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Optical coherence tomography biomarkers and their association with baseline visual acuity in diabetic macular edema. A cross-sectional observational study.

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Abstract

Background

Diabetic macular edema is a major cause of visual impairment in individuals with diabetes mellitus and remains a significant contributor to functional vision loss.

Objectives

To determine the frequency of key optical coherence tomography biomarkers in diabetic macular edema and to evaluate their association with baseline best-corrected visual acuity.

Methods

This cross-sectional observational study included 100 eyes of 100 consecutive patients with diabetic macular edema attending a tertiary care teaching hospital in South India. All participants underwent comprehensive ophthalmic examination, including best-corrected visual acuity assessment using Snellen charts, subsequently converted to logMAR units for statistical analysis. Spectral-domain optical coherence tomography was performed to document central macular thickness and qualitative biomarkers, including intraretinal cystoid spaces, subretinal fluid, ellipsoid zone disruption, disorganization of retinal inner layers, and hyperreflective foci. Associations between biomarkers and baseline visual acuity were analyzed using appropriate statistical tests, with $p<0.05$ considered significant.

Results

Participants were predominantly aged 41–60 years (48%) and >60 years (38%), with male predominance (62%). Diabetes duration exceeded five years in 78% of patients, and diffuse edema was observed in 71%. Moderate visual impairment (6/18–6/60) occurred in 62%. Increased central macular thickness was present in 82%, intraretinal cysts in 76%, hyperreflective foci in 57%, ellipsoid zone disruption in 44%, and disorganization of retinal inner layers in 41%. Visual acuity was significantly worse in eyes with ellipsoid zone disruption (0.92 ± 0.21 logMAR; $p<0.001$) and disorganization of retinal inner layers (0.95 ± 0.22 logMAR; $p<0.001$). Subretinal fluid showed no significant association ($p=0.087$).

Conclusion

Microstructural retinal disruption demonstrates strong association with poorer baseline visual acuity in diabetic macular edema.

Recommendations

Routine evaluation of prognostically relevant optical coherence tomography biomarkers should be integrated into baseline assessment to enhance risk stratification and individualized clinical decision-making.

Keywords: Diabetic macular edema; Optical coherence tomography; Visual acuity; Ellipsoid zone; Disorganization of retinal inner layers.
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Introduction.

Diabetic macular edema (DME) is one of the most frequent and vision-threatening microvascular complications of diabetes mellitus and remains a major cause of visual disability worldwide. Long-term epidemiological studies have demonstrated that the risk of diabetic retinopathy and its sight-threatening sequelae, including DME, increases progressively with the duration of diabetes, underscoring its chronic and cumulative impact on vision [1]. With the rising global and national prevalence of diabetes, the burden of DME continues to escalate, affecting patients' quality of life, occupational productivity, and long-term visual prognosis, particularly when diagnosis and treatment are delayed.

Conventional clinical examination and fundus bio microscopy play a crucial role in detecting macular edema; however, they are limited in their ability to identify subtle retinal structural alterations that directly impact visual function. The advent of optical coherence tomography (OCT) has transformed the evaluation of DME by providing high-resolution, cross-sectional imaging of retinal layers in a rapid, non-invasive manner. Spectral-domain OCT allows precise quantification of central retinal thickness and detailed visualization of intraretinal morphology, enabling objective assessment of disease severity [2].

Beyond retinal thickness, OCT has facilitated the identification of several qualitative biomarkers that reflect underlying pathophysiological processes in DME. These include intraretinal cystoid spaces, subretinal fluid, hyperreflective foci, disruption of the photoreceptor ellipsoid zone, and disorganization of the retinal inner layers (DRIL). Such features are thought to represent varying contributions of vascular leakage, inflammatory activity, neurodegeneration, and photoreceptor damage [3,4]. Increasing evidence suggests that these microstructural changes are closely linked to functional outcomes and may explain the heterogeneity in visual acuity among patients with comparable degrees of macular thickening.

