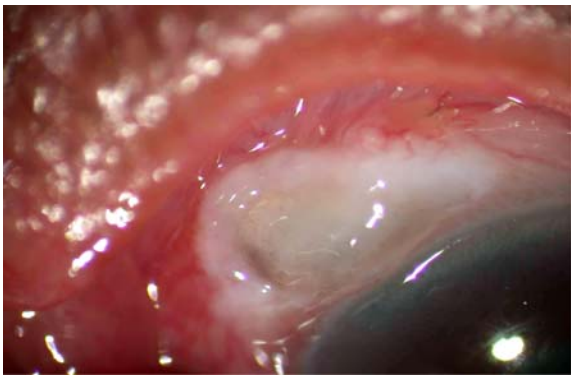
Definition of IBP

IBP was defined as a filtering bleb with visible subconjunctival pigment. IBP characteristics were classified by grading, appearance, and location. IBP was classified into three grades according to pigmentation visible by broad-beam light of the slit lamp. Grade I was light brown pigmentation, grade II was brown pigmentation, and grade III was dark brown or almost black pigmentation (Fig. 1). Appearance of IBP was defined as either a clump or discrete pigment (Fig. 2). Location of IBP was determined, using the slit lamp, as either overlying the sclera, or underneath the conjunctival epithelium (Fig. 3).

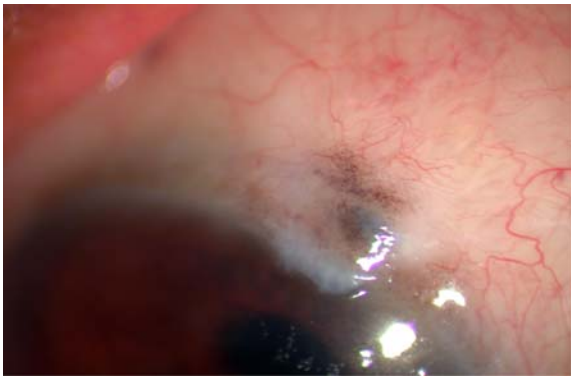
Patient selection

Consecutive glaucoma patients, who underwent trabeculectomy or combined phacoemulsification with intraocular lens (IOL) implantation and trabeculectomy (combined surgery) between January 1998 and June 2002, were recruited to the study. Forty-two patients demonstrated IBP during the study period. The authors' previously reported patients (n = 8) were also included in this group. One case was excluded because the patient, an 8-year old boy, developed endophthalmitis related to trabeculectomy nine months postoperatively. He had undergone pars plana vitrectomy for endophthalmitis and later developed phthisis bulbi. Forty consecutive patients without IBP were selected to be a control group, and were followed-up for the study period.

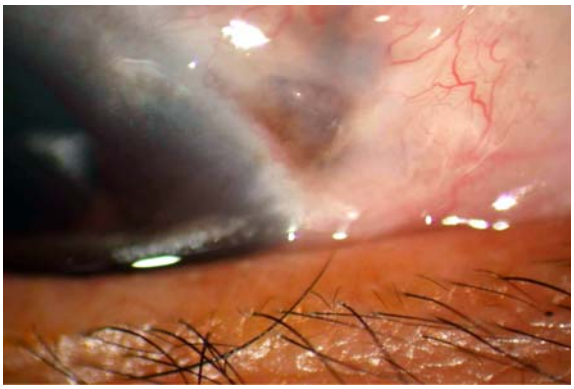
A preoperative history and ocular examination, including visual acuity test, slit lamp examination, Goldmann applanation tonometry, gonioscopy, dilated ophthalmoscopy, optic disc evaluation, and Humphrey visual field test were obtained. Indication for trabeculectomy was uncontrolled glaucoma (IOP $\geq$ 22 mmHg) despite medication and/or laser treatment. The indication for combined surgery was coexisting cataract and uncontrolled glaucoma, either with or without medication. For patients who did not tolerate medication, even an IOP of less than 22 mmHg was considered an indication for surgery. Patients with



