

Anterior Segment OCT Imaging of Bleb Morphological Changes as Predictors of Success After Bleb Needling

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Abstract

Objectives: To determine the bleb morphology and anterior segment changes after needling in trabeculectomy patients with filtration failure by anterior segment-optical coherence tomography (AS-OCT), and to identify morphological predictors of success.

Materials and Methods: Thirty-two eyes of 32 patients who underwent trabeculectomy with mitomycin C and experienced filtration failure underwent bleb needling with subconjunctival 5-fluorouracil injection. AS-OCT imaging was performed before and at several time points up to 6 months post-needling. Intraocular pressure (IOP), anterior chamber depth, and bleb height and width were measured. Complete success was defined as achieving IOP \leq 19 mmHg without medication, and qualified success as IOP \leq 19 mmHg with medication at 6 months.

Results: The mean age of the patients was 61.7 ± 7.8 years (range, 44-76), and the mean interval between trabeculectomy and needling was 6.6 ± 6.1 months (range, 1-26). IOP was 27.70 ± 5.11 mmHg preoperatively (preop), 18.32 ± 7.51 mmHg at 1 month, and 20.90 ± 7.03 mmHg at 6 months. The decrease in IOP was statistically significant (p=0.015 and p=0.397, respectively). Bleb width was 3.74 ± 0.67 mm preop, 4.16 ± 0.55 mm at 1 month, and 3.9 ± 0.49 mm at 6 months (p=0.001 and p=0.047, respectively). Bleb height was 0.45 ± 0.16 mm preop, 0.41 ± 0.11 mm at 1 month, and 0.40 ± 0.11 mm at 6 months (p=0.812 and p=0.249,

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respectively). The success rate of needling was 75% at 1 month and 40.6% at 6 months. There were significant differences in age, preop IOP, and bleb height after needling between indistinct and encapsulated blebs. Choroidal effusion developed in 3 patients and resolved with medical treatment. Ahmed glaucoma valve implantation was performed in 6 patients who could not reach the target IOP.

Conclusion: AS-OCT imaging provides an objective and reproducible evaluation of bleb morphological changes after needling. Reduced bleb height, particularly in encapsulated blebs, and increased microcyst density observed on AS-OCT predict successful aqueous humor drainage. Incorporating AS-OCT assessments into clinical practice could improve postoperative management by enabling early detection of bleb dysfunction and guiding timely interventions.

Keywords: Anterior segment OCT, bleb dysfunction, needling, glaucoma, trabeculectomy

Introduction

Trabeculectomy remains the gold standard surgical approach for lowering intraocular pressure (IOP) in patients unresponsive to maximal medical therapy. Its long-term efficacy depends on the sustained function of a filtering bleb. However, postoperative scarring due to fibroblast proliferation and extracellular matrix deposition often compromises bleb functionality. Antimetabolites such as mitomycin C (MMC) and 5-fluorouracil (5-FU) are routinely used to inhibit fibrotic remodeling and enhance surgical success.¹

Despite these adjunctive strategies, bleb failure remains a prevalent complication, particularly in eyes with encapsulated or indistinct blebs. Encapsulation has been reported in 13-29% of cases, and approximately 20% of trabeculectomy patients eventually require bleb needling revision.^{2,3} Bleb needling has emerged as a minimally invasive, cost-effective outpatient intervention to restore aqueous outflow by mechanically disrupting subconjunctival fibrosis and reestablishing bleb functionality.



Bleb morphology provides valuable insight into filtration efficacy. Conventional assessment methods, such as slit-lamp biomicroscopy and grading systems like the Indiana Bleb Appearance Grading System and Moorfields Bleb Grading System, are limited by their subjective nature and inability to visualize internal structures. Advances in anterior segment imaging have introduced high-resolution, non-contact modalities like anterior segment optical coherence tomography (AS-OCT), which enables the detailed visualization of internal bleb morphology, including bleb height, width, microcysts, and the scleral flap.

