



Corneal Structural Alterations Under Chronic Hyperglycemia: Biomechanical and Densitometric Insights in Type 2 Diabetes with and Without Retinopathy

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Abstract

Objectives: To evaluate and compare corneal biomechanical properties and densitometry in healthy individuals and type 2 diabetic patients, with and without non-proliferative diabetic retinopathy (NPDR), and to investigate potential associations with glycemic control.

Methods: This prospective, observational study included 61 diabetic patients (30 without DR and 31 with NPDR) and 76 healthy controls. Comprehensive ophthalmic examinations were performed for all participants, including Corvis ST for corneal biomechanical assessment and Scheimpflug-based densitometry. Glycated hemoglobin (HbA1c) and blood glucose levels were recorded in the diabetic group. Patients with proliferative DR were excluded to maintain more homogeneous cohorts.

Results: Diabetic patients demonstrated significantly higher stiffness parameters (stress-strain index) and corneal densitometry compared with healthy controls ($p < 0.001$). In subgroup analyses, the tomographic biomechanical index (TBI) was lower among diabetic patients with retinopathy than those without ($p = 0.036$), suggesting an additional impact of retinopathy on corneal biomechanics. Moderate correlations were identified between HbA1c and specific corneal deformation parameters, highlighting the influence of metabolic control on corneal properties. Blood glucose levels exhibited a moderate positive correlation with TBI ($p = 0.033$).

Conclusion: Corneal biomechanics and densitometry differ significantly between diabetic patients and healthy controls, with further alterations in those with non-proliferative retinopathy, and these changes may correlate with glycemic control.

Keywords: Corneal biomechanics, corneal densitometry, corvis ST, Type 2 diabetes mellitus

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Introduction

Diabetes mellitus (DM) is a systemic metabolic disorder characterized by chronic hyperglycemia due to impaired glucose regulation (1). It affects multiple organ systems and remains a leading cause of blindness in developed countries (2,3). While ophthalmologists primarily concentrate on diabetic retinopathy (DR), it is also important to recognize that diabetes can lead to significant structural and biomechanical alterations in the cornea (4). Previous research has indicated an increase in central corneal thickness in individuals with diabetes, potentially resulting from epithelial and endothelial cell dysfunction, which impairs corneal hydration regulation and leads to edema (4-6). Chronic hyperglycemia may also lead to oxidative stress and changes in the corneal extracellular matrix composition (7,8). These findings suggest that these factors may contribute to alterations in the biomechanical characteristics of the cornea in patients with DM.

The corvis ST (CST) (Oculus, Wetzlar, Germany) is a dynamic, non-contact device based on Scheimpflug imaging, designed to assess corneal biomechanical properties *in vivo* (9). It applies a controlled air puff to deform the cornea, while a high-speed Scheimpflug camera records 4300 images per second over a 100-ms duration (10,11). This high-resolution, real-time imaging allows for detailed analysis of the corneal deformation process, offering valuable biomechanical insights in diabetic patients. Moreover, corneal densitometry (CD), increasingly recognized as a reliable biomarker of corneal transparency, provides valuable insights into corneal tissue integrity (12,13). Scheimpflug-based anterior segment tomography enables a quantitative assessment of CD through the analysis of backscattered light, offering a detailed, layer-by-layer evaluation of corneal clarity (14).

Several studies have demonstrated corneal biomechanical differences between diabetic and non-diabetic individuals, with notable associations between biomechanical properties and systemic glycemic control markers such as glycated hemoglobin (HbA1c) (15-17). Poorly controlled diabetes has been linked to increased corneal stiffness and altered dynamic corneal response parameters, which may impact intraocular pressure (IOP) measurements and glaucoma risk assessment (18). However, there remains a gap in knowledge regarding the correlation between corneal biomechanics, glycemic control, and the presence of DR.

This study aims to evaluate and compare corneal biomechanical properties across three distinct groups: healthy individuals, diabetic patients without retinopathy (DM-no DR), and those with DR. Furthermore, the relationship between HbA1c levels and corneal biomechanical metrics will be explored to assess the potential impact of glycemic control on corneal behavior. The findings may offer valuable insight into

the utility of corneal biomechanics as a non-invasive marker for both ocular manifestations and systemic progression of diabetes.

Methods

This prospective, observational study was conducted at a tertiary hospital, following approval by the Institutional Review Board (193–2024-KAEK-11/July 15, 2025) and in accordance with the Declaration of Helsinki. Informed consent was obtained from all participants before enrollment.

