

Evaluation of corneal backward light scattering in type 2 diabetes mellitus

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Abstract

• **AIM:** To compare the corneal backward light scattering values in type 2 diabetes mellitus (DM) patients with those of age and sex-matched healthy controls.

• **METHODS:** The study included 30 patients (30 eyes) with type 2 DM and 30 control subjects (30 eyes). Duration of diabetes, most recent hemoglobin A1c levels, along with the status of diabetic retinopathy, and existing medical treatment of all subjects were recorded. All subjects underwent a complete ophthalmologic examination. In addition, backward light scattering (densitometry) was measured to assess changes in corneal transparency using tomography (Pentacam HR).

• **RESULTS:** The type 2 DM patients included 12 males and 18 females and control subjects included 16 males and 14 females. The age was 50.40 ± 7.80 y (range: 40-68y) of the diabetic group and 49.30 ± 9.50 y (range: 40-73y) of control group. The diabetic group demonstrated significantly higher mean densitometry values of the anterior (6-10 mm) zone ($P=0.047$), the total anterior layer ($P=0.036$) and the total cornea ($P=0.043$) than control group. The corneal densitometry of the diabetic eyes demonstrated no significant correlation with hemoglobin A1c levels and DM duration.

• **CONCLUSION:** Diabetic group has higher densitometry in anterior corneal (6-10 mm) zone, total anterior cornea, and total cornea and with no correlation with hemoglobin A1c levels and DM duration.

• **KEYWORDS:** corneal backward light scattering; densitometry; type 2 diabetes mellitus; Pentacam

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INTRODUCTION

It is anticipated that the number of diabetic patients will reach almost 552 million by the year 2030^[1]. Saudi Arabia is considered the second highest in the Middle East and is the seventh in the world for the frequency of diabetes mellitus (DM)^[2]. Type 2 DM constitutes about 90% of cases and is characterized by overweight and insulin resistance^[3]. Many studies^[4-9] evaluated the impact of DM on the corneal endothelium, epithelium, corneal sensitivity and central corneal thickness. However, a few number of studies^[10-13] investigated the effect of DM on the corneal backward light scattering and their results were controversial. Yang and Li^[10] showed significantly higher densitometry values in 2 to 6 mm central zones of total cornea in the diabetic eyes compared to the control eyes. However, Ramm *et al*^[11] confirmed that the corneal densitometry of all corneal zones of the diabetic eyes [insulin dependent diabetes mellitus (IDDM) and non-insulin dependent diabetes mellitus (NIDDM) patients] was significantly reduced than in the control eyes. Yang and Li^[10] found a weak relationship between the existence of DM and the corneal densitometry at 0 to 2 mm and 2 to 6 mm corneal zones in the anterior, the posterior and the total corneal depth. Conversely, Calvo-Maroto *et al*^[12] documented no significant associations between the corneal densitometry of the central zones (3 and 5 mm) of the diabetic eyes (IDDM and NIDDM patients) and DM duration. Ramm *et al*^[11] demonstrated a significant negative association between hemoglobin A1c (HbA1c) value and the densitometry values of the total central layer ($r=-0.424$, $P=0.044$). However, Özyol *et al*^[13] found no significant correlation between the total corneal densitometry and HbA1c levels. Ramm *et al*^[11] confirmed a significant negative correlation between the densitometry values and the diabetic retinopathy (DR) staging ($r=-0.271$, $P=0.019$). Their

study documented that the diabetic eyes with maculopathy showed lower total densitometry values than eyes without maculopathy. On the contrary, Calvo-Maroto *et al*^[12] showed no significant association between the corneal densitometry of central zones (3 and 5 mm) of the diabetic eyes (IDDM and NIDDM patients) and DR staging.

It was established that the Scheimpflug system was superior in the objective evaluation of back scatter of the entire cornea compared to confocal microscopy which can assess only a sample area. In addition, it is a quick, and reliable method for measuring corneal densitometry^[13-14].

The aim of this study was to compare the corneal backward light scattering values in type 2 diabetic patients with those of healthy age and sex-matched non-diabetic controls using Pentacam HR. In addition, the correlation between corneal backscattering values and DM duration, HbA1c levels, status of DR was evaluated.