The present study aimed to use AS-OCT parameters to evaluate morphological changes in blebs after needling revision for failed trabeculectomy and identify imaging biomarkers predictive of successful treatment outcomes.

Material and Methods

Study Design and Participants

This prospective observational study included 32 eyes of 32 patients who underwent trabeculectomy with MMC (Misintu; Koçsel Pharmaceuticals, Kocaeli, Türkiye) between January 2018 and October 2023. Patient age, gender, type of glaucoma, and time between surgery and needling were recorded. Bleb filtration failure was defined clinically as elevated IOP (>19 mmHg), increased vascularization, indistinct bleb margins, subconjunctival scarring, or Tenon cyst formation (encapsulated bleb). In patients who underwent needling within the first month after trabeculectomy, the indication was either persistent filtration failure despite maximal tolerated medical therapy or early encapsulation characterized by rapid fibrotic thickening of the bleb wall. Patients with prior glaucoma drainage device implantation or insufficient followup were excluded. Slit-lamp examination and AS-OCT were used to classify blebs into two morphological subtypes: 1) indistinct blebs, characterized by low elevation, poorly defined margins, and minimal microcystic appearance, and 2) encapsulated blebs, which were elevated, thick-walled, welldemarcated, and hyperreflective on AS-OCT.

Needling Procedure

All patients underwent bleb needling performed under topical anesthesia (0.5% proparacaine: Alcaine; Alcon, Puurs, Belgium) in a sterile setting. A 26-gauge needle was introduced through the conjunctiva approximately 5 mm temporal to the bleb, and adhesions were dissected in multiple directions beneath the conjunctiva and over the scleral flap. Adequate filtration was confirmed when the bleb was observed to be elevated and expanded. Subsequently, 0.1 mL (5 mg) of 5-FU (Fluorouracil-Koçak 5000 mg/100 mL; Koçak Pharmaceuticals, İstanbul, Türkiye) was injected subconjunctivally in the superior quadrant (Figure 1).

Imaging and Data Collection

Data were recorded before needling (preoperative) and at 1 hour, 1 week, 1 month, and 6 months post-needling

(postoperative). IOP was measured by Goldmann applanation tonometry. Anterior chamber depth (ACD) was measured by the same clinician using a Zeiss IOL Master (Carl Zeiss Meditec, Dublin, CA, USA). AS-OCT was recorded with a Heidelberg Spectralis OCT (Heidelberg Engineering Inc., Heidelberg, Germany) in a 400x400 µm scan area resolution. AS-OCT images were captured horizontally for bleb width and vertically for bleb height. The immediate post-injection period was avoided to minimize the effect of transient microcyst inflation from 5-FU. To ensure standardization, all OCT scans were obtained by the same experienced operator using a predefined imaging protocol. Baseline images were used as a reference to reproduce the scan location at each visit, and the patient's fixation was aligned identically at every examination. Bleb height and bleb width were quantified using the OCT device software. Bleb height was defined as the vertical length of the subconjunctival fluid space at the corneal base. Bleb width was defined as the horizontal length between the medial and lateral edges of the subconjunctival fluid cavity (in millimeters), including the bleb wall (Figure 2).

Reproducibility

All AS-OCT measurements were taken by a clinician masked to the IOP outcomes (A.G.). A second independent examiner (N.A.), also masked to the clinical data, repeated the measurements in a randomly selected subset of 15 eyes to evaluate interobserver reliability. Intraobserver reproducibility was assessed by repeating measurements twice at an interval of one month. Intraclass correlation coefficients (ICCs) were calculated to determine both intraobserver and interobserver reliability.

