

Evaluation of Optical Coherence Tomography Parameters in Diabetic Macular Edema Patients Who Underwent Phacoemulsification and Intravitreal Bevacizumab

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ABSTRACT

Purpose: To evaluate optical coherence tomography (OCT) findings after simultaneous phacoemulsification and bevacizumab injection in diabetic macular edema (DME) cases

Material-Method: Preoperative and postoperative OCT images of the cases were analyzed retrospectively. Initial and final best corrected visual acuity (BCVA), central macular thickness (CMT), epiretinal membrane (ERM), presence of vitreomacular traction (VMT), disorganization of the retinal inner layers (DRIL), ellipsoid zone (EZ) and external limiting membrane (ELM) disruption length were recorded.

Results: Initial and postoperative BCVA of the 16 included patients were 0.82 ± 0.38 and 0.56 ± 0.45 logMAR ($p=0.02$), respectively. While no significant difference was found between the initial and postoperative CMT (249.31 ± 128.92 vs. 292.75 ± 186.75 μm $p=0.15$), DRIL length increased significantly (444.60 ± 290.81 vs. 585.40 ± 324.10 μm $p=0.02$). There was a strong correlation between preoperative DRIL length and postoperative BCVA ($p<0.05$, $r=0.78$).

Conclusion: Simultaneous phacoemulsification and IVB treatment in DME cases may lead to an increase in DRIL length. The use of OCT parameters may be useful to estimate the final BCVA in these cases.

Keywords: Diabetic macular edema, phacoemulsification, optical coherence tomography, intravitreal bevacizumab

INTRODUCTION

Diabetic macular edema (DME) is associated with increased oxidative stress, inflammation, and vascular dysfunction due to prolonged exposure to hyperglycemia. During the course of the disease, increased levels of vascular endothelial growth factor (VEGF), cytokines, angiopoietin, and matrix metalloproteases lead to DME through blood-retinal barrier dysfunction and increased vascular permeability (1). In diabetic retinopathy (DR), DME and the presence of cataracts are the main causes of reduced vision loss. In these patients, uncomplicated cataract surgery may

cause macular edema through increased angiogenic cytokines and disruption of the blood-retinal barrier (2).

Bevacizumab is a recombinant, humanized monoclonal antibody that targets all isoforms of VEGF. It has been shown to reduce central retinal thickness, even in chronic diffuse ischemic DME cases (3). Some studies show that intravitreal bevacizumab (IVB) administered simultaneously with cataract surgery maintains the clinical stability of DR and improves visual acuity (4, 5).

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Spectral domain optical coherence tomography (SD-OCT) is a noninvasive and easily applicable imaging method that displays retinal anatomy at high resolution. It is the most frequently preferred method for monitoring DME cases in clinical practice. The effects of various anatomical findings obtained from OCT images on visual prognosis in DME cases have been investigated (6-8).

The aim of this study was to investigate how simultaneous IVB application with cataract surgery would affect preoperative OCT findings in patients with DME. It also aimed to evaluate the factors associated with postoperative visual acuity. To our knowledge, our study is the first to evaluate OCT biomarkers other than CMT in patients undergoing simultaneous IVB with cataract surgery.

METHODS

Cases diagnosed with DME in our clinic between 2020-2025 were retrospectively screened. Approval was obtained from the institutional ethics committee before starting this study. Procedures related to the study were initiated after obtaining informed consent from the patients. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or National Research Committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

The inclusion criteria for the study were the presence of DRP associated with type 2 DM, simultaneous bevacizumab injection with phacoemulsification in our clinic, availability of high-resolution OCT images before and after surgery, and at least 6 months follow-up. Exclusion criteria; OCT images that could not be evaluated well due to media opacities, presence of degenerative myopia, tractional retinal detachment, glaucoma, previous eye surgery, and development of intraoperative complications such as posterior capsule rupture.

In this study, DR was classified according to the International Clinical Disease Severity Scale for DR (9). According to this classification, NPDR is characterized by microaneurysm, intraretinal hemorrhage, venous beading, or intraretinal microvascular abnormalities. PDR is characterized by neovascularization of the optic disc, retina, iris, or iridocorneal angle, vitreous hemorrhage, or tractional retinal detachment. Active PDR cases were not included in the

study. Patients who were previously diagnosed with PDR and underwent panretinal photocoagulation and were stable but required cataract surgery were included in the study.