A: Grade I IBP: light brown pigmentation

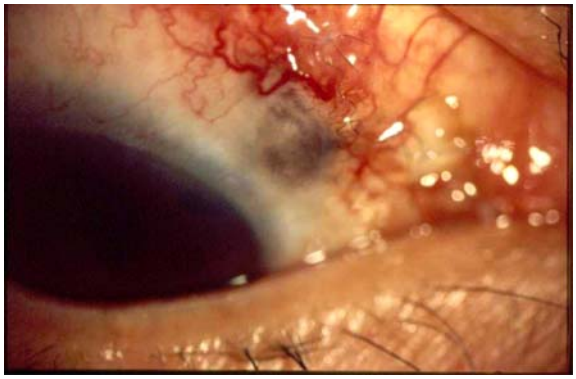


B: Grade II IBP: brown pigmentation

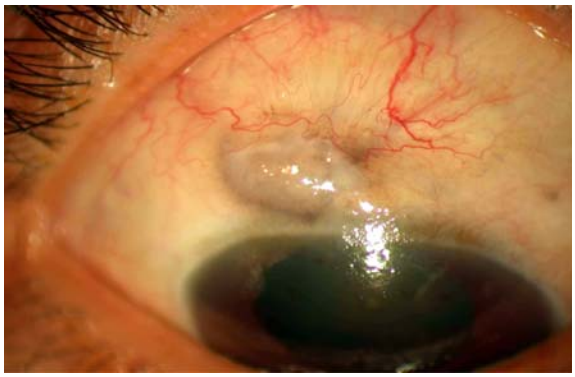


C: Grade III IBP: dark brown pigmentation

Fig. 1 IBP grading



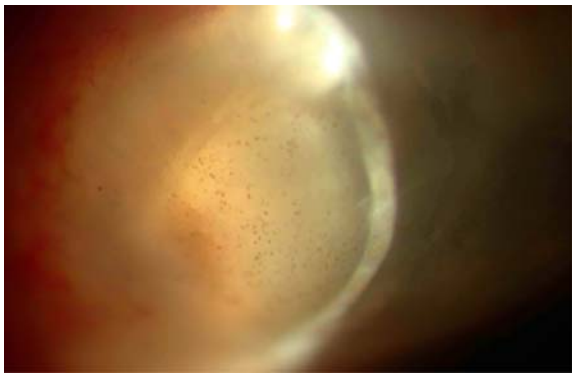
A: Clump of pigment in the filtering bleb. The black nylon suture is seen above the IBP



B: Discrete pigments or starry sky pattern of pigment

Fig. 2 IBP appearance

A: IBP overlying the scleral bed of trabeculectomy



B: Slit light demonstrates IBP scattered underneath the conjunctival epithelium

Fig. 3 IBP location in the bleb

angle-closure glaucoma had undergone laser iridectomy at the time of diagnosis. Informed consent was obtained from all patients. All surgical procedures were performed by one surgeon (BW).

If the patients underwent bilateral eye surgery, the first eye was selected for the present study. If the patient had bilateral IBP, the authors selected the first eye in which IBP was detected.

Surgical techniques

Trabeculectomy was performed with a standard technique[9] under local anesthesia. In brief, the authors performed a superior limbus-based conjunctival incision and a triangular scleral flap incision. Mitomycin C (0.4 mg/ml), if used, was then locally applied for 2 to 4 minutes on the scleral bed, followed by irrigation with a balanced salt solution. A corneal paracentesis was made, and internal sclerectomy with basal iridectomy was performed. The scleral flap and conjunctival incision were sutured. Reformation of the AC was performed and the blebs were examined for leaks.

Combined surgery was performed in a separate site. In brief, the authors first performed a temporal clear cornea incision phacoemulsification and IOL implantation, then a superior site trabeculectomy. All patients received topical corticosteroid and antibiotic for four weeks or until the intraocular inflammation subsided, then the drugs were tapered off.

Routine postoperative examination was performed by both observers at 1 day, 1 week, 1 month, 3 months, and at 3-month intervals thereafter. Filtering

blebs were classified into four types as mentioned above. IOP and other relevant complications were recorded. Complications were managed as necessary. The follow-up visits were sometimes more frequent. If cataracts developed after trabeculectomy, clear corneal incision phacoemulsification or extracapsular cataract extraction (ECCE) with IOL implantation was subsequently performed.

Definition of outcome measures

Overall success of the procedure was defined as a final IOP of less than 22 mmHg. Complete success was defined as a final IOP of less than 22 mmHg without additional glaucoma medications or transconjunc-tival needling revision (TCNR). Qualified success was defined as an IOP of less than 22 mmHg with medication or if TCNR was performed. If preoperative IOP was less than 22 mmHg, IOP reduction of greater than 20% was defined as success. The procedure was considered a failure if the IOP was 22 mmHg or higher with additional medications, or glaucoma surgeries. Hypotony was defined as an IOP less than or equal to 5 mmHg.