Definition of Success

In this study, surgical success was defined using a target IOP cutoff of \leq 19 mmHg, which was selected as a stricter and more clinically relevant threshold than commonly used values. This cutoff aligns with the clinical practice of aiming to maintain IOP within the high teens, particularly in early- to moderate-stage glaucoma, as suggested by recent staging-oriented guidelines. Complete success was defined as achieving an IOP \leq 19 mmHg without medication at 6 months. Qualified success was defined as achieving IOP \leq 19 mmHg with glaucoma medication. Failure was defined as IOP >19 mmHg despite treatment or the need for additional glaucoma surgery. The final success rate was calculated as the proportion of patients who achieved the target IOP without needing medication at 6-month follow-up relative to the total number of patients.

Ethical Approval

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ondokuz Mayis University Clinical Research Ethics Committee (approval number: OMÜ KAEK 2023/116, date: 27.04.2023). Although the study protocol was registered and approved by the institutional review board as a retrospective observational study, data collection was performed prospectively. Ethical approval for the analysis of patient data was obtained during the data collection period.



Figure 1. a) Appearance of an indistinct bleb before needling. b) Five days after needling, there is bleb elevation due to aqueous humor outflow. c) Appearance of the bleb 1 hour after needling. Aqueous humor outflow and subconjunctival injection of 5-fluorouracil resulted in diffuse bleb dilatation. The anterior chamber volume was preserved

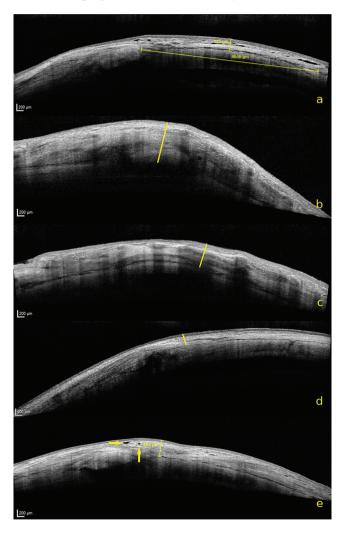


Figure 2. Measuring bleb height and width in micrometers with AS-OCT (yellow lines). The vertical distance based on the sclera indicates the bleb height. a) Bleb width was determined as the horizontal distance between the two edges of the bleb wall, which contained significant cysts. b) Encapsulated bleb before needling. c) Encapsulated bleb after needling. d) Indistinct bleb before needling. Note the decrease in postoperative height in the encapsulated bleb (yellow lines) and increase in postoperative height and number of microcysts (arrows) in the indistinct bleb

AS-OCT: Anterior segment-optical coherence tomography

Written informed consent was obtained from all participants prior to enrollment and before any study-related procedures.

Statistical Analysis

All statistical analyses were performed using the SPSS 26 statistical program (Armonk, NY: IBM Corp). No formal sample size calculation was performed; this was an exploratory prospective observational study. The clinical and bleb morphology parameters before and after needling were compared between indistinct and encapsulated blebs using the independent samples t-test and the Mann-Whitney U test. Dependent groups were compared using the Wilcoxon signed-rank test and paired samples t-test. For repeated measurements across time points, repeated-measures analysis of variance (ANOVA) or Friedman test for non-parametric data was additionally applied to account for intra-subject variability. Categorical variables were analyzed using Pearson's chi-square test. A value of p<0.05 was considered significant.

Results

The mean age of the study participants (15 females, 17 males) was 61.1 ± 7.8 years (range, 44-76). Glaucoma subtypes included primary open-angle glaucoma (n=11), pseudoexfoliative glaucoma (n=8), narrow-angle glaucoma (n=4), uveitic glaucoma (n=6), and glaucoma secondary to intravitreal silicone oil (n=3). The mean interval between trabeculectomy and bleb needling was 6.6 ± 6.1 months (range, 1-26). All patients had uncontrolled IOP despite maximal medical therapy before the needling procedure. Seventeen patients presented with indistinct blebs, while 15 had encapsulated blebs. Eleven patients had early filtration failure (≤ 3 months), and 21 had late filtration failure (> 3 months) (Table 1).