The eyes of 42 patients were examined in the study, and 16 eyes of 16 patients who met the inclusion criteria were identified. All patients underwent a complete ophthalmologic examination. It includes best corrected visual acuity (BCVA, logMAR), biomicroscopic anterior segment examination, intraocular pressure measurement with Goldmann applanation tonometry, dilated fundus examination, and SD-OCT (version 2015.1.0.90; Optovue, Inc., Fremont, CA, USA) examination at each visit.

The treatment protocol was performed by a single surgeon (A.M.). All patients were treated according to the pro-re-nata protocol before phacoemulsification. After the first three consecutive intravitreal anti-VEGF injections, patients were administered intravitreal anti-VEGF drugs during follow-up examinations according to the presence or recurrence of diffuse ME affecting the fovea center. After the first three consecutive anti-VEGF injections, follow-up visit intervals were adjusted according to the patient's availability. Treatment of cases with cataracts that made posterior segment examination difficult was planned as phacoemulsification and simultaneous IVB.

The surgical technique consisted of opening a 2.8 mm corneoscleral incision, complete continuous curvilinear capsulorhexis, phacoemulsification, and intracapsular implantation of a foldable intraocular lens followed by IVB injection. Bevacizumab was prepared sterile by the hospital pharmacy, containing 0.05 mL (1.25 mg) of bevacizumab injected intravitreally using a 30-gauge needle. After surgery, all patients received topical moxifloxacin and 0.1% prednisolone drops for 1 month.

Preoperative OCT examinations included central macular thickness (CMT), presence of epiretinal membrane (ERM), vitreomacular traction (VMT), hyperreflective points, and serous detachment (SD). In addition, the average length of disorganization of the retinal inner layers (DRIL), ellipsoid zone (EZ) disruption, and external limiting membrane (ELM) disruption were recorded. Postoperative OCT images at 3 months were evaluated for CMT, DRIL length, EZ disruption length, and ELM disruption length. The scan acquisition protocol for SD-OCT included a raster scan

centered on the fovea. For analysis, a 1 mm² area at the center of the fovea on the OCT was selected. Manual segmentation was applied for the measurements. CMT, DRIL, EZ, and ELM disruption length measurements were manually measured separately by two independent examiners (S.M. and B.S.) using calipers on the OCT. Three consecutive B-scans were evaluated: the midline scan passing through the center of the fovea, and one B-scan immediately above and below the midline scan. The average of these three values was used for quantitative analysis. The mean measurements were compared, and the ambiguity of those found to be significantly different between the two investigators was resolved by a third investigator (A.M.). The area from the upper edge of the inner limiting membrane to the upper edge of the retinal pigment epithelium was determined with a caliper and recorded as the CMT value. DRIL was defined as the horizontal extent of disorganization of the boundaries between the ganglion cell-inner plexiform layer complex, the inner nuclear layer, and the outer plexiform layer (10).

All measurements are presented as mean \pm standard deviation. Descriptive analyses were performed after checking normal distribution using the Kolmogorov-Smirnov test. Paired-Samples T test was used to compare pre- and postoperative parameters. Additionally, correlation analysis was performed to determine the factors affecting the resulting BCVA. Statistical analyses were performed using SPSS version 22 (SPSS Inc. Chicago, IL., USA). P < 0.05 was considered a statistically significant ratio.

RESULTS

A total of sixteen eyes of sixteen patients were included in the study. The mean age of the participants was 63.31 \pm 10.85 years. Eight (50%) were male and 8 (50%) were female. Of the 16 eyes, 13 (81.3%) had NPDR and 3 (18.8%) had PDR. The mean initial BCVA was 0.82 \pm 0.38 logMAR. A mean of 2.19 \pm 3.08 (range 0-10) intravitreal injections

were administered to 9 patients (56.3%) for the treatment of ME before surgery. Preoperatively, ERM was detected in 8 (50%) patients, VMT in 2 (12.5%) patients, hyper-reflective points in 8 (50%) patients, SD in 4 (25%) patients, and DRIL in 13 (81.3%) patients. The mean CMT was 249.31 \pm 128.92 μ m, while the mean DRIL length was 444.60 \pm 290.81 μ m.