Visual acuity in DME often shows wide inter-individual variability, even in eyes with similar central macular thickness, highlighting the limitations of thickness-based assessment alone. Studies have demonstrated that the integrity of the ellipsoid zone and organization of inner retinal layers are critical determinants of visual function, with disruption of these structures being associated with poorer visual acuity [4–6]. Consequently, evaluating OCT biomarkers that correlate with baseline visual acuity has important clinical implications for prognostication, treatment planning, and patient counseling.

In the Indian context, published data examining the association between OCT biomarkers and baseline visual acuity in DME remain limited, particularly from tertiary care government institutions that cater to diverse socioeconomic populations. Generating locally relevant evidence is therefore essential for refining baseline assessment protocols and optimizing routine clinical decision-making.

The objectives of this study were to describe the distribution of key OCT biomarkers in eyes with diabetic macular edema and to analyze their association with baseline best-corrected visual acuity.

Materials and Methods

Study design, setting, and period

This hospital-based cross-sectional observational study was undertaken to evaluate optical coherence tomography (OCT) biomarkers and their association with baseline visual acuity among patients with diabetic macular edema. The study was conducted at Sarojini Devi Eye Hospital, Osmania Medical College and its associated teaching hospital, Hyderabad, Telangana, India. This tertiary care referral centre delivers comprehensive ophthalmic services and caters to both urban and rural populations. Eligible participants were recruited consecutively over the study period from 25 August 2025 to 30 October 2025.

Study population and sample size

The study included 100 eyes from 100 consecutive patients diagnosed with diabetic macular edema who satisfied the predefined inclusion criteria during the

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recruitment period. Only one eye per participant was analyzed to eliminate inter-eye correlation bias. The sample size was calculated using the single-population proportion formula for cross-sectional studies:

$$n = (Z^2 \times p \times (1 - p)) / d^2$$

where Z represents the standard normal deviate at 95% confidence (1.96), p is the anticipated proportion, and d denotes the absolute precision. Assuming a conservative prevalence estimate of 50% (p = 0.5) to maximize sample size and a precision of 10% (d = 0.1), the calculated minimum sample size was:

$$n = (1.96^2 \times 0.5 \times 0.5) / (0.1)^2 = 96.04.$$

After rounding up and accounting for potential exclusions due to poor-quality imaging or incomplete data, the final sample size was fixed at 100 participants within the stipulated study period.

Inclusion criteria

Adult patients with type 1 or type 2 diabetes mellitus presenting with clinically evident and OCT-confirmed diabetic macular edema, and who provided written informed consent, were included in the study.

Exclusion criteria

Eyes with coexisting retinal pathologies, advanced media opacities precluding adequate fundus visualization, historywith prior intravitreal injections, previous intraocular surgery within the preceding six months, or poor-quality OCT scans were excluded from analysis.

Clinical evaluation

All participants underwent a detailed clinical evaluation, including demographic profiling and documentation of diabetes duration. A comprehensive ophthalmic examination was performed in all cases. Best-corrected visual acuity was assessed using standard Snellen charts and converted to logarithm of the minimum angle of resolution units for statistical analysis.

OCT assessment

Spectral-domain optical coherence tomography was performed for all study eyes using a standardized imaging protocol. Central macular thickness was quantitatively recorded. Qualitative assessment of OCT biomarkers included the presence of intraretinal cystoid spaces, subretinal fluid, ellipsoid zone disruption, disorganization of retinal inner layers, hyperreflective foci, and vitreomacular interface abnormalities.

Bias: potential sources and how they were addressed

Selection bias was minimized by enrolling consecutive eligible patients presenting during the study period, using predefined inclusion/exclusion criteria, and including only one eye per patient to avoid within-subject correlation. Information/measurement bias was reduced by using a standardized protocol for best-corrected visual acuity testing and spectral-domain OCT acquisition, excluding poor-quality scans, and applying uniform operational definitions for OCT biomarkers. Observer bias was limited by having OCT biomarker assessment performed by trained ophthalmologists/retina clinicians using consistent grading criteria; where feasible, discrepant interpretations were resolved by consensus. Confounding was partially controlled by restricting the sample (excluding other retinal diseases and recent intraocular interventions) and by applying appropriate statistical tests for associations, with a predefined significance threshold ($p<0.05$). Data entry errors were reduced through double-checking of case record forms and dataset validation prior to analysis.

