Foveal Sensitivity as a Biomarker for Early Maculopathy in Diabetic Patients *Hind Ibrahim Helmy Yousef ¹, Rasha Muhammad Ibrahim Rashed ², Hanan Saied Hegazy ²

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ABSTRACT

Background: Hyperglycemia is linked to diabetic retinopathy (DR) and diabetic macular oedema (DME). Neurodegeneration in the retina is the cause of their development. Even in the absence of DR that is clinically apparent, this neurodegeneration results in diminished foveal sensitivity.

Aim: To compare foveal sensitivity in diabetic to nondiabetic patients by using standard automated perimetry a (10-2) protocol.

Patients and methods: A prospective, cross-sectional, comparative study was conducted at the Ophthalmology Department, Al-Zahraa University Hospital in Cairo, Egypt. All participants, who ranged in age from 18 to 60 years, were divided into two groups: Group (A) included sixty eyes from thirty diabetic patients without retinopathy, while Group (B) included sixty eyes from 30 non-diabetic patients. Every participant had a detailed history taking, full ocular examination, visual field testing, and OCT investigation.

Results: The control group had substantially better mean values for visual acuity (VA), best corrected visual acuity (BCVA), central foveal thickness (CFT), foveal sensitivity (FS1), (FS3), and (FS5) degrees, and mean deviation (MD) than the diabetic group. MD and foveal sensitivity (FS1), (FS3), and (FS5) showed a substantial positive connection. Significant mild positive correlations were found between pattern standard deviation and FS1, FS3, and FS5, between VA and FS1, FS3, and FS5, and between BCVA and FS1, FS3, and FS5.

Conclusion: Standard automated perimetry can detect those who are at risk of future vision loss through functional abnormalities in the fovea prior to any substantial structural changes.

Keywords: Foveal Sensitivity, Maculopathy, Diabetes Mellitus, Standard Automated Perimetry, Pattern Standard Deviation, Mean Deviation.

INTRODUCTION

Diabetes mellitus (DM) constitutes one of the most significant global health crises, with its prevalence continuing to rise at an alarming rate. Projections suggest that the worldwide incidence of diabetes could quadruple by the year 2030. Recent epidemiological research indicates that the total prevalence of diabetic retinopathy (DR) is estimated to be as high as 35%. Furthermore, specific complications of DR, such as proliferative DR and diabetic macular oedema (DME), each account for a substantial prevalence of approximately 7% (1).

DME is recognized as the most frequent retinal consequence in DR, and its severity may not necessarily correlate with the overall severity of the underlying retinopathy. The early diagnosis of this condition is complicated by the challenge of detecting subtle morphological and functional abnormalities that are directly linked to subsequent visual outcomes ⁽²⁾.

Both DME and DR have been traditionally classified as microvascular complications of diabetes. However, increasing evidence highlights that retinal neurodegeneration is equally crucial for the initiation and progression of both conditions. It has been demonstrated that early neurodegeneration can lead to a quantifiable reduction in foveal sensitivity, which can be detected even before any visible vascular lesions begin to appear ⁽³⁾.

Since visual acuity (VA) is a poor indicator of early disease, it is frequently used to diagnose visual impairment, but it does not change significantly until approximately 55% of all neuroretinal channels are destroyed. Hence, it is not a reliable prognostic indicator in the early stages of the disease ⁽⁴⁾.

Since the 1990s, standard automated perimetry (SAP) has been the most widely adopted clinical test for evaluating retinal sensitivity. This method provides detailed insights into decreased retinal sensitivity (RS), which shows a strong correlation with the extent of retinal non-perfusion in individuals with DR. A lower mean deviation (MD) value, a decrease in foveal sensitivity, and a higher pattern standard deviation (PSD) value all lend support to the notion that the number of localized spots with lower RS increases proportionally with the severity of the retinopathy ⁽⁵⁾.

Numerous investigations have demonstrated that microperimetry (MP) can simultaneously measure retinal sensitivity within the central 20 degrees of the macula, providing a high level of detail. This method is particularly beneficial for patients who exhibit unstable or parafoveal fixation. Despite its clinical utility, the sole disadvantage of MP is the exorbitant cost associated with the device. As a result, SAP remains a viable and effective alternative tool for detecting early functional alterations

Received: 30/04/2025 Accepted: 30/06/2025 in the fovea of diabetic patients when performed using a 10-2 testing procedure ⁽⁶⁾.