The mean BCVA at the last visit was 0.56 \pm 0.45 logMAR. The mean postoperative refractive values (spherical equivalent) of the cases were -0.42 ± 1.17 . Posterior capsule opacities were detected in 4 (23.5%) cases and were opened with the aid of an ND:YAG laser capsulotomy. Of the OCT parameters, the mean CMT was 292.75 \pm 186.75 μ m, the mean DRIL length was 585.40 \pm 324.10 μ m, the EZ disruption length was 291.87 \pm 339.26 μ m, and the ELM disruption length was 172.26 \pm 305.21 μ m. A mean of 0.75 \pm 1.06 (range 0-3) intravitreal injections were administered to 7 patients (43.7%) for postoperative ME treatment. Demographic, clinical, and OCT features of the cases are summarized in Table 1.

Comparison of BCVA and OCT parameters at the initial and final visits is summarized in Table 2. Final BCVA improved significantly compared to baseline (0.82 ± 0.38 vs. 0.56 ± 0.45 logMAR p=0.02, respectively). DRIL length also increased significantly compared to preoperative data at the final visit (444.60 ± 290.81 vs. 585.40 ± 324.10 p=0.02, respectively). No significant difference was found in CMT, EZ and ELM disruption length (p > 0.05).

According to the correlation analysis results, a moderate correlation was found between the final BCVA and preoperative BCVA, CMT, EZ and ELM length (p < 0.05). A strong correlation was found with the preoperative DRIL length (p < 0.05, r=0.78). A moderate correlation was found between the final BCVA and postoperative data CMT, DRIL length, EZ and ELM length (p < 0.05) (Table 3).

Table 1: Clinical characteristics of the studied eyes.

Demographical/clinical/OCT features	Mean±SD
Age (years)	63.31±10.85
Gender	
Male	8
Female	8
Laterality	
Right	10
Left	6
Fundus examination	
NPDR	13
PDR	3
Number of injections	35
Previous injection history	
Yes	9
No	7
Initial OCT parameters	
DRIL (+/-)	13/3
ERM (+/-)	8/8
VMT (+/-)	2/14
Hyperreflective point (+/-)	8/8

OCT: Optical coherence tomography, BCVA: Best corrected visual acuity, LogMAR: Logarithm of the minimum angle of resolution, DRIL: Disorganization of retinal inner layers, ERM: Epiretinal membrane, NPDR: Nonproliferative diabetic retinopathy, PDR: Proliferative diabetic retinopathy, VMT: vitreomacular traction, SD: Standard deviation.

Table 2: Comparison of preoperative and postoperative visual acuity with optical coherence tomography parameters

	Preoperative (Mean±SD)	Postoperative (Mean±SD)	P Value
BCVA (logMAR)	0,82 ± 0,38	0,56 ± 0,45	0.02*
CMT (μm)	249,31 ± 128,92	292,75 ± 186,75	0.15*
DRIL length (μm)	444,60 ± 290,81	585,40 ± 324,10	0.02*
EZ disruption length (μm)	230,75 ± 305,26	291,87±339,26	0.34*
ELM disruption length (μm)	184,60 ± 323,67	172,26±305,21	0.60*

BCVA: Best corrected visual acuity, CMT: Central macular thickness, EZ: Ellipsoid zone, ELM: External limiting membrane, DRIL: Disorganization of retinal inner layers, SD: Standard deviation, *Paired sample t test, P<0.05 is considered statistically significant.

Table 3: Correlation analysis between optical coherence tomography findings and resulting BCVA parameters

		Final BCVA (logMAR)	Postoperative CMT (μm)	Postoperative EZ disruption length (μm)	Postoperative ELM disruption length (μm)	Postoperative DRIL length (μm)
Preoperative BCVA (logMAR)	correlation coefficient	0.52 [#]	0.47 [#]	0.23 [#]	0.36 [#]	0.24 [#]
	P value	0.03*	0.06	0.39	0.17	0.38
Preoperative CMT (μm)	correlation coefficient	0.66 [#]	0.79 [#]	0.41 [#]	0.44 [#]	0.54 [#]
	P value	0.05*	<0.05*	0.10	0.10	0.03*
Preoperative EZ disruption length (μm)	correlation coefficient	0.61 [#]	0.43 [#]	0.70 [#]	0.92 [#]	0.51 [#]
	P value	0.01*	0.08	0.02*	<0.05*	0.04*
Preoperative ELM disruption length (μm)	correlation coefficient	0.60 [#]	0.36 [#]	0.70 [#]	0.96 [#]	0.50 [#]
	P value	0.01*	0.18	<0.05*	<0.05*	0.06
Preoperative DRIL length (μm)	correlation coefficient	0.78 [#]	0.54 [#]	0.76 [#]	0.81 [#]	0.77 [#]
	P value	<0.05*	0.03*	<0.05*	<0.05*	<0.05*