Statistical analysis

Collected data were entered into a structured database and analyzed using standard statistical software. Descriptive statistics were used to summarize demographic, clinical, and OCT-related variables. Associations between OCT biomarkers and baseline visual acuity were assessed using appropriate

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inferential statistical tests. A p-value less than 0.05 was considered statistically significant.

Ethical considerations

The study protocol was reviewed and approved by the Institutional Ethics Committee of Osmania Medical College and associated hospital, Hyderabad, Telangana, India. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrolment. Confidentiality of patient data was strictly maintained, and participants were informed of their right to withdraw from the study at any stage without affecting their standard clinical care.

Results

Participant Flow

During the study period, consecutive patients presenting with clinically suspected diabetic macular edema were screened for eligibility at the tertiary care center. Patients who met predefined inclusion and exclusion criteria and provided written informed consent were enrolled.

A total of **100 eligible patients (100 eyes)** were included in the study. Only one eye per participant was analyzed to avoid inter-eye correlation. Patients with coexisting retinal diseases, recent intraocular surgery, prior intravitreal therapy, or poor-quality OCT scans were excluded during the eligibility assessment phase, as per protocol.

As this investigation employed a cross-sectional design without longitudinal follow-up, all enrolled participants completed baseline clinical and imaging evaluations. There was **no post-enrollment attrition**, and all 100 enrolled eyes were included in the final statistical analysis.

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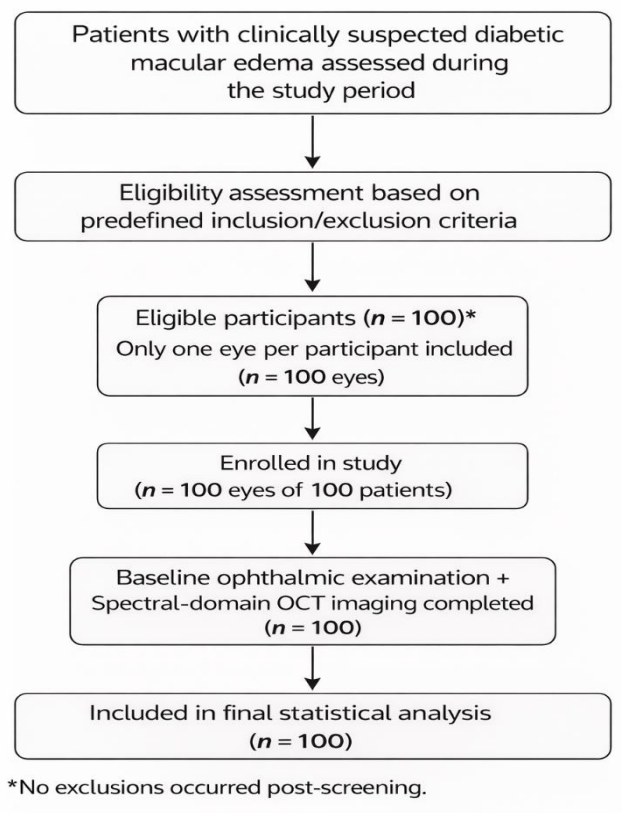

Figure 1: Participant Flow Diagram

A total of 100 eyes of 100 patients with diabetic macular edema were analyzed. The demographic and clinical profile of the study participants is summarized in Table 1.

Table 1. Demographic and clinical profile of study participants (N = 100)

Variable	Category	n (%)
Age group (years)	≤40	14 (14.0)
	41–60	48 (48.0)
	>60	38 (38.0)
Sex	Male	62 (62.0)
	Female	38 (38.0)
Duration of diabetes	<5 years	22 (22.0)
	5–10 years	46 (46.0)
	>10 years	32 (32.0)
Type of DME	Focal	29 (29.0)
	Diffuse	71 (71.0)

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The majority of patients were aged above 40 years, with males constituting a higher proportion. Most participants had diabetes for more than five years, and diffuse DME was more common than focal DME. Baseline visual acuity distribution is shown in Table 2. Moderate visual impairment was the predominant presentation, while a smaller proportion of eyes retained relatively preserved vision at presentation.

