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RESEARCH ARTICLE

Correlation of Optical Coherence Tomography Biomarkers with Visual Outcomes in Patients with Diabetic Macular Edema: A Prospective Longitudinal Study

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ABSTRACT

Background: Diabetic macular edema (DME) is one of the major causes of visual impairment among diabetic patients worldwide. Optical coherence tomography (OCT) plays an important role in identifying retinal structural changes and biomarkers associated with disease severity and visual prognosis.

Aim: To evaluate the correlation between OCT biomarkers and visual outcomes in patients with diabetic macular edema.

Materials and Methods: This prospective longitudinal study was conducted in the Department of Ophthalmology, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India, from July 2024 to June 2025. A total of 100 patients with diabetic macular edema were included. Detailed ophthalmic examination, best corrected visual acuity (BCVA), fundus examination, and spectral-domain OCT imaging were performed. OCT biomarkers including central macular thickness (CMT), disorganization of retinal inner layers (DRIL), hyperreflective foci (HRF), subretinal fluid (SRF), ellipsoid zone disruption (EZD), and intraretinal cysts (IRC) were evaluated. Statistical analysis was performed using SPSS version 26.0. Pearson correlation coefficient, paired t-test, ANOVA, and multivariate regression analysis were used. $p<0.05$ was considered statistically significant.

Results : The mean age of study participants was 58.6 ± 8.7 years. Significant improvement in visual acuity was observed during follow-up, with mean BCVA improving from 0.82 ± 0.24 logMAR at baseline to 0.51 ± 0.19 logMAR at 12 months ($p<0.001$). Mean central macular thickness decreased significantly from 468.4 ± 92.5 µm to 311.2 ± 58.6 µm ($p<0.001$). DRIL, ellipsoid zone disruption, and hyperreflective foci demonstrated significant negative correlation with final visual acuity ($p<0.001$). Multivariate regression analysis identified DRIL and ellipsoid zone disruption as independent predictors of poor visual outcome.

Conclusion: OCT biomarkers show strong correlation with visual outcomes in diabetic macular edema. DRIL, ellipsoid zone disruption, and hyperreflective foci were associated with poorer visual prognosis. OCT biomarker evaluation may help in prognostication and individualized management of DME.

Keywords: Diabetic macular edema, Optical coherence tomography, OCT biomarkers, DRIL, Visual acuity, Ellipsoid zone disruption

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Introduction

Diabetes mellitus is a rapidly increasing global health problem associated with multiple microvascular complications including diabetic retinopathy and diabetic macular edema.[1] Diabetic macular edema remains one of the leading causes of visual impairment among working-age adults worldwide.[2]

The development of diabetic macular edema is primarily related to breakdown of the blood-retinal barrier, increased vascular permeability, inflammatory mediator release, and retinal capillary leakage resulting in fluid accumulation within retinal layers.[3] Persistent retinal edema may lead to irreversible photoreceptor damage and progressive visual loss.[4]

Optical coherence tomography has revolutionized retinal imaging by providing high-resolution cross-sectional visualization of retinal architecture.[5] Spectral-domain OCT is currently considered the gold standard imaging modality for diagnosis and monitoring of diabetic macular edema.[6]

Several OCT-derived biomarkers have been investigated for their role in predicting visual outcomes and treatment response in DME.[7] Important biomarkers include central macular thickness, disorganization of retinal inner layers, hyperreflective foci, intraretinal cysts, subretinal fluid, and ellipsoid zone integrity.[8]

Central macular thickness has traditionally been used as an anatomical indicator of retinal edema severity.[9] However, retinal thickness alone may not adequately correlate with functional visual outcomes.[10]

Disorganization of retinal inner layers has emerged as an important biomarker associated with visual impairment

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in DME.[11] Similarly, disruption of the ellipsoid zone reflects photoreceptor damage and has been associated with poor visual prognosis.[12]

Hyperreflective foci observed on OCT are believed to represent inflammatory cell aggregates or lipid extravasation and may indicate chronic retinal inflammation.[13] Identification of OCT biomarkers may therefore help in predicting disease progression and optimizing individualized treatment strategies.[14]

Materials And Methods

Study Design

Prospective longitudinal observational study.

Study Duration

July 2024 to June 2025.

Study Location

Department of Ophthalmology, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India.

Sample Size

100 patients diagnosed with diabetic macular edema.

Inclusion Criteria

- Patients aged ≥18 years with diabetic macular edema
- OCT-confirmed macular edema
- Patients willing to participate

Exclusion Criteria

- Macular edema due to causes other than diabetes
- Previous vitreoretinal surgery
- Media opacity affecting OCT quality
- Retinal vascular occlusion
- Uveitis
- Poor follow-up compliance

Methodology

All patients underwent:

- Best corrected visual acuity assessment
- Slit lamp examination
- Fundus examination
- Intraocular pressure measurement
- Spectral-domain OCT imaging

Visual acuity was converted into logMAR units for statistical analysis.