Results

All patients were Asian. There were 41 IBP cases and 40 control cases. Of the 41 IBP cases, 17 (41.5%) were male and 24 (58.5%) were female (mean age = 64.9 years old; range, 39-90). There were five cases (12.5%) with diabetes mellitus. The iris color of all patients was brown. Diagnosis and previous ocular surgery are shown in Table 1.

IBP occurred in 32 patients (78%) who underwent trabeculectomy and in nine cases (22%) of combined surgery. In the control group, there were 30 trabeculectomy cases (75%) and 10 combined surgery cases (25%). MMC was applied in 32 IBP cases (78%) and in 32 control cases (80%). Four types of IOL

Table 1. Demographic data of patients

	IBP (n = 41) n (%)	Controls (n = 40) n (%)	p-value
Gender			0.440
Male	17 (41.5%)	20 (50%)	
Female	24 (58.5%)	20 (50%)	
Mean age (SD)	64.9 (10.9)	60.5 (14.3)	0.123
Eye			0.420
OD	19 (46.3%)	15 (37.5%)	
OS	22 (53.7%)	25 (62.5%)	
Diabetes mellitus	5 (12.2%)	5 (12.5%)	0.967
Diagnosis			0.083
AACG	16 (39%)	5 (12.5%)	
CACG	18 (43.9%)	20 (50%)	
POAG	2 (4.9%)	6 (15%)	
Pseudophakic glaucoma	-	3 (7.5%)	
Exfoliation glaucoma	2 (4.9%)	2 (5%)	
Uveitic glaucoma	2 (4.9%)	2 (5%)	
AR syndrome	1 (2.4%)	1 (2.5%)	
Angle recession	-	1 (2.5%)	
Previous ocular surgery			0.549
Phaco	1	-	
Trabeculectomy	1	1	
Combined surgery	-	1	
Goniosynechialysis	-	1	
Phaco with GSL	1	-	
Pars plana vitrectomy	1	1	

IBP = intra-bleb pigmentation, AACG = acute angle-closure glaucoma, CACG = chronic angle-closure glaucoma, POAG = primary open-angle glaucoma, AR syndrome = Axenfeld-Rieger's syndrome. Phaco = phacoemulsification, GSL = goniosynechialysis

were used. Statistical analyses of these parameters indicated no statistically significant difference between IBP patients and control groups ($p > 0.05$) (Table 2).

Intraocular pressure and medication

In all patients, final IOP was significantly decreased from preoperative IOP ($p < 0.001$). Mean preoperative IOP in IBP patients was 33.39 mmHg (range, 11-64, SD 11.55). At the final visit, the mean IOP reduction was 19.27 vs. 16.60 mmHg ($p = 0.368$), and percent IOP reduction was 51.8% vs. 46.2% ($p = 0.331$), in the IBP and control groups, respectively. Mean final IOP after the procedures with or without adjunctive MMC was not significantly different, 14.12 vs. 14.95 mmHg, ($p = 0.525$). Mean IOP at 12, 24, 36, and 48 months was not different between groups ($p > 0.05$).

The mean preoperative number of medications was not statistically different. The mean medication reduction was 2.1 vs. 1.8 in the IBP and control groups, respectively ($p = 0.251$). Mean final number of medications of the groups, 0.32 vs. 0.55, was also not statistically different ($p = 0.212$).

Success rate and survival analysis

The mean follow-up period was 22.8 months (range, 2.03-55.77). The complete success of both groups was 71.6%, and overall success was 92.6%. Complete success was achieved more often in the IBP cases than in controls [34 (82.9%) and 24 cases (60%), respectively; $p = 0.022$, Chi-square test]. Overall success was 39 (95.1%) and 36 cases (90%, $p = 0.379$) (Table 3). Qualified success was 12.2% and 30%, respectively.

Of eyes with complete success, Kaplan-Meier survival analysis for the time to bleb failure was significantly greater in the IBP group than in the control group, median 49.9 vs. 35.5 months ($p = 0.013$, log rank test) (Fig. 4). For overall success, the Kaplan-Meier mean time of survival was 51.6 and 50.1 months, respectively ($p = 0.403$). The follow-up period was 54.6 vs. 55.8 months, respectively ($p = 0.354$) (Table 4).