SUBJECTS AND METHODS

Ethical Approval The study was a hospital-based, non-randomized, case-control, observational and quantitative study. It got the Institutional Review Board (IRB) approval of Health Sciences Colleges Research on Human Subjects, College of Medicine, King Saud University, Riyadh, Saudi Arabia [30.10.2022 (05.04.1444) Ref. No.22/0811/IRB]. It adhered to the tenets of the Declaration of Helsinki. All the participants signed a comprehensive consent after explanation of the possible consequences of the study prior to investigations.

Study Design All patients were recruited from Magrabi Hospital, Riyadh, Saudi Arabia by the non-randomized convenience sampling method. The diagnosis of type 2 DM was based on the criteria of the World Health Organization (WHO)^[15]. Control patients did not have DM that was confirmed by random blood sugar test. The inclusion criterion was age 40-80y.

The study excluded participants who have history of past intraocular surgery, previous refractive surgery, contact lens use within 2wk, corneal abnormalities such as keratoconus, corneal scarring pathology such as infections, dystrophies, trauma, ectatic corneal diseases, or age-related corneal degenerations. Also, patients with intraocular pressure (IOP) more than 21 mm Hg were excluded in this study.

Age, gender, duration of diabetes, most recent HbA1c, along with the status of DR, and existing medical treatment were recorded. All subjects underwent a complete ophthalmologic examination including visual acuity evaluation utilizing Snellen chart, refraction using auto-refractometer (Topcon RK-8800 Autorefractor/keratometer, Japan) and IOP measurement using air puff tonometer, slit-lamp biomicroscopy, and fundus examination. If both eyes met the eligibility criteria, a randomized eye was selected for statistical analysis.

Table 1 Demographics of control and diabetic patients

Variable	mean±SD (range)	
	Diabetic group	Control group
Patients/eyes	30	30
Age, y	50.4±7.8 (40-68)	49.3±9.5 (40-73)
Sex (male/female)	12/18	16/14
Duration of diabetes (y)	9.7±5.2 (1-17)	-
HbA1c (%)	7.7±1.5 (7.0-11.5)	-

SD: Standard deviation; HbA1c: Hemoglobin A1c.

Backward light scattering (densitometry) was measured to assess changes in corneal transparency using Scheimpflug tomography (Pentacam HR; Oculus, Wetzlar, Germany). The imaging is intended to mechanically trace corneal apex and get nearly 25 images above different cornea's meridians along with the uniform source of blue light. The grayscale unit is used to label the outcome of corneal densitometry; the value ranges from zero (*i.e.*, least light scattering) to a hundred (*i.e.*, greatest light scattering). For the assessment of the local densitometry, the 12 mm diameter area was divided into 4 concentric radial zones: a central zone 2 mm, a second zone from 2 to nearly 6 mm while the next zone from 6 to nearly 10 mm and lastly, a fourth zone from 10 to 12 mm. The corneal depth is divided into: The anterior layer constitutes the anterior 120 µm, while the posterior layer constitutes the most posterior 60 µm of the cornea. The central corneal layer is calculated by deducting the anterior and posterior layers from the total corneal thickness^[10,12-13]. Three replicate measurements of each eye were documented, and the mean of these measurements were used for statistical analysis.

Statistical Analysis Data was analyzed using statistical software (SPSS version 22.0, SPSS Inc., USA). Descriptive statistics [mean±standard deviation (SD), 95% confidence intervals (CI), minimum, maximum and frequencies] were used for assessing the demographics and the clinical parameters. Normality of the data distributions for the two groups was determined using the Kolmogorov-Smirnov test. Unpaired *t* test was used for comparison between the diabetic and non-diabetic patients. Pearson correlation test was performed to find the association between the backscattering values and HbA1c levels and DM duration. Spearman correlation test was performed to find the association between the backscattering values and the presence or the absence of DR. A value of *P*<0.05 was considered statistically significant and a value of *P*<0.01 was considered statistically highly significant.

RESULTS

The study included 23 diabetic eyes without DR, 7 eyes with non-proliferative DR (NPDR) and 30 control (non-diabetic) eyes. There was no significant difference in mean age or sex. The demographics and the clinical characteristics of the participants are summarized in Table 1.