Table 2. Distribution of baseline visual acuity among studied eyes (N = 100)

Baseline BCVA (Snellen equivalent)	n (%)
≥6/12	24 (24.0)
6/18–6/24	34 (34.0)
6/36–6/60	28 (28.0)
<6/60	14 (14.0)

The frequency of OCT biomarkers is detailed in Table 3. Increased central macular thickness and intraretinal cystoid spaces were the most commonly observed features. Ellipsoid zone disruption, DRIL, and hyperreflective foci were noted in a substantial proportion of eyes, whereas vitreomacular interface abnormalities were less frequent.

Table 3. Frequency of OCT biomarkers in diabetic macular edema (N = 100)

OCT biomarker	Present n (%)
Increased central macular thickness (CMT ≥300 µm)	82 (82.0)
Intraretinal cystoid spaces	76 (76.0)
Subretinal fluid (SRF)	38 (38.0)
Disruption of ellipsoid zone (EZ)	44 (44.0)
Disorganization of retinal inner layers (DRIL)	41 (41.0)
Hyperreflective foci (HRF)	57 (57.0)
Vitreomacular interface abnormalities	19 (19.0)

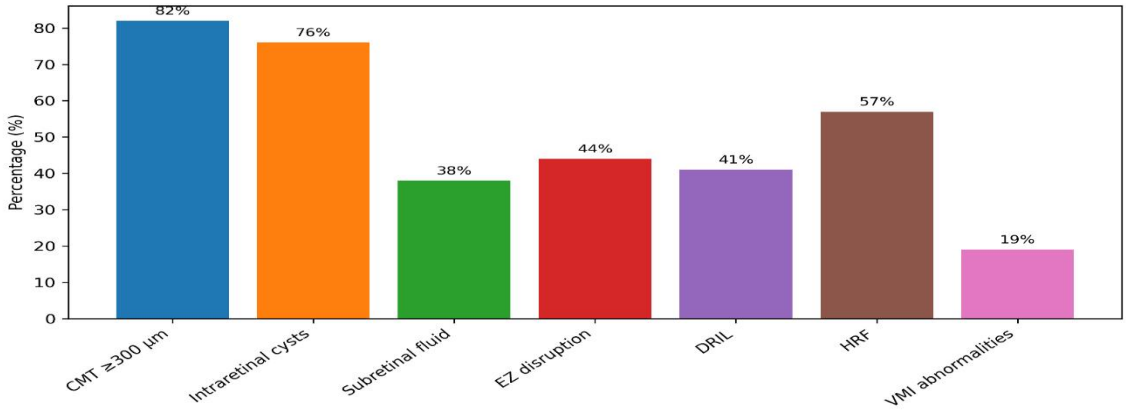

Figure 1: Frequency of OCT Biomarkers in Diabetic Macular Edema

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The association between OCT biomarkers and baseline visual acuity is presented in Table 4. Eyes with ellipsoid zone disruption and DRIL demonstrated significantly poorer visual acuity. Increased central macular thickness, intraretinal cysts, and hyperreflective foci were also significantly associated with reduced baseline vision. The presence of subretinal fluid alone did not show a statistically significant association with visual acuity.

Table 4. Association between OCT biomarkers and baseline visual acuity (N = 100)

OCT biomarker	Mean BCVA (logMAR) ± SD	p value
CMT ≥300 µm	0.78 ± 0.24	0.012
Intraretinal cysts	0.81 ± 0.26	0.009
Subretinal fluid	0.74 ± 0.23	0.087
EZ disruption	0.92 ± 0.21	<0.001
DRIL	0.95 ± 0.22	<0.001
Hyperreflective foci	0.83 ± 0.25	0.015

Discussion

The present study evaluated key optical coherence tomography biomarkers in diabetic macular edema and analyzed their association with baseline visual acuity in a tertiary care setting. Moderate visual impairment (6/18–6/60) was observed in 62% of eyes, with a mean baseline visual acuity ranging from 0.74 to 0.95 logMAR depending on biomarker status. The findings reinforce that visual impairment in diabetic macular edema is multifactorial and cannot be adequately explained by retinal thickness alone. Microstructural integrity of retinal layers demonstrated stronger statistical associations with functional outcomes than thickness measurements [7,8].