Cox regression analysis of IBP patients and controls revealed that complete success was related to Type I blebs ($p = 0.037$) and diabetes mellitus ($p = 0.013$). Type II and Type III blebs were failure factors ($p = 0.007$ and $p = 0.035$, respectively). Type IV blebs were not correlated with bleb failure ($p = 0.358$). There was no relation between, sex, age, eye site, diagnoses, procedures, or use of MMC to complete success ($p > 0.05$). IBP grades did not relate to complete success ($p = 0.192$).

Table 2. Procedures and intraocular lens

	IBP (n = 41) n (%)	Controls (n = 40) n (%)	p-value
Procedure			0.746
Trabeculectomy	32 (78%)	30 (75%)	
Combined Surgery	9 (22%)	10 (25%)	
Mitomycin C	32 (78%)	32 (80%)	0.829
Intraocular Lens			0.131
PMMA	1	4	
Silicone	3	-	
Acrylic	3	2	
Hydrogel	2	4	

PMMA IOL (MC50BD, Alcon, Fort Worth, TX), silicone IOL (SI30NB, Allergan, Irvine, CA), acrylic IOL (Acrysof MA60BM, Alcon, Fort Worth, TX) and hydrogel IOL (Hydroview, Bausch & Lomb Surgical, Claremont, CA)

Table 3. Surgical success of the procedures

Surgical success	IBP (n = 41) n (%)	Controls (n = 40) n (%)	p-value
Complete	34 (82.9%)	24 (60%)	0.022
Overall	39 (95.1%)	36 (90%)	0.379

IBP = intra-bleb pigmentation

Table 4. Survival analysis of time to bleb failure

	IBP (months)	Controls (months)	p-value (Log rank test)
Complete success (median)	49.9	35.5	0.013
95% confidential interval	49.9	26.0, 45.1	
Overall success (mean)	51.6	50.1	0.403
95% confidential interval	47.6, 55.9	44.9, 55.4	
Follow-up period	54.6	55.8	0.354

Bleb and IBP evaluation

Mean time to first appearance of IBP was 146 days (4.9 months) postoperative, (range 9-1204 days, SD 245). Bilateral IBP was demonstrated in five cases. The authors studied only the first eye to develop IBP. IBP was increased in one case (Fig. 5). On the other

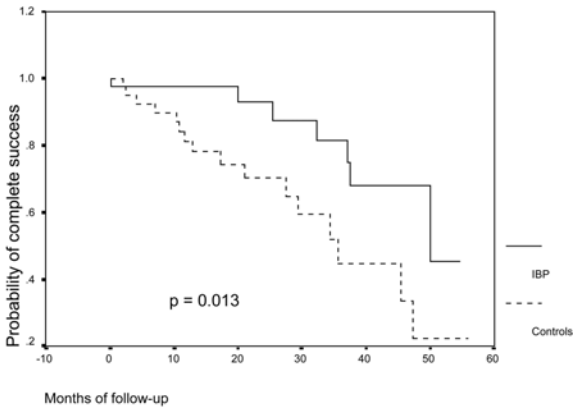


Fig. 4 Survival analysis of time to bleb failure in complete success

hand, IBP diminished in one case (Fig. 6). The IBP disappeared in two cases, 14.7 and 18.6 months after their first appearance. Both had an encapsulation and IBP disappeared, but IOP was still controlled. These two cases were included in the IBP group.

Of the IBP patients, IBP grade I occurred in 21 cases (51.2%), grade II in 10 cases (24.4%), and grade III in 10 cases (24.4%). A clump of pigments was observed in 15 cases (36.6%) and discrete pigments were observed 26 cases (63.4%). IBP location was more common underneath the conjunctival epithelium (31 cases; 75.6%) than overlying the scleral bed (10 cases; 24.4%).

In IBP patients, there were Type I blebs (80.5%), Type II blebs (14.6%), and Type IV blebs (4.9%). In controls, there were Type I (38.5%), Type II (25.6%), Type III (5.1%), and Type IV blebs (30.8%; p = 0.001).