Table 2 Descriptive statistics for corneal densitometry for study groups

Clinical parameter	Densitometry measurements, mean (95% confidence intervals)				
	0-2 mm	2-6 mm	6-10 mm	10-12 mm	Total
Anterior					
Diabetic group (n=30)	26.4 (25.1-27.7)	23.5 (22.6-24.3)	30.9 (29.1-32.6)	35.2 (32.4-38.0)	28.3 (27.1-29.5)
Control group (n=30)	23.6 (22.9-24.3)	21.6 (21.0-22.2)	25.7 (23.8-27.6)	31.2 (29.2-33.1)	24.8 (23.8-25.9)
<i>P</i>	0.071	0.086	0.047 ^a	0.242	0.036 ^a
Central					
Diabetic group (n=30)	15.3	14.0 (13.6-14.3)	20.4 (19.4-21.4)	21.1 (19.8-22.5)	17.4 (16.8-18.0)
Control group (n=30)	14.7 (14.3-15.0)	13.5 (13.2-13.9)	17.6 (16.3-18.8)	18.5 (17.7-19.3)	15.9 (15.2-16.5)
<i>P</i>	0.238	0.372	0.082	0.096	0.076
Posterior					
Diabetic group (n=30)	12.5 (12.2-12.8)	11.8 (11.6-12.0)	16.6 (15.9-17.3)	16.6 (15.8-17.5)	14.3 (13.9-14.7)
Control group (n=30)	11.9 (11.6-12.2)	11.2 (10.9-11.6)	14.7 (13.8-15.6)	14.6 (14.1-15.2)	13.1 (12.6-13.5)
<i>P</i>	0.149	0.187	0.097	0.060	0.056
Total					
Diabetic group (n=30)	18.1 (17.5-18.7)	16.4 (16.0-16.9)	22.7 (21.6-23.7)	24.6 (22.9-26.4)	20.0 (19.3-20.7)
Control group (n=30)	16.7 (16.3-17.1)	15.5 (15.0-15.9)	19.3 (18.0-20.6)	21.4 (20.4-22.5)	17.9 (17.2-18.6)
<i>P</i>	0.065	0.118	0.057	0.122	0.043 ^a

All densitometry values represented in grayscale units. ^aSignificant at *P*<0.05.

Table 3 Pearson’s correlation coefficients between clinical measurements within diabetic group

Variables	Anterior corneal densitometry total	Duration of diabetes	HbA1c	Central corneal densitometry total	Posterior corneal densitometry total
Duration of diabetes	0.063	-	-	-	-
HbA1c	-0.115	0.352	-	-	-
Central corneal densitometry total	0.941 ^b	-0.005	-0.134	-	-
Posterior corneal densitometry total	0.884 ^b	0.075	-0.210	0.949 ^b	-
Total corneal densitometry	0.986 ^b	0.044	-0.141	0.981 ^b	0.944 ^b

HbA1c: Hemoglobin A1c. ^b*P*<0.01.

Table 4 Spearman’s correlation coefficients between clinical measurements within diabetic group

Variables	Anterior corneal densitometry total	Duration of diabetes	Total corneal densitometry
Duration of diabetes	-0.001	-	-
Total corneal densitometry	0.982 ^b	-0.026	-
Retinopathy presence	0.027	-0.358	0.036

^b*P*<0.01.

Mean of the anterior corneal (6-10 mm) densitometry values was significantly higher in the diabetic group (30.9, 95%CI, 29.1-32.6) than in the control group (25.7, 95%CI, 23.8-27.6; *P*=0.047). Also, mean of the anterior corneal total densitometry values was significantly higher in the diabetic group (28.3, 95%CI, 27.1-29.5) than in the control group (24.8, 95%CI, 23.8-25.9; *P*=0.036). In addition, mean of the total corneal densitometry was significantly higher in the diabetic group (20.0, 95%CI, 19.3-20.7) than in the control group (17.9, 95%CI, 17.2-18.6; *P*=0.043). Descriptive statistics of the corneal densitometry of the study groups are shown in Table 2. The corneal densitometry of the diabetic eyes demonstrated no significant correlation with HbA1c and DM duration using Pearson’s correlation coefficients (Table 3). Moreover, the corneal densitometry of diabetic eyes demonstrated no

significant correlation with the presence or the absence of DR using Spearman correlation coefficients (Table 4).