The mean IOP significantly decreased from 27.7 ± 5.11 mmHg preoperatively to 11.61 ± 6.13 mmHg postoperatively, then gradually increased to 20.9 ± 7.03 mmHg at 6 months. According to Friedman's test, the overall difference in IOP across time points was statistically significant (p=0.001). Pairwise comparisons with Bonferroni correction revealed significant reductions in IOP from preoperative to postoperative 1 hour, 1 week, and 1 month (p<0.05), whereas the difference between preoperative and 6-month values was not statistically significant

(p=0.397) (<u>Figure 3</u>). The success rate was 75% at 1 month and 40.6% at 6 months post-needling.

Regarding measurement reproducibility, intra-observer ICCs for AS-OCT were 0.969 for bleb height and 0.920 for bleb width. Inter-observer ICCs were 0.988 for bleb height and 0.943 for bleb width.

The mean ACD was 3.26 ± 0.57 mm preoperatively and decreased to 2.90 ± 0.44 mm postoperatively. Repeated-measures ANOVA revealed a significant overall change in ACD over time (p=0.001). Post-hoc pairwise analysis showed a significant reduction at postoperative 1 hour compared to baseline (p=0.001) but no significant differences at later follow-up visits (all p>0.05) (Table 1).

AS-OCT analysis showed a significant increase in bleb width, from 3.74 ± 0.67 mm preoperatively to 3.90 ± 0.49 mm at 6 months. Friedman's test revealed a significant overall difference in bleb width across time points (p=0.001). Pairwise analysis indicated significant increases from baseline at postoperative 1 hour, 1 week, and 1 month (all p<0.01), and the 6-month value remained significantly higher than baseline (p=0.047).

Bleb height changed significantly, initially increasing from 0.45 ± 0.16 mm before needing to 0.47 ± 0.17 mm at 1 hour after needling, then gradually decreasing to 0.40 ± 0.11 mm at 6 months (RM-ANOVA: F=3.897, p=0.021, η^2 =0.140). However, post-hoc pairwise comparisons with Bonferroni correction did not reveal significant differences from baseline at any individual follow-up time point (all p>0.05). Table 1 shows the bleb height, width, ACD, and IOP values recorded at the follow-up points.

Subgroup analysis by bleb morphology revealed that patients with indistinct blebs had a significantly higher mean age than those with encapsulated blebs (65.3±5.4 vs. 56.1±7.3 years, p=0.001). Gender distribution, glaucoma subtype, and time to needling did not differ significantly between the groups. However, pre-needling IOP was lower in the indistinct bleb group (24.73±3.22 mmHg) compared to the encapsulated bleb group (30.67±4.78 mmHg, p=0.001). Post-needling IOP values were similar between groups at all time points.

The success rate was slightly higher in the indistinct bleb group than in the encapsulated bleb group (82.4% vs. 66.7% at 1 month; 41.2% vs. 40.0% at 6 months). Bleb height was consistently greater in encapsulated blebs across all time points (Table 2).

<u>Table 3</u> demonstrates that preoperative IOP correlated significantly with bleb height (r=0.59, p=0.002) and width (r=0.42, p=0.036). No significant correlations were observed at postoperative 1 hour or 1 month. At 6 months, IOP was negatively correlated with bleb width (r=-0.52, p=0.010), while the correlation with bleb height was not significant.

Choroidal effusion developed in three patients on the fifth postoperative day and resolved with medical therapy. Six patients who failed to achieve target IOP despite needling and adjunctive medical therapy subsequently underwent Ahmed glaucoma valve implantation.