The following OCT biomarkers were assessed:

- Central macular thickness (CMT)
- DRIL
- Hyperreflective foci
- Intraretinal cysts
- Subretinal fluid
- Ellipsoid zone disruption

Patients received treatment according to standard institutional protocol including anti-VEGF therapy and/or focal laser therapy.

Statistical Analysis

Data were analyzed using SPSS version 26.0. Quantitative variables were expressed as mean ± standard deviation. Pearson correlation coefficient, paired t-test, ANOVA, and multivariate regression analysis were used. $p<0.05$ was considered statistically significant.

Ethical Clearance

Institutional ethical committee approval was obtained prior to commencement of the study. Written informed consent was obtained from all participants.

Results

A total of 100 patients with OCT-confirmed diabetic macular edema were enrolled and completed the 12-month prospective follow-up. All patients underwent serial ophthalmic examination, visual acuity assessment, and OCT imaging at baseline, 3 months, 6 months, and 12 months.

The mean age of study participants was 58.6 ± 8.7 years, ranging from 41 to 76 years. Male participants constituted 62% of the study population. The mean duration of diabetes mellitus was 10.4 ± 4.8 years, and hypertension was present in 54% of patients. Baseline demographic and clinical characteristics are summarized in Table 1.

Table 1 demonstrates the baseline demographic and systemic clinical profile of the enrolled diabetic macular edema patients.

Figure 1 illustrates that the majority of patients belonged to the 50–69 years age group.

OCT biomarker analysis demonstrated that intraretinal cysts were the most common retinal abnormality, observed in 76% of patients. Hyperreflective foci were present in 63%, DRIL in 48%, ellipsoid zone disruption in 42%, and subretinal fluid in 36% of cases. Distribution of OCT biomarkers is summarized in Table 2 and illustrated in Figure 2.

Table 2 demonstrates the prevalence of important OCT biomarkers identified among study participants.

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Variable	*Value*
Total participants	100
Mean age (years)	58.6 ± 8.7
Age range (years)	41–76
Male	62 (62%)
Female	38 (38%)
Mean duration of diabetes (years)	10.4 ± 4.8
Hypertension	54 (54%)
Mean HbA1c (%)	8.3 ± 1.2
Baseline BCVA (logMAR)	0.82 ± 0.24
Baseline CMT (µm)	468.4 ± 92.5

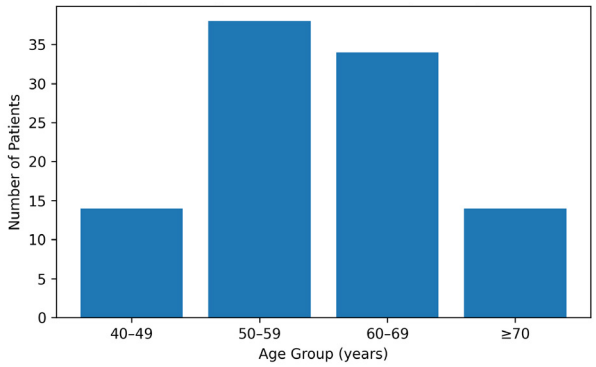

Figure 1: Age Distribution of Study Participants

Table 2: Distribution of OCT Biomarkers Among DME Patients

OCT Biomarker	*Number (n)*	*Percentage (%)*
Intraretinal cysts (IRC)	76	76.0
Hyperreflective foci (HRF)	63	63.0
DRIL	48	48.0
Ellipsoid zone disruption	42	42.0
Subretinal fluid (SRF)	36	36.0

Figure 2 graphically represents the frequency of major OCT biomarkers among patients with diabetic macular edema.

Significant improvement in visual acuity was observed during the follow-up period. Mean BCVA improved progressively from 0.82 ± 0.24 logMAR at baseline to 0.69 ± 0.21 logMAR at 3 months, 0.59 ± 0.20 logMAR at 6 months, and 0.51 ± 0.19 logMAR at 12 months. The improvement was statistically significant at each follow-up interval ($p<0.001$). Detailed visual acuity changes are summarized in Table 3 and represented in Figure 3.

Table 3 demonstrates progressive improvement in visual acuity throughout the study period.

Figure 3 demonstrates gradual functional visual recovery following treatment and follow-up.