BCVA: Best corrected visual acuity, CMT: Central macular thickness, EZ: Ellipsoid zone, ELM: External limiting membrane, DRIL: Disorganization of retinal inner layers, [#] Pearson correlation analysis, *P<0.05 is considered statistically significant.

DISCUSSION

This study evaluated the OCT parameters after simultaneous IVB injection with phacoemulsification in patients with DME. In addition, the effect of the initial OCT parameters on the final BCVA was investigated. According to the study, CMT values did not change in the postoperative period compared to the preoperative values, while BCVA and DRIL length increased significantly.

After cataract surgery, DRP may worsen due to inflammation. In the postoperative period, it has been shown that inflammatory markers such as IL-1 β and angiogenic growth factors such as VEGF and hepatocyte growth factor (HGF) increase. In addition, a decrease has been detected in the anti-angiogenic agent pigment epithelium-derived growth factor (PEDF) (11). This may damage vascular endothelial cells, leading to disruption of the blood-retinal barrier and the development of DME. Simultaneous anti-VEGF application in this patient group may contribute to overcoming this process with less damage. In their study on DME patients, Lanzagorta et al. applied IVB injection simultane-

ously with phacoemulsification to half of the cases, while bss (balanced salt solution) was applied to the other half as a control group. In the postoperative 3rd and 6th month controls, it was determined that BCVA was significantly better and macular thickness was thinner in the bevacizumab group (4). In a similar study, an increase in CMT was observed in the postoperative period compared to the preoperative period in the group that underwent only phacoemulsification. In the IVB group, CMT decreased compared to the preoperative period. The results of the study showed that IVB not only has the potential to prevent the increase in retinal thickness, but also has the potential to reduce retinal thickness after cataract surgery in eyes with DME (5). A meta-analysis of six clinical trial reports comparing cataract surgery with and without concurrent IVB therapy in patients with DME revealed the following results. BCVA measured 1 and 3 months after cataract surgery was significantly better in the IVB group compared to the control group. However, the difference at 6 months was not statistically significant. CMT was significantly lower in the IVB group compared to the control group at 1, 3, and 6

months after surgery, and DR progression was less frequent in the IVB group compared to the control group(12). In our study, CMT did not change significantly in cases where IVB was applied simultaneously with phacoemulsification, while BCVA increased significantly. However, DRIL length increased significantly in the postoperative period. The increase in postoperative BCVA seems to be related to cataract extraction rather than IVB injection. Although cataract surgery may worsen progression in these patients, it is necessary to improve vision and better monitor posterior segment involvement. According to our results, 43.7% of patients continued to require injections 3 months postoperatively. Concurrent IVB administration may slow the worsening of DR symptoms but did not completely eliminate the need for additional treatment.

Some OCT parameters have been used to predict visual prognosis in DME cases. These possible parameters are: integrity of the ELM and EZ, photoreceptor outer segment thickness, status of the cone outer segment tips, presence of hyperreflective foci, and presence of subretinal fluid (6-8, 13-15). The ELM consists of connections between Müller cells and photoreceptor cells, protecting the integrity of the inner segments of photoreceptors. ELM disruption is associated with Müller cell and photoreceptor damage. Müller cells contribute to the production of VEGF and other growth factors, making them an important factor in the pathogenesis of DR (16). Koç et al. have shown that anti-VEGF therapy can be time-consuming and not always beneficial in eyes with extensive Müller cell damage(17). DME attacks can damage photoreceptors, leading to permanent vision loss. The photoreceptor layer is assessed by examining the integrity of the EZ in OCT images. It has been shown that EZ disruptions can be limitedly corrected with treatment (18, 19). In our study, no difference was found between the preoperative and postoperative EZ and ELM disruption length. This may be related to the initial EZ and ELM disruption being resistant to IVB treatment. Alternatively, concurrent cataract surgery may have limited this improvement in the short term postoperatively. More comprehensive studies are needed to determine long-term outcomes. Furthermore, in this study, preoperative EZ and ELM disruption length were associated with outcome BCVA. Just as in patients who underwent IVB alone, in patients who underwent concurrent cataract surgery with

IVB, the initial EZ and ELM disruption lengths can be used to predict outcome BCVA.