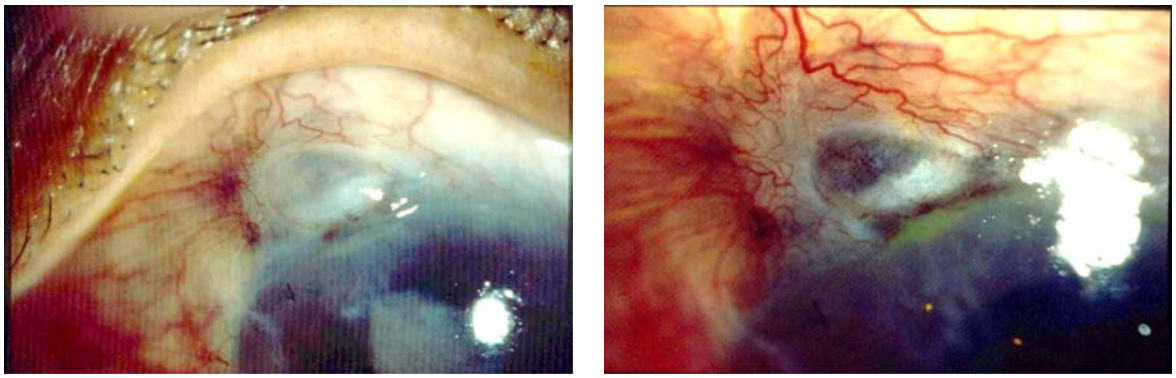
Regression analyses revealed that Type I and Type II blebs had significant levels of IBP (p = 0.016 and 0.004, respectively). No other parameters, *e.g.*, sex, age, diagnosis, procedures, MMC application, complications, and postoperative hypotony, were correlated with IBP development (p > 0.05). TCNR was performed more frequently in the control group than in the IBP group (20% vs. 2.4%, p = 0.012).

Discussion

IBP is an interesting sign that is seldom investigated in clinical evaluation of filtering bleb.

IBP-a favorable sign

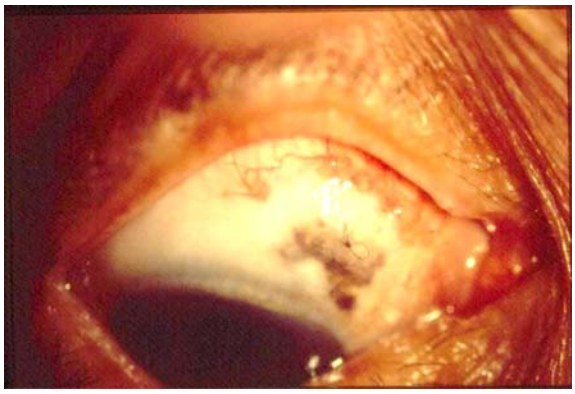
The present data suggests that IBP is associated with successful filtering surgery. Complete success is important for both clinicians and patients, because no additional treatment is required to control IOP. Complete success in IBP patients was achieved more often than in controls (83% vs. 60%) during the 54-month follow-up period. The survival time to bleb failure of IBP patients was also significantly longer than that of the control group (50 vs. 35 months). Other parameters tended to be better in the IBP group than in controls, but they did not reach statistical significance, *e.g.*, overall success (95% vs. 90%), mean final IOP



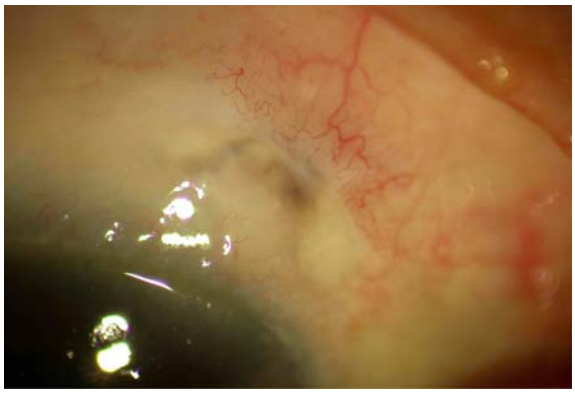
A: Grade I IBP is noted in the superior limbus of filtering bleb. White mature cataract is developed after trabeculectomy. Light reflection artifact is noted on the right side of the lens

B: Patient underwent temporal clear cornea cataract extraction, and grade III IBP is demonstrated in the superior limbus, as well as in the superior part of the bleb. Light reflection artifact is noted on the right side of the bleb

Fig. 5 IBP increase



A: Grade III IBP has a sheet-like appearance, unlike melanin granules. Iris pigment epithelial cells are thought to deposit in the bleb. The black nylon suture is seen above the IBP



B: Three years later, IBP diminished from grade III to grade I. Episcleral fibrosis obscures the inferior part of filtering bleb, and the remaining IBP is noted in the superior part of the bleb

Fig. 6 Diminished IBP

(14.1 vs. 14.95 mmHg), percent of mean IOP reduction (52% vs. 46%), and a reduction in the mean number of medications required (2.1 vs. 1.8).