Discussion

Trabeculectomy remains the cornerstone surgical technique for effectively lowering IOP in glaucoma patients unresponsive to medical or laser therapies.⁸ The long-term success of trabeculectomy primarily depends on the sustained function of the filtering bleb, which can be compromised by subconjunctival fibrosis. Antimetabolites such as MMC and 5-FU are widely used to suppress postoperative scarring and maintain bleb

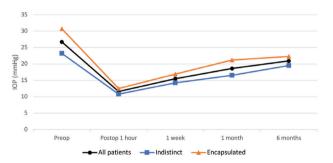


Figure 3. Intraocular pressures (IOP) according to follow-up times

Variables	Preop	Postop 1 hour	Postop 1 week	Postop 1 month	Postop 6 months	p
IOP	27.70±5.11	11.61±6.13	15.55±8.2	18.65±7.51	20.9±7.03	0.001a
p ^b		0.015	0.001	0.015	0.397	
ACD (mm)	3.26±0.57	2.90±0.44	3.24±0.59	3.52±0.5	3.24±0.41	0.001a
p ^b		0.726	0.998	0.159	0.988	
Bleb width (mm)	3.74±0.67	4.30±0.88	4.29±0.60	4.16±0.55	3.90±0.49	0.001a
p ^b		0.001	0.006	0.001	0.047	
Bleb height (mm)	0.45±0.16	0.47±0.17	0.43±0.13	0.41±0.11	0.40±0.11	0.021 ^c
p ^d		0.989	0.999	0.812	0.249	

Statistically significant results (p<0.05) are indicated in bold. 'Friedman's test, comparison across all time points; bWilcoxon signed-rank test with Bonferroni correction, pairwise comparisons to preop; 'Repeated measures ANOVA, comparison across all time points; Bonferroni-corrected t-tests, pairwise comparisons to preop. IOP: Intraocular pressure, ACD: Anterior chamber depth, Preop: Preoperative, Postop: Postoperative

functionality.9 However, fibrosis and subsequent bleb failure can still occur despite these adjunctive treatments.

Bleb needling revision, a minimally invasive outpatient procedure, can restore aqueous humor outflow by mechanically disrupting subconjunctival adhesions beneath the bleb wall. ^{10,11} In our study, needling targeted adhesions over the scleral flap without penetrating the anterior chamber. AS-OCT was employed to monitor these structural changes objectively, and it demonstrated excellent reproducibility, as evidenced by the high ICCs (ICC ≥0.92).

The success rates of bleb needling vary significantly in the literature due to differences in patient populations, study methodologies, antimetabolite usage, and the criteria used to define success. In our study, the success rates at 1 and 6 months post-needling were 75% and 40.6%, respectively. Previous studies have yielded variable results, with Ewing and Stamper¹² reporting a high success rate of 91.7%, Shah et al.¹³ reporting 77.7% success in pediatric patients, and Shin et al.¹⁴ indicating a cumulative success rate of 45% at 1 year (declining to 28% at 4 years). Rotchford and King¹⁵ observed that the success rate decreased from 64.2% at 6 months to 13% at 48 months, while Tsai et al.¹⁶ reported success rates of approximately 70% at 6 months. The variability among these findings underscores the complexity of bleb needling outcomes and the importance of clearly defined success criteria.

The morphological characteristics of filtration blebs provide critical insights into their functional status. Functional blebs typically exhibit slight elevation, minimal conjunctival vascularization, and the presence of microcysts, whereas non-functional blebs demonstrate intense vascularization, encapsulation, and limited microcystic features.⁴ In our study, encapsulated blebs consistently exhibited higher bleb heights and were associated with lower initial success rates compared to indistinct blebs. Younger patient age was significantly correlated with encapsulated blebs and poorer outcomes, aligning with prior research indicating increased fibrosis in younger individuals.¹⁷

Advanced imaging modalities such as ultrasound biomicroscopy, confocal microscopy, and particularly AS-OCT have transformed bleb evaluation by providing detailed and objective visualization of internal bleb structures. ^{18,19,20} AS-OCT is a non-contact method that provides high-resolution cross-sectional images of anterior segment structures. Leung et al. ²¹ classified blebs based on their OCT appearance, describing functional blebs as having fluid-filled cavities and diffuse microcysts with moderate reflectivity. Similarly, Kawana et al. ²² evaluated bleb drainage pathways, bleb wall microcysts, and the scleral flap using three-dimensional OCT imaging and described functional blebs as exhibiting a fluid-filled cavity with diffuse microcysts in the bleb wall. Guthoff et al. ²³ correlated cystic elevation on AS-OCT with higher IOP and demonstrated that needling effectively reduced cyst height.