DISCUSSION

This study was performed to compare the corneal backward light scattering values in type 2 diabetic patients with those of age and sex-matched non-diabetic healthy controls in Riyadh, Saudi Arabia. The diabetic group in this study demonstrated significantly higher mean densitometry values of the anterior 6-10 mm zone (*P*=0.047), the total anterior layer (*P*=0.036) and the total cornea (*P*=0.043) than in the control group. This finding was in agreement with Özyol *et al*^[13] who found that the total anterior layer and the total corneal densitometry in the 0 to 2 mm zone showed significantly higher values in the diabetic eyes than in the controls (*P*=0.024, *P*=0.020 respectively). However, they documented

no significant difference in any concentric zones in the center and the posterior layers. As well, their study did not find any significant difference in the total corneal densitometry of the anterior to the posterior layers over the entire 12 mm diameter area, though the values of the diabetic eyes were greater than the controls in their study. They clarified this finding by the normal variations in total corneal diameter that leads to an inclusion of sclera in the measurement in eyes with a smaller corneal diameter. Moreover, the subclinical age-associated deteriorating situations may influence the measurements in their study. Yang and Li^[10] showed significantly higher densitometry values in 2 to 6 mm central zones of total cornea in the diabetic eyes compared to the control eyes in 70 to 79y age group ($P=0.003$). Additionally, they documented a higher total light backscatter at the total corneal thickness at all concentric radial zones. They predicted that the different results reported by the different studies may be due to the difference of the population samples. In addition, they reported that the corneal densitometry measured using Scheimpflug system may be a valuable technique for early screening and management of the diabetic peripheral neuropathy and the measurable assessment of the corneal transparency.

Calvo-Maroto *et al*^[12] calculated the mean central corneal backscatter for each eye from the seven different meridians analyzed (range 70° to 110°). They demonstrated significant differences in the corneal backscatter between the diabetic and the control groups for the 3-mm and 5-mm central zones ($P=0.016$, $P=0.014$ respectively). Furthermore, they confirmed significantly higher corneal backscatter for the 3-mm central zone than for the central 5-mm in the control subjects ($P<0.001$). Conversely, no significant difference in the corneal backscatter was detected between the 2 zones for the diabetic patients in their study. However, Ramm *et al*^[11] confirmed that the corneal densitometry of all corneal zones of the diabetic eyes (IDDM and NIDDM patients) was significantly reduced than in control eyes. However, Tekin *et al*^[16] detected no significant difference in the densitometry values between the diabetic patients with type 1 DM and the controls. They clarified this outcome by the inclusion of patients in their study with controlled HbA1c values and short DM durations. They excluded patients with DR or maculopathy.

Corneal densitometry in diabetic eyes in the current study demonstrated no significant association with DM duration using Pearson's correlation coefficients. This finding agreed with Calvo-Maroto *et al*^[12] who documented no significant association between the corneal densitometry of the central zones (3 and 5 mm) of the diabetic eyes (IDDM and NIDDM patients) and DM duration. Likewise, Ramm *et al*^[11] found no significant association between DM duration and the densitometry values in their study. Conversely, Yang and Li^[10]

found a weak relationship between the existence of DM and the corneal densitometry at 0 to 2 mm and 2 to 6 mm corneal zones in the anterior, the posterior, and the total corneal depth. As well, Özyol *et al*^[13] found highly significant positive correlation between the anterior total corneal densitometry values and DM duration ($r=0.802$, $P=0.001$). This finding can be attributed to the longer DM duration in their study. The mean of DM duration in their study was $13.0\pm 5.9y$ (1-16y) compared to that of our study $9.7\pm 5.2y$ (1-17y).

The corneal densitometry in the diabetic eyes in this study documented no significant relationship with HbA1c using Pearson's correlation coefficients. This result matched with Özyol *et al*^[13] who did not find any significant relationship between the total corneal densitometry and HbA1c levels. They elucidated this result by the fact that HbA1c values specifies mean glycemic values in the previous 2 to 3mo only which may vary from time to time and they evaluated the association between the corneal densitometry and HbA1c values obtained at that time only as we did in our study. In opposition, Ramm *et al*^[11] demonstrated a significant negative association between the HbA1c value and the densitometry values of the total central layer ($r=-0.424$, $P=0.044$).

The corneal densitometry in the diabetic eyes in the present study, demonstrated no significant correlation with presence or absence DR using Spearman correlation coefficients. This outcome may be due to the small sample size and the short DM duration of the patients enrolled in this study. This was in agreement with Calvo-Maroto *et al*^[12] who showed no significant association between the corneal densitometry of the central zones (3 and 5 mm) of the diabetic eyes (IDDM and NIDDM patients) and DR staging. They clarified this finding in their pilot study because of the small sample size and the unconsidered demonstration of the different stages of DR. On the other hand, Ramm *et al*^[11] confirmed a significant negative correlation between the densitometry values and DR staging ($r=-0.271$, $P=0.019$). Their study documented that the diabetic eyes with maculopathy showed lower total densitometry values than eyes without maculopathy.