One reason for these favorable results is that IBP patients have a greater number of Type I blebs than controls (80.5% vs. 38.5%). Thin and cystic blebs allow for transconjunctival aqueous flow[10,11], so that IOP might be better controlled. Aqueous fluid in thin and cystic blebs might correlate with the greater survival time in IBP patients than in controls because the aqueous humor has an inhibitory effect on Tenon's fibroblast proliferation[12]. In addition, MMC, a possible confounding factor, did not affect bleb characteristics, complete success, or survival time between the groups ($p > 0.05$). Furthermore, thin-walled blebs provide a better view for detecting pigment.

IBP might be involved in wound healing following filtering surgery. Fan et al[13] cultured Tenon's fibroblast with iris pigment epithelium (IPE), and reported that the higher concentration of IPE related to less Tenon's fibroblast proliferation. Because IPE inhibits Tenon's fibroblast proliferation *in vitro*, IPE might correlate with a thin and functioning bleb clinically.

IBP origin

Intraocular pigments deposited in the corneal endothelium (Krukenberg spindles), trabecular meshwork[14,15] and pigmented membrane on IOL derive from IPE[16]. Ulrich et al speculated that melanin granules in the excised overhanging bleb were derived from uveal melanocytes[4]. IBP appears to derive from either IPE and/or uveal melanocyte, due to mechanical disruption of the iris and IPE from surgical procedures[17,18], inflammation[14,16,19], and IPE proliferation[20,21]. Histopathologic study is required, however, to better understand the origin of IBP and its status in the bleb.

Limitations of the study included that it was a retrospective study. The sample size was small, because IBP is an uncommon finding. Filtering bleb evaluation and IBP grading were subjective. IOP measurement was based on un-masked manner, which might be a bias. The follow-up period of approximately 2 years might not represent long-term success in glaucoma, a chronic disease. A prospective study should be conducted to validate this finding.

Conclusion

In conclusion, IBP presents as "tracer elements" of aqueous flow from the AC to the filtering bleb. IBP appears to be a favorable sign, in terms of complete success and survival time, because it is associated with thin-walled blebs. Clinicians should carefully observe IBP when evaluating filtering blebs.

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การประเมินผลแบบเปรียบเทียบของแผลผ่าตัดต้อหินที่มีเม็ดสี

บุญส่ง วนิชเวชารุ่งเรือง, วรวรรณ นฤมิตชัย, สมพร จันทรา

วัตถุประสงค์: *เพื่อเปรียบเทียบลักษณะทางคลินิก รวมถึงความสำเร็จของการผ่าตัดต้อหินในแผลผ่าตัด ถุงน้ำชนิดที่มี และไม่มีเม็ดสี*

วัสดุและวิธีการ: *ได้ศึกษาย้อนหลังผู้ที่มีเม็ดสี 41 ราย เปรียบเทียบกับผู้ที่ไม่มีเม็ดสี 40 ราย ในผู้ป่วยที่ได้รับการรักษาทั้งการผ่าตัดต้อหินอย่างเดียว และผ่าตัดต้อหินร่วมกับต้อกระจก*

ผลการศึกษา: *ระยะเวลาการตรวจผู้ป่วย 22.8 เดือน ผู้ที่มีเม็ดสีมีอัตราความสำเร็จสูงกว่าผู้ที่ไม่มี (83% และ 60%) และพบว่าผู้ที่มีเม็ดสีมีลักษณะผนังของถุงน้ำที่บางกว่า ปัจจัยต่าง ๆ เช่น เพศ อายุ การวินิจฉัยโรค การใช้สารไมโตมัยซิน ไม่มีผลต่อการเกิดเม็ดสี*

สรุป: *แผลผ่าตัดต้อหินที่มีเม็ดสี อาจใช้เป็นลักษณะบ่งบอกว่าแผลผ่าตัดมีโอกาสสำเร็จสูงกว่าซึ่งอาจเป็นผลจากการที่มีลักษณะของผนังของถุงน้ำที่บางกว่า เม็ดสีที่เห็นอาจเป็นตัวบ่งบอกถึงการไหลของน้ำจากช่องด้านหน้าของตามายังถุงน้ำ จักษุแพทย์ควรสังเกตเม็ดสีทุกครั้งที่ตรวจแผลผ่าตัดต้อหิน*