In our study, AS-OCT analysis revealed a significant increase in bleb width immediately post-needling, followed by a gradual decline. These findings reflect the transient nature of needling effects and suggest the potential need for repeated interventions. Conversely, bleb height significantly decreased, particularly in encapsulated blebs, suggesting the effective disruption of subconjunctival fibrosis and improved aqueous drainage. Persistently elevated bleb height after needling may serve as a predictor of filtration failure, thereby necessitating alternative surgical approaches such as glaucoma drainage implants.

ACD typically decreases postoperatively due to improved aqueous outflow. Although an initial decrease in ACD was observed immediately post-needling in our study, subsequent measurements showed no significant long-term change. This outcome is consistent with the findings of Lenzhofer et al.²⁴, who suggested that there is no direct association between ACD and surgical success.

Recent studies further support the prognostic value of AS-OCT based morphometrics in evaluating filtering bleb function and postoperative IOP control. A 2023 study by Sun et al.²⁵ demonstrated that AS-OCT-derived Wuerzburg Bleb Classification System scores showed significant correlations with IOP at multiple postoperative intervals (1, 2, 3, 6, and 12 months), and that specific features such as microcyst presence were strong predictors of surgical success (p<0.05). Likewise, a recent cross-sectional analysis using sweptsource AS-OCT found that internal bleb reflectivity, maximal bleb height, and pixel intensity metrics effectively discriminated functioning versus failing blebs with high diagnostic accuracy (area under the curve ≥0.75).²⁶

Our findings complement this emerging evidence. We observed a significant positive correlation between preoperative IOP and bleb height (r=0.59, p=0.0018) and width (r=0.42, p=0.036), suggesting that filtering blebs in eyes with higher baseline IOP are initially larger. Additionally, the negative correlation between IOP and bleb width at 6 months (r=-0.52, p=0.010) demonstrates the importance of sustained bleb patency (reflected by maintained width) for long-term IOP control. These results highlight the dynamic prognostic implications of AS-OCT-based bleb metrics and support their integration into postoperative monitoring protocols for more targeted intervention.

Study Limitations

The present study has several limitations. First, the patient cohort was heterogeneous in terms of glaucoma subtype, and the number of cases in the indistinct and encapsulated bleb groups was relatively small. Second, the inclusion of uveitic glaucoma may have introduced bias, as intraocular inflammation can alter wound healing and subconjunctival fibrosis, potentially affecting the response to needling. Nevertheless, we included these patients to better reflect the heterogeneity encountered in real-world clinical practice. Future studies with larger, more homogeneous cohorts, particularly those focusing exclusively on non-inflammatory glaucomas, are needed to clarify these effects. Additionally, further research should investigate advanced AS-OCT parameters, including bleb wall reflectivity, microcyst density, scleral flap visualization, and internal bleb architecture,