A significant reduction in retinal thickness was observed during the study period. Mean central macular

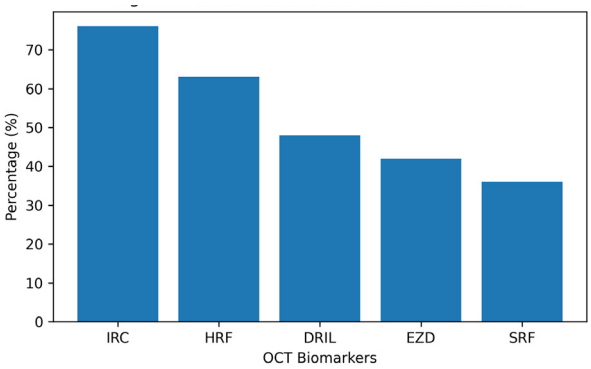

Figure 2: Distribution of OCT Biomarkers in DME

Table 3: Change in Best Corrected Visual Acuity During Follow-up

Follow-up Duration	*Mean BCVA (logMAR)*	*Mean Improvement*	*p-value*
Baseline	0.82 ± 0.24	—	—
3 months	0.69 ± 0.21	0.13	<0.001
6 months	0.59 ± 0.20	0.23	<0.001
12 months	0.51 ± 0.19	0.31	<0.001

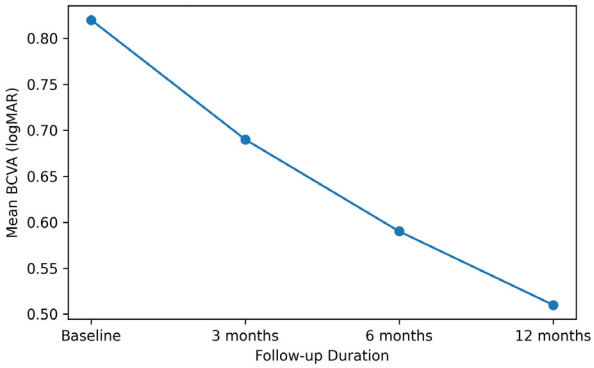

Figure 3: Improvement in Mean BCVA During Follow-up

thickness decreased from 468.4 ± 92.5 µm at baseline to 398.7 ± 76.3 µm at 3 months, 349.5 ± 64.1 µm at 6 months, and 311.2 ± 58.6 µm at 12 months (p<0.001). These findings are summarized in Table 4 and illustrated in Figure 4.

Table 4 demonstrates significant anatomical improvement in retinal edema during the follow-up period.

Figure 4 illustrates progressive reduction in retinal edema over the 12-month study period.

Correlation analysis revealed that DRIL, hyper-reflective foci, and ellipsoid zone disruption demonstrated significant negative correlation with final visual acuity.

Table 4: Reduction in Central Macular Thickness During Follow-up

Follow-up Duration	*Mean CMT (µm)*	*Mean Reduction (µm)*	*p-value*
Baseline	468.4 ± 92.5	—	—
3 months	398.7 ± 76.3	69.7	<0.001
6 months	349.5 ± 64.1	118.9	<0.001
12 months	311.2 ± 58.6	157.2	<0.001

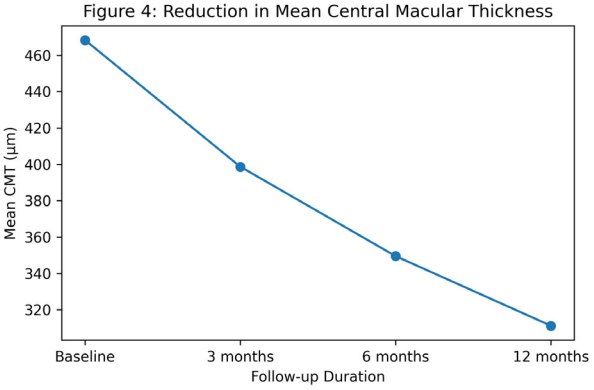

Figure 4: Reduction in Mean Central Macular Thickness During Follow-up

Ellipsoid zone disruption showed the strongest negative correlation (r = −0.76, p<0.001), followed by DRIL (r = −0.71, p<0.001). Subretinal fluid demonstrated mild positive association with better visual outcomes. These findings are summarized in Table 5.

Table 5 demonstrates statistically significant correlation between OCT biomarkers and visual outcomes among DME patients.

Patients with DRIL demonstrated significantly poorer final visual acuity compared to patients without DRIL. Mean final BCVA among DRIL-positive patients was 0.72 ± 0.16 logMAR compared to 0.39 ± 0.11 logMAR among DRIL-negative patients (p<0.001). Similarly, ellipsoid zone disruption was associated with worse final visual outcomes. Comparative subgroup analysis is shown in Table 6.