PATIENTS AND METHODS

A prospective, cross-sectional, comparative study was carried out over the course of six months, from March 2024 to September 2024, at the Ophthalmology Department of Al-Zahraa University Hospital in Cairo, Egypt.

The participants were divided into two groups: Group (A): 30 diabetic patients (type 1 & 2) with 60 eyes who had no retinopathy or maculopathy that could be clinically identified, as further verified by optical coherence tomography. Group (B): 30 non-diabetic individuals with 60 eyes serve as a healthy control group free of systemic and ocular illnesses.

Inclusion criteria: Participants ranged in age from 18 to 60 years, with or without diabetes, without retinopathy or clinical maculopathy, and patients have mild cataracts (nuclear sclerosis (NS) grades II–III and grade I for posterior subcapsular cataract (PSC) according to the lens opacities grading system) were included.

Exclusion criteria: Patients with severe diabetic retinopathy, those who have had treatment for the condition, patients who are not cooperative, patients with near-vision impairments or any other eye condition that affects the visual field, like glaucoma, are unable to appreciate perimetry stimuli, patients who suffer from maculopathy due to ocular or systemic disorders, or patients who have posterior subcapsular cataracts grade II or more were excluded from the study.

All patients were subjected to:

Complete history taking

It included the personal history (name, age, parity, residence, occupation, and medical habits, especially smoking), the present history, visual symptoms and type and details of diabetes (duration, control and treatments), and the past history of ocular diseases such as diabetic retinopathy, surgeries and systemic diseases other than diabetes.

Complete ophthalmic examination

- ✓ Best corrected visual acuity (BCVA) was examined for all participants leveraging a Snellen's visual acuity chart. The obtained values were subsequently converted to a logMAR scale to facilitate robust statistical analysis. Visual acuity was systematically categorized as:
 - ✓ Excellent visual Acuity 6/6-6/9
 - ✓ Mild visual impairment 6\12-6/18
 - ✓ Moderate visual impairment 6/24-6/60
 - ✓ Severe visual impairment < 6/60

This classification system provides a standardized framework for the clinical and statistical evaluation of visual function in the patient cohort.

Anterior segment examination using slit lamp (Topcon, Tokyo, Japan),

Intra Ocular Pressure measurement (using Goldman applanation tonometer) (Keeler, UK),

Posterior segment examination by slit lamp biomicroscopy with 90D lens (volk U.S.A).

We used the Lens Opacities Classification System III (LOCS III) for cataract grading.

Optical Coherence Tomography (OCT)

To exclude structural macular edema or maculopathy we used the (AVANTI WIDE FIELD spectral-domain OCT from OPTOVUE). (Optovue, Inc, Fremont, CA). In order to thoroughly cover the macular region, the scan methodology used a scan area that was usually set at 6x6 mm. The transverse resolution was around 15 μ m, whereas the axial resolution was about 5 μ m. With 70,000 A-scans per second, the scan speed reduced motion artefacts and enhanced image quality. The inner retinal layers and the Foveal Avascular Zone (FAZ) were given special attention in order to guarantee proper retinal layer segmentation. To improve the signal-to-noise ratio—which is essential for identifying minute alterations in the foveal region—image averaging techniques were used.

Visual Field Testing

Visual field testing was conducted using the **Humphry** Field Analyzer (HFA) 750 (Carl Zeiss Meditec, Inc., Dublin, CA). The test was performed with Goldmann III boosts of different sizes and utilized the Swedish interactive threshold algorithm (SITA) standard 10-2 software to ensure a precise and efficient assessment of each patient's visual field (6). This combination of hardware and software is a standard in ophthalmological research for its reliability in detecting visual field defects. When fixation loss was less than 20%, the test was confidential and trustworthy. The mean foveal sensitivity was assessed at degrees 1, 3, and 5 for each patient in the diabetic and normal groups. The central retina was split into three concentric squares, with the center four spots representing degree 1, the surrounding twelve points representing degree 3, and the surrounding twenty points representing degree 5

Ethical approval: The study was authorized by Al-Azhar University's Ethics Committee, which made sure that all practices adhered to moral standards. Every participant gave their informed permission before enrolment, guaranteeing they were completely aware of the goals, methods, possible advantages, and hazards of the study. Additionally, participants were told that their involvement in the research was completely voluntary and that they may leave at any moment without it having an impact on their medical care or connection with their treating physician.