Variables	Indistinct (n=17)	Encapsulated (n=15)	p value	
Age (years), mean ± SD	65.3±5.4	56.1±7.3	0.001 ^a	
Gender, n				
Female	6	9	0.162 ^b	
Male	11	6		
Glaucoma type, n				
Primary open-angle glaucoma	7	4		
PEX glaucoma	5	3		
Narrow-angle glaucoma	1	3	0.524 ^b	
Uveitic glaucoma	2	4		
Secondary to silicone oil injection	2	1		
Time to bleb dysfunction, n (%)				
Early (≤3 months)	5 (29.4)	6 (40)	0.529 ^b	
Late (>3 months)	12 (70.6)	9 (60)	0.727	
Time between surgery and needling (months), mean ± SD	5.7±4.4 (1-14)	7.7±7.4 (1-26)	0.711 ^b	
Success, n (%)				
1 month	14 (82.4)	10 (66.7)		
6 months	7 (41.2)	6 (40)		
IOP (mmHg), mean ± SD				
Preop	24.73±3.22	30.67±4.78	0.001 ^a	
Postop 1 hour	10.75±7.17	12.53±5.34	0.379 ^b	
Postop 1 week	14.25±7.95	16.93±8.51	0.373ª	
Postop 1 month	16.53±6.25	21.21±8.32	0.095ª	
Postop 6 months	19.47±5.40	22.33±8.31	0.305 ^b	
ACD (mm), mean ± SD				
Preop	3.11±0.56	3.45±0.56	0.173 ^b	
Postop 1 hour	2.91±0.51	2.90±0.36	0.950ª	
Postop 1 week	3.27±0.72	3.21±0.43	0.711 ^b	
Postop 1 month	3.59±0.54	3.45±0.47	0.719 ^b	
Postop 6 months	3.31±0.48	3.10±0.19	0.312ª	
Bleb width (mm), mean ± SD				
Preop	3.74±0.84	3.75±0.47	0.975ª	
Postop 1 hour	4.49±1.12	4.10±0.49	0.211ª	
Postop 1 week	4.32±0.68	4.27±0.55	0.822ª	
Postop 1 month	4.21±0.65	4.11±0.43	0.909 ^b	
Postop 6 months	4.05±0.57	3.75±0.51	0.182ª	
Bleb height (mm), mean ± SD				
Preop	0.34±0.09	0.59±0.13	0.001ь	
Postop 1 hour	0.40±0.17	0.56±0.14	0.001ь	
Postop 1 week	0.38±0.12	0.50±0.12	0.002 ^b	
Postop 1 month	0.37±0.12	0.45±0.11	0.017 ^b	
Postop 6 months	0.34±0.05	0.48±1.07	0.001 ^b	

Table 3. Correlation between intraocular pressure and bleb morphological parameters at different time points (Pearson correlation analysis)

IOP		Bleb height	Bleb width
Preop	r	0.59	0.42
	P	0.002	0.036
Postop 1 hour	r	0.22	0.08
	P	0.254	0.674
Postop 1 week	r	-0.18	-0.05
	p	0.361	0.801
Postop 6 months	r	-0.31	-0.52
	P	0.118	0.010

Statistically significant results (p<0.05) are indicated in bold. IOP: Intraocular pressure, Preop: Preoperative, Postop: Postoperative

to establish their value as predictive biomarkers for bleb function and needling success.

Conclusion

AS-OCT imaging provides objective and reproducible insights into morphological bleb changes after needling. In our study, reduced bleb height (particularly in encapsulated blebs) and increased bleb width were associated with improved aqueous outflow and short-term procedural success. Incorporating AS-OCT into postoperative follow-up may help predict bleb functionality, identify early signs of failure, and guide timely re-intervention, ultimately improving long-term surgical outcomes.

Ethics

Ethics Committee Approval: The study was conducted in accordance with the Declaration of Helsinki and approved by the Ondokuz Mayis University Clinical Research Ethics Committee (approval number: OMÜ KAEK 2023/116, date: 27.04.2023).

Informed Consent: Informed consent was obtained from all subjects prior to their participation in the study.

Declarations

Authorship Contributions

Surgical and Medical Practices: N.A., Concept: N.A., Design: A.G., Data Collection or Processing: A.G., Analysis or Interpretation: A.G., Literature Search: A.G., Writing: A.G., N.A.

Conflict of Interest: No conflict of interest was declared by the authors.

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