Table 6 demonstrates significantly poorer visual outcomes among patients with adverse OCT biomarkers.

Multivariate regression analysis identified DRIL and ellipsoid zone disruption as independent predictors of poor visual outcome after adjustment for age, duration of diabetes, HbA1c levels, and central macular thickness. Detailed regression analysis is summarized in Table 7.

Table 7 demonstrates that DRIL and ellipsoid zone disruption were the strongest independent predictors of poor visual prognosis.

Figure 5 illustrates the relationship between structural retinal biomarkers and functional visual outcomes in diabetic macular edema patients.

Table 5: Correlation Between OCT Biomarkers and Final Visual Acuity

OCT Biomarker	*Correlation Coefficient (r)*	*p-value*
DRIL	−0.71	<0.001
Hyperreflective foci	−0.62	<0.001
Ellipsoid zone disruption	−0.76	<0.001
Intraretinal cysts	−0.48	0.003
Subretinal fluid	+0.29	0.041

Table 6: Comparison of Final Visual Acuity According to OCT Biomarker Status

OCT Biomarker	*Present*	*Absent*	*p-value*
DRIL	0.72 ± 0.16	0.39 ± 0.11	<0.001
Ellipsoid zone disruption	0.76 ± 0.18	0.42 ± 0.13	<0.001
Hyperreflective foci	0.68 ± 0.15	0.45 ± 0.12	0.002

Values expressed as mean final BCVA (logMAR).

Table 7: Multivariate Logistic Regression Analysis of Predictors of Poor Visual Outcome

Variable	*Odds Ratio (OR)*	*95% Confidence Interval*	*p-value*
DRIL	3.84	1.82–7.91	<0.001
Ellipsoid zone disruption	4.29	2.01–8.68	<0.001
Hyperreflective foci	2.12	1.08–4.16	0.031
Duration of diabetes >10 years	1.76	1.02–3.42	0.044
HbA1c >8%	1.93	1.10–3.88	0.039

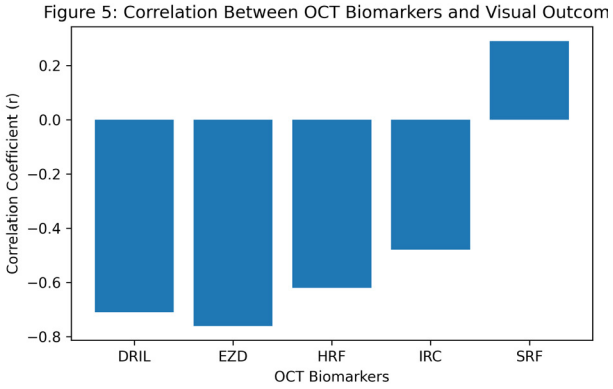

Figure 5: Correlation Between OCT Biomarkers and Final Visual Outcome

Discussion

The present prospective longitudinal study demonstrated significant association between OCT biomarkers and visual outcomes in diabetic macular edema patients.[15]

The demographic profile observed in the present study was comparable to previous studies evaluating diabetic retinal disease among middle-aged and elderly diabetic populations.[16]

Significant improvement in visual acuity observed during follow-up was similar to findings reported in previous clinical studies evaluating anti-VEGF therapy in DME.[17]

Reduction in central macular thickness significantly correlated with improvement in visual acuity, consistent with previous OCT-based studies.[18]

DRIL emerged as one of the strongest predictors of poor visual outcome in the present study. Previous investigators have also reported significant association between DRIL extent and visual impairment.[19]

Ellipsoid zone disruption demonstrated strong negative correlation with visual recovery among DME patients, indicating the importance of photoreceptor integrity in visual prognosis.[20]

Hyperreflective foci were significantly associated with poorer visual outcomes and may reflect chronic retinal inflammation and blood-retinal barrier dysfunction.[21]

Subretinal fluid was associated with comparatively better visual outcomes, suggesting relatively preserved photoreceptor architecture in such cases.[22]

Previous investigators have emphasized the importance of OCT biomarkers in predicting treatment response and monitoring disease progression in diabetic macular edema.[23]

Biomarker-based OCT assessment may facilitate individualized therapeutic planning and prognostic counseling among DME patients.[24]

The findings of the present study support the growing role of OCT biomarkers as important prognostic indicators in diabetic macular edema.[25]

Conclusion

OCT biomarkers demonstrate significant correlation with visual outcomes in diabetic macular edema. DRIL, ellipsoid zone disruption, and hyperreflective foci were strongly associated with poorer visual prognosis, whereas reduction in central macular thickness correlated with visual improvement. OCT biomarker evaluation may help in individualized treatment planning and prognostication in DME patients.

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