All the information gathered was kept completely confidential. It should be mentioned that no government, community, or organization provided financial assistance for this study. The study was conducted in accordance with ethical standards, including the Declaration of Helsinki and its amendments.

Statistical Analysis

All data were accurately entered, coded, and tabulated using the Statistical Package for Social Science (SPSS), specifically Version 27.0 for Windows (IBM Corp., Armonk, NY). The selection of appropriate statistical analyses for each parameter was determined by the nature of the data collected. The normality of continuous data distribution was assessed using the Shapiro-Wilk's test. For parametric numerical data, descriptive statistics included the mean, standard deviation (\pm SD), and range. Conversely, for non-parametric numerical data, the median and interquartile range (IQR) was utilized. Nonnumerical data were summarized using frequencies and percentages. To evaluate the statistical significance of differences between the means of the two study groups for parametric data, the Student T-Test was employed. For non-parametric data, the Mann-Whitney U test was used to assess the statistical significance of differences amongst the two groups.

RESULTS

Analysis of the demographic data for the studied cohorts showed a statistically significant age-related difference between the groups, with a corresponding p-value of 0.009. Conversely, no statistically significant difference was detected between the studied groups concerning the distribution of sex, as indicated by a p-value of 0.41 (Table 1).

Table (1): Sociodemographic characteristics of the studied patients

	Control N= 30	DM N= 30	P- Value
Age (year)			
Mean \pm SD	42±9.46	48.4 ± 8.83	0.009
Range(min-max)	(24-58)	(20-60)	
	12(40%)	9(30%)	
Sex	18(60%)	21(70%)	0.41

P-value >0.05: Not significant, P- value <0.05 is statistically significant, p<0.001 is highly significant.

According to anterior segment examination, in the DM group two cases (6.6%) had PSC+1 Oculi unitas (OU), five cases (16.7%) had NS+1 OU, MGD was found in 1 (3.3%), while no abnormality detected in 22 (73.4%) of cases and among all participants in the control group. Regarding posterior segment examination there was no abnormality detected in all groups (figure 1).

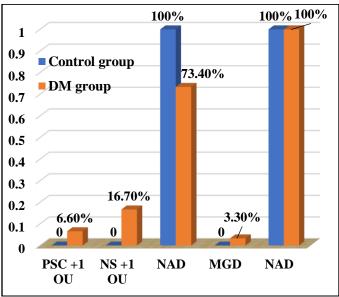


Figure (1): Distribution of Slit lamp examination among diabetic and control groups

Analysis of **visual acuity (VA)** in the control group revealed that 59 eyes (98%) demonstrated excellent visual acuity, with only 1 eye (2%) showing signs of mild visual impairment. In the diabetic group, 57 eyes (95%) had excellent VA, and 3 eyes (5%) were classified as having mild visual impairment. A highly statistically significant difference was observed between the two studied groups concerning both VA and **best-corrected visual acuity** (**BCVA**). Specifically, the mean values for both VA and BCVA were turned to be significantly higher in the control group when compared to the diabetic group, a finding supported by a p-value of less than 0.001 (Table 2). This result indicates a quantifiable difference in visual function between the two cohorts.

Table (2): Visual acuity and best corrected visual acuity (VA) among the studied patients

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Control		DM	P-
	eyes= 60	eyes= 60	Value
VA			
logMAR	0.1420±0.14738	0.2507±0.09766	<0.001
Mean \pm SD	0.18 (0: 0.48)	0.3 (0: 0.50)	
Median			
(Range)			
BCVA			
logMAR			
Mean \pm SD	0.042 ± 0.07743	0.1 ± 0.09756	<0.001
Median	0(0: 0.18)	0.18(0: 0.30)	
(Range)			

VA: Visual Acuity, BCVA: Best Corrected Visual Acuity P-value >0.05: Not significant, P-value <0.05 is statistically significant, p<0.001 is highly significant

A statistically significant difference was identified between the groups under study with regard to the findings for Central Foveal Thickness (CFT). It was observed that the mean CFT in the control group was significantly higher than that in the diabetic group, with a supporting p-value of 0.010. This outcome indicates a possible decrease in foveal thickness among diabetic patients, even when macular edema is not clinically evident (Figure 2).