Regarding the normative values of the corneal densitometry in the control group, this study found higher anterior corneal total densitometry values than for both the central and the posterior layers. Mean of the anterior, the central, the posterior and the total corneal densitometry values was 24.8 (23.8-25.9), 15.9 (15.2-16.5), 13.1 (12.6-13.5) and 17.9 (17.2-18.6) respectively. This finding matched with Ni Dhubhghaill *et al*^[17] who showed significantly higher densitometry values of the anterior layer 25.81 ± 5.14 than for both the central ($P<0.001$) and the posterior layers ($P<0.001$). Additionally, they demonstrated the lowest densitometry values in the central zone (0-2 mm, 16.76 ± 1.87) and the highest values in the peripheral zone (10-

12 mm, 27.36 ± 7.47). Their finding was in agreement with the current study which showed densitometry values in the central zone 16.7 (16.3-17.1) compared to 21.4 (20.4-22.5) in the peripheral zone. This outcome can be explained by the normal variability of the white-to-white corneal diameter^[18]. Ní Dhubhghaill *et al*^[17] further elucidated that finding by the inclusion of portions of the limbus and sclera in the evaluation of the densitometry values of the peripheral zones in subjects with a small corneal diameter may result in higher values.

The augmented light backscattering in the diabetic patients can be attributed to corneal edema, increased corneal thickness and polymegathism or pleomorphism of corneal endothelium^[19]. Yang and Li^[10] speculated that the anterior layer which corresponds to the corneal epithelial and anterior stromal strata as demarcated with corneal densitometry software was the most vulnerable layer in the diabetic cornea for the increased backward light scattering. Moreover, Özyol *et al*^[13] explained the significant difference of the backscattering in their diabetic group compared to the control group by the existence of ultra-structural alterations in the anterior layer of cornea in the diabetic eyes such as a condensed, multilayered epithelial basement membrane, glycogen granules buildup in the basal epithelial cells, motivation of the keratocytes and prompted stromal collagen crosslinking^[20]. Furthermore, Quadrado *et al*^[21] documented significant declines in basal epithelial cells, anterior stromal keratocytes and endothelial cell concentrations in cornea of type 2 diabetic patients *via in vivo* confocal microscopy. Additionally, Grus *et al*^[22] reported that the abnormalities of tear film composition and thickness may contribute to the elevated backscattering in the diabetic cornea. Light scattering can be divided into an intraocular scattering (forward light scattering) and light scattered backward (backward light scattering)^[12]. No accurate relationship between them was detected until nowadays^[10,23]. Hwang *et al*^[24] demonstrated an increased level of the intraocular scattering in the diabetic corneas compared to the controls and confirmed the association between the severity of DR and the increased intraocular scattering. Schiano Lomoriello *et al*^[25] evaluated early changes of the corneal sub-basal plexus in type 1 diabetic cornea using *in vivo* confocal microscopy and reported a significant affection of the optical quality of the diabetic cornea compared to controls. Patel *et al*^[26] assessed the influence of the intraocular scattering on vision after penetrating keratoplasty and confirmed that the increased stray light may cause visual complaints. Ní Dhubhghaill *et al*^[17] reported that the significant correlation between the increased backward light scattering and the reduced visual quality is not essentially established.

This study is the first one in Saudi Arabia to evaluate the corneal backward light scattering values in type 2 diabetic

patients using Pentacam HR. This study documented a statistically significant difference in the densitometry of the anterior corneal (6-10 mm zone), the total anterior cornea and the total cornea of the diabetic group compared to the control group. This study confirmed the potentiality of using optical quality assessment for monitoring of the corneal abnormalities caused by DM. Further prospective longitudinal studies using a large sample size are recommended to confirm these results and to evaluate the correlation between corneal backscattering values and HbA1c levels, DM duration, status of DR. In addition, the effect of the corneal backscatter on the visual quality of the diabetic cornea needs more investigations. Additionally, the relationship between the intraocular scattering and the backward light scattering necessitates verification.

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