Another biomarker is DRIL length, which has been reported to predict visual prognosis independently of CMT (20). In DME cases, retinal inner segment deterioration is more decisive than EZ and ELM disruption rates for predicting poor visual outcome. The presence of DRIL leads to anatomical interruption in the visual transmission pathway. DRIL may be related to the disorganization or destruction of cells in the inner retinal layers such as bipolar and amacrine cells. Thus, it may result in the interruption of the pathways that transmit visual information from photoreceptors to ganglion cells (20). Radwan et al. examined the factors affecting BCVA in eyes with ME associated with DR and other causes. The factor most strongly associated with the change in BCVA over time in DR-associated ME was the change in DRIL over time. There was no such relationship between DRIL and BCVA in non-diabetic eyes with ME. Furthermore, the presence of pretreatment DRIL in eyes with DR-associated ME was found to be effective in predicting BCVA after ME resolution(21). Gabriel et al. reported a case series in which patients received six initial doses of IVB and were then switched to other agents if necessary. The study found that those with baseline DRIL had significantly worse BCVA despite treatment over a 2-year follow-up period (22). In these studies, patients were followed only with intravitreal injection therapy. Yumuşak et al. reported the results of cataract surgery in patients with refractory DME. According to the study, BCVA increased significantly at postoperative month 1 compared to preoperative levels and was similar at postoperative months 1 and 3. CMT increased significantly at postoperative months 1 and 3 compared to baseline (23). According to the study that presented the six-month results of cases that received intravitreal 4 mg triamcinolone simultaneously with cataract surgery, complete improvement in DME was observed in 71% of cases and partial improvement in 29% of cases compared to the preoperative period (24). Our study showed that in cases undergoing cataract surgery and IVB injection in the presence of DME, there was a moderate correlation between final BCVA and the initial CMT, EZ and ELM disruption length, and a strong correlation with the initial DRIL length. Based on our literature search, we were unable to identify any studies with a similar design to ours. Our results are preliminary for more comprehensive

studies on this subject. In our study, increased DRIL length in the postoperative period suggested that cataract surgery in these cases may negatively impact prognosis. We considered several possible reasons for this. The first is artifact in preoperative OCT sections related to cataract. However, we selectively excluded cases with poor image quality that could affect the measurements. The second possible reason is the development of transient postoperative inflammation. Inflammation-related disruption of the blood-retinal barrier may contribute to the persistence of DRIL. Another possible mechanism is the progression of neurodegeneration following surgery. Midena et al. suggested that DRIL development is associated with the deterioration of Müller cells. They found an increase in glial fibrillary acid protein (GFAP) in the aqueous humor of DME patients in eyes with DRIL compared to those without DRIL, which is associated with Müller cell dysfunction (25). More detailed studies are needed to confirm these hypotheses.

Our study has some limitations. Our results are exploratory because they are limited by the small sample size. Since it is a retrospective study involving a single surgeon, there may be a high risk of bias in patient selection before surgery. Preoperative OCT images in cases requiring cataract surgery are difficult to clearly evaluate. Therefore, we were able to include a limited number of participants. These findings can be confirmed in a prospective study with a large number of participants and evaluation of images obtained at certain intervals. Additionally, we didn't have a control group because we didn't perform cataract surgery alone without IVB in patients with ME and cataract. Therefore, the study group could not be compared with patients who underwent cataract surgery without IVB. This limits the ability to draw conclusions about the effect of simultaneous IVB injection on postoperative DRIL length and BCVA.

In conclusion, IVB applied simultaneously with uncomplicated cataract surgery in DME cases may result in visual improvement. In these cases, even if IVB injection provides stabilization in CMT, it may be insufficient to reduce DRIL length. In DME cases, careful treatment selection should be made by considering not only the CMT but also the DRIL length, EZ, and ELM disruption length. In order to minimize the factors affecting postoperative visual improvement, IVB injection may be considered more frequently before and simultaneously with phacoemulsification surgery.

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