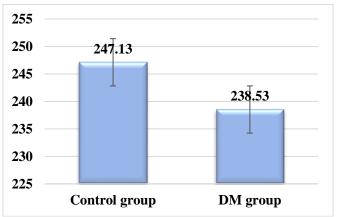


Figure (2): Distribution of central foveal thickness among diabetic and control groups.

A highly statistically significant difference was also observed between the studied groups concerning **foveal sensitivity** at 1, 3, and 5 degrees. The mean values for foveal sensitivity at all three degrees were found to be significantly higher in the control group when compared to the diabetic group, indicating a quantifiable reduction in foveal function in the latter cohort (Table 3).

Table (3): Foveal Sensitivity 1, 3, and 5 degrees among the studied patients

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	Control DM group group eyes= 60 eyes= 60		P- Value
FS 1 Mean ± SD	31.63±1.7	29.37±4.17	<0.001
Median	30.75(30: 35)	29.9	
(Range)		(15.20: 34.25)	
FS3			
Mean \pm SD	31.65±1.66	29.62±3.6	0.004
Median	30.91	30.91	
(Range)	(28.1: 34.7)	(18: 33.9)	
FS5			
Mean \pm SD	31.29±0.97	28.83±3.89	< 0.001
Median	30.9	29.9	
(Range)	(30: 33.65)	(15.40:33.40)	

FS 1: Foveal Sensitivity 1 degree, FS3: Foveal Sensitivity 3 degrees, FS5: Foveal Sensitivity 5 degrees, P- value >0.05: Not significant, P- value <0.05 is statistically significant, p<0.001 is highly significant.

Analysis of the study groups revealed a significant difference in visual function metrics. The **Mean Deviation (MD)** in the control group was -2.05 \pm 0.96, while it was -4.05 \pm 3.37 in the diabetic group. A statistically significant difference was found between the

two groups regarding MD, with a p-value of less than 0.001. Regarding **Pattern Standard Deviation (PSD)**, the mean value was 1.42 ± 0.41 in the control group and 1.92 ± 1.27 in the DM group. Although the mean PSD was greater in the DM group, this difference did not reach the threshold for statistical significance, as evidenced by a p-value of 0.228 (Table 4). This indicates a clear difference in overall retinal sensitivity but no significant difference in the localized variability of the visual field between the two cohorts.

Table (4): Mean deviation and pattern standard deviation among the studied patients

	Control group eyes= 60	DM group eyes= 60	P- Value
MD Mean ± SD Median	-2.05±0.96 -2.24	-4.05±3.37 -3.32	<0.001
(Range)	(-3.50:48)	(-7.65:64)	
PSD Mean ± SD Median (Range)	1.42±0.409 1.33 (0.79: 2.86)	1.92±1.27 1.38 (0.91: 6.15)	0.228

MD: Mean Deviation, PSD: Pattern Standard Deviation P - value >0.05: Not significant, P- value <0.05 is statistically significant, p<0.001 is highly significant.

Analysis of the data revealed a nuanced pattern in **foveal sensitivity (FS)** based on sex. The mean FS at 1 degree was 30.75 ± 3.4 in the male cohort and 30.2 ± 3.3 in the female cohort. At 3 degrees, the mean FS was 30.8 ± 2.96 in males and 30.9 ± 2.96 in females. A statistically significant difference was found between the two groups for both FS1 and FS3. However, regarding FS5, the mean value was 30.2 ± 3.04 in males and 29.8 ± 3.1 in females, and no statistically significant difference was observed between the groups for this measurement. This suggests that while differences in central foveal function exist, they do not extend to the more peripheral foveal region (Table 5).