Increased central macular thickness (≥300 µm) was present in 82% of eyes and showed a statistically significant association with worse visual acuity (mean 0.78 ± 0.24 logMAR; p=0.012). Intraretinal cystoid spaces, noted in 76% of eyes, were also significantly correlated with reduced vision (0.81 ± 0.26 logMAR; p=0.009). However, the magnitude of association was modest compared to markers of retinal layer disruption, supporting prior evidence that thickness alone has limited predictive value [7,8].

Ellipsoid zone disruption, observed in 44% of eyes, demonstrated one of the strongest associations with poor baseline vision (0.92 ± 0.21 logMAR; p<0.001). Similarly, disorganization of retinal inner layers, present in 41%, showed the highest mean logMAR value (0.95 ± 0.22; p<0.001). These findings underscore the critical role of photoreceptor and inner retinal integrity in determining visual function, consistent with earlier reports [8,9].

Hyperreflective foci were identified in 57% of eyes and were significantly associated with visual impairment (0.83 ± 0.25 logMAR; p=0.015), suggesting a contribution of inflammatory and lipid-mediated mechanisms [10,11]. In contrast, subretinal fluid, present in 38% of cases, did not demonstrate a statistically significant association with visual acuity (p=0.087), aligning with prior observations that its prognostic impact is variable [12–14].

Collectively, these statistically supported findings highlight the importance of integrating both quantitative and qualitative optical coherence tomography biomarkers in the functional assessment of diabetic macular edema.

Generalizability

The study population reflects patients attending a large government tertiary care hospital in South India,

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encompassing diverse socioeconomic and clinical backgrounds. The findings are therefore applicable to similar hospital-based diabetic populations, although extrapolation to community-based or treated cohorts should be done cautiously.

Conclusion

This study demonstrates that specific OCT biomarkers are closely associated with baseline visual acuity in diabetic macular edema. Disruption of the ellipsoid zone and disorganization of retinal inner layers showed the strongest relationship with poorer vision, emphasizing the importance of microstructural retinal integrity. While central macular thickness and intraretinal cysts remain common findings, they alone do not adequately explain functional impairment. Comprehensive OCT-based evaluation at presentation provides valuable prognostic information and supports more individualized clinical assessment in patients with diabetic macular edema.

Limitations

The study had a relatively small sample size and a short recruitment period. Longitudinal follow-up and treatment response were not evaluated. The analysis focused on baseline visual acuity without assessing contrast sensitivity or other functional outcomes. Being a single-center hospital-based study, selection bias cannot be excluded.

Recommendations

Routine OCT evaluation in diabetic macular edema should extend beyond central macular thickness to include qualitative assessment of prognostically relevant biomarkers. Ellipsoid zone integrity and DRIL should be specifically documented at baseline to aid visual prognostication. Incorporating standardized OCT biomarker reporting into clinical practice may improve treatment planning, patient counseling, and outcome prediction. Future studies with longitudinal design are encouraged to evaluate the impact of these biomarkers on treatment response and long-term visual outcomes.

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Abbreviations

BCVA – Best-corrected visual acuity;
CMT – Central macular thickness;
DME – Diabetic macular edema;
DRIL – Disorganization of retinal inner layers;
EZ – Ellipsoid zone;
HRF – Hyperreflective foci;
OCT – Optical coherence tomography;
SD-OCT – Spectral-domain optical coherence tomography.

Source of funding

Study has no funding

Conflict of interest

Author declares no cconflict of interest.

Author contributions

KF-Concept and design of the study, results interpretation, review of literature and preparing first draft of manuscript. Statistical analysis and interpretation, revision of manuscript. **GSS**-Concept and design of the study, results interpretation, review of literature and preparing first draft of manuscript, revision of manuscript.**AF-**Review of literature and preparing first draft of manuscript. Statistical analysis and interpretation.

Data availability

Data available on request

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