Table (5): Relation between sex and sensitivity (FS1, FS3 and FS5 among the studied patients

	Male	Female	P-
	N=21	N= 39	Value
Fs1 (Mean \pm SD)	30.75 ± 3.4	30.2 ± 3.3	0.01
FS3 (Mean \pm SD)	30.8 ± 2.96	30.9 ± 2.96	0.01
FS5 (Mean \pm SD)	30.2 ± 3.04	29.8 ± 3.1	0.7

FS5: Foveal Sensitivity. P- Value >0.05: Not significant, P-value <0.05 is statistically significant, p<0.001 is highly significant, SD: standard deviation.

As depicted in Table 6, a significant strong positive correlation was observed between Mean Deviation (MD) and foveal sensitivity (FS) at all three measured degrees (1, 3, and 5). Additionally, a significant but mild positive correlation was found between both Visual Acuity (VA) and Best Corrected Visual Acuity (BCVA) and FS at all

three degrees. Conversely, no statistically significant correlation was established between Pattern Standard Deviation (PSD) and FS1, FS3, and FS5. A significantly weak positive correlation was also identified between Central Foveal Thickness (CFT) and foveal sensitivity at 1, 3, and 5 degrees. These results collectively illustrate the complex interrelationships between these functional and structural ophthalmic parameters.

Table (6): Correlation between different parameters

among diabetic group

Correlations				
		FS1	FS3	FS5
VA log MAR	r	0.443	0.426	0.441
	P-value	0.001*	0.001*	0.001*
BCVA log MAR	r	0.359	0.382	0.380
	P-value	0.001*	0.001*	0.001*
CFT	r	0.088	0.091	0.019
	P-value	0.34	0.324	0.839
MD	r	0.785	0.752	0.770
	P-value	0.001*	0.001*	0.001*
PSD	r	-0.362	-0.346	-0.270
	P-value	0.001*	0.001*	0.001*

r: Spearman correlation VA: Visual Acuity, BCVA: Best Corrected Visual Acuity, MD: Mean Deviation, PSD: Pattern Standard Deviation, FS 1: Foveal Sensitivity 1 degree, FS3: Foveal Sensitivity 3 degrees, FS5: Foveal Sensitivity 5 degrees.

DISCUSSION

The mean age of the diabetic group in the present study was 48.4 ± 8.83 years, while for the control group it was 42 ± 9.46 years. The two groups studied showed a statistically significant difference in their ages, pointing to a noteworthy disparity regarding this demographic variable.

In the current study, 57 (95%) eyes in the diabetic group had excellent VA and 3 (5%) eyes had mild VA impairment, whereas 59 (98%) eyes in the control group had excellent VA and 1 (2%) eye had moderate VA impairment. Regarding VA and BCVA, there was a highly statistically significant difference between the groups under study. Compared to the control group, the diabetic group's mean VA and BCVA was noticeably lower. Comparatively, in the diabetic group of the investigation conducted by Sahu and Kharole (7), a considerable portion of individuals, 51.1% (24 of 47), demonstrated best-corrected visual acuity (BCVA) in the excellent category. This was followed by cohorts with mild visual impairment at 29.8% (14 of 47) and moderate visual impairment at 19.2% (9 of 47). This distribution revealed a notable difference in visual acuity between the two cohorts, as the DM group showed a significantly worse performance. In contrast, the majority of individuals within the control group had BCVA in the category of excellent visual acuity, accounting for a high percentage of 95.3%. This finding highlights a clear divergence in visual function between the groups.

In their investigation into how diabetes affects visual acuity and how blood glucose levels relate to it, **Kurawa and Sadiq** ⁽¹⁰⁾ discovered that diabetic patients experienced more frequent and severe visual impairment than controls.

Our study results have revealed that the mean of CFT was significantly lower in the diabetic group (238.53 ± 13.97) compared to the control group (247.13 ± 19.04) (p=0.010).

Similarly, the central macular thickness (CMT) in diabetic individuals was $236.29\pm40.31~\mu m$, which was considerably thinner than the CMT in non-diabetic cases, which was $244.25\pm30.51~\mu m$, according to a research by **Pokhrel** *et al.* ⁽¹¹⁾. This can be explained by the fact that individuals in the diabetic group experienced neuronal degeneration, which resulted in a decrease in central macular thickness.

In a related study, **Dumitrescu** *et al.* ⁽¹²⁾ found that the central macular thickness of individuals with type 2 diabetes mellitus was noticeably smaller than that of the control eyes. According to **Soni** *et al.* ⁽¹³⁾, diabetic individuals with little retinopathy may have selective thinning of the inner retinal layers in the central retina as a result of early neuronal death in DR. Additionally, **Ezhilvendhan** ⁽¹⁴⁾ proposed that neural tissue loss causes macular thickness to diminish in early diabetes. However, CMT progressively rises as diabetes worsens and vascular permeability increases.

We found several statistically significant differences among the study participants, which might be a helpful metric for the early identification of macular alterations like MD and foveal sensitivity value. In terms of Foveal Sensitivity, there was a highly statistically significant difference between the groups under study at 1 degree, 3 degrees, and 5 degrees. In comparison to the control group (31.63±1.7, 31.65±1.66, and 31.29±0.97, respectively), the diabetic group's mean Foveal Sensitivity 1, 3, and 5 degrees was considerably lower (29.37±4.17, 29.62±3.6, and 28.83±3.89, respectively).

Similarly, **Somilleda-Ventura** *et al.* $^{(9)}$ discovered that the control group's mean foveal sensitivity (34.77±0.5) was statistically substantially higher than that of the DM group (32.87 ± 0.6). Consistent with **Sahu and Kharole's** $^{(7)}$ findings, the case group's mean foveal sensitivity was 28.57 ± 7.54, whereas the control group's was 32.16 ± 7.09. On average, the situational group exhibited considerably lower foveal edge awareness than the normative group. Our study's findings also align with those of **Somilleda-Ventura** *et al.* $^{(9)}$.

Our analysis of the data demonstrated a statistically significant difference between the two cohorts. The Mean Deviation (MD) in the diabetic group was found to be - 4.05 ± 3.37 , which was significantly lower than the mean MD of -2.05 \pm 0.96 recorded in the control group. This outcome indicates a quantifiable reduction in overall retinal sensitivity in the DM cohort.

The results of this study are consistent with research by Sahu and Kharole (7), in which the mean deviation (MD) value in their case group was recorded as -6.05 \pm 7.93, while it was -3.28 ± 1.70 in the control group. Their findings similarly demonstrated a statistically significant difference in the mean MD value between the case and control cohorts (p = 0.027). Furthermore, a similar outcome was observed by Bengtsson et al. (8), which provides additional corroboration. The MD value is a global index that provides a measure of overall retinal sensitivity. A value of 0 dB is considered the benchmark for a standard, healthy visual field, while a value of approximately -30 dB corresponds to a functionally blind field. Consequently, a negative MD value directly denotes a reduction in overall retinal sensitivity. The DM group's mean PSD in this study was 1.92±1.27, higher than the control group's mean PSD of 1.42±.41; nevertheless, this difference in PSD is none statistically significant.

According to **Sahu and Kharole** ⁽⁷⁾, the control group's mean PSD was 1.90 with a standard deviation of ± 1.55 , whereas the case group's was 2.58 with a standard deviation of ± 2.25 . Although the difference was none statistically significant, the case group's PSD was higher than the control group.

The mean deviation in our study was significantly positively correlated with FS1, FS3, and FS5. The associations between Visual Acuity and FS1, FS3, and FS5, BCVA and FS1, FS3, and FS5, and FSD and FS1, FS3, and FS5 were all significantly somewhat favorable.

Among the inherent limitations of this research are its **small sample size** and **non-randomized design**. A more robust **cohort study** would have been a preferable methodology, as it would permit extensive follow-ups, thereby enabling a more effective and thorough investigation into the long-term clinical outcomes and disease progression.

CONCLUSION

Foveal sensitivity was found to be significantly reduced in diabetic patients, even in the absence of clinically evident macular involvement. This finding underscores the value of Standard Automated Perimetry (SAP) as a diagnostic tool, as it is capable of detecting functional changes in the fovea before any significant structural alterations become apparent. Consequently, SAP can be effectively employed as a screening method to identify individuals at high risk of future vision loss, thereby aiding in the proactive reduction of visual morbidity.

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