Inclusion criteria were IOP <21 mmHg by applanation tonometry and refractive error <5 diopters spherical equivalent and astigmatism <3 diopters in type 2 DM patients older than 18 years. Patients with DM with a history of corneal disorder or systemic collagen disease, contact lens wear within 2 weeks prior to enrollment, irregular astigmatism, previous refractive surgery or any ocular surgery, glaucoma, and/or chronic topical IOP-lowering medication use were excluded from the study. Another exclusion criterion was proliferative DR (PDR) because of difficulties in obtaining an adequate sample of untreated cases. By omitting these patients, more homogeneous cohorts were maintained, thereby helping to ensure the validity of the biomechanical and densitometric assessments. Sixty-one eyes of 61 DM patients were included in the study. Seventy-six age- and sex-matched individuals without a history of DM or ocular disease were defined as the control group. DM patients were divided into two subgroups: with (DM-DR) and without (DM-nonDR) DRP.

All patients had a thorough ophthalmologic examination of the anterior and posterior segments prior to the measurements. The diagnosis of non-PDR (NPDR) was based on dilated fundus examination and color fundus photography. Optical coherence tomography (OCT) and OCT angiography (OCTA) were used as supportive tools when clinically indicated. NPDR severity was classified according to international clinical DR/Early Treatment DR Study (ETDRS)-based criteria and categorized as mild, moderate, or severe NPDR. Mild NPDR was defined by the presence of microaneurysms only. Moderate NPDR included cases with microaneurysms accompanied by intraretinal hemorrhages, hard exudates, or cotton wool spots not meeting criteria for severe NPDR. Severe NPDR was defined according to the ETDRS 4-2-1 rule, including extensive intraretinal hemorrhages/microaneurysms in four quadrants, venous beading in two or more quadrants, or prominent intraretinal microvascular abnormalities in at least one quadrant. All NPDR gradings were performed by a single experienced retina specialist who was masked to corneal biomechanical and densitometry results. When both eyes of a participant were eligible for inclusion, one eye was randomly selected for analysis to ensure statistical independence and to avoid inter-eye correlation bias.

To rule out any corneal alterations, ocular biometry (IOL-Master; Carl Zeiss Meditec, Oberkochen, Germany) and corneal topography were conducted. Corneal biomechanical assessment was performed using the CST (Oculus, Wetzlar, Germany). All measurements were obtained by a single experienced examiner under standardized room conditions. Participants were instructed to blink immediately before acquisition, and the eye was aligned using the device's fixation target. Only measurements fulfilling the built-in quality specification (QS) criteria (e.g., "OK") were accepted. The device records the dynamic corneal response to an air puff using ultra-high-speed Scheimpflug imaging and provides deformation parameters (A1/A2 length and velocity, peak distance, highest concavity radius, and deformation amplitude) as well as derived indices, including the stress-strain index (SSI) and tomographic biomechanical index (TBI). For each participant, one eye was included in the analysis. CD was assessed using Scheimpflug tomography (Pentacam HR; Oculus, Wetzlar, Germany). Densitometry values were recorded in grayscale units (GSU), where higher values indicate increased backscatter (reduced transparency). We extracted densitometry parameters corresponding to the anterior, central, and posterior corneal layers, as well as the total densitometry value (CD ant, CD center, CD post, and CD total). Only scans meeting the device QS were included. HbA1c and blood glucose levels were recorded in diabetic patients. In addition, the duration of DM was assessed in the patients' anamneses.

During CST measurement, a two-dimensional image of the cross-section of the deforming cornea is created using a high-speed Scheimpflug camera to measure the apical displacement of the cornea and the IOP. During the deformation process, amplitude, duration, and velocity of the corneal appplanation are recorded (19). Measurements with the CST were only taken once in every eye because previous reports described reliable and good quality results even after a single measurement time point (20-22).

All data were analyzed with the Statistical Package for the Social Sciences (Version 25; IBM Statistics, NY). The test for normal distribution of the data in both groups was performed using the Kolmogorov-Smirnov test. Since the data were normally distributed, Student's *t*-test was applied. When we divided DM patients into subgroups and compared them with healthy controls, a one-way analysis of variance test was used, and a Bonferroni correction was made. The Pearson correlation test was used for the effect of HbA1c, blood glucose level, and duration of DM on CST measurement results. *P* values below 0.05 were accepted as statistically significant.

Results

Sixty-one eyes of 61 patients with DM and 76 eyes of 76 healthy controls were included in the study. Baseline data of

diabetic patients and healthy controls are summarized in Table 1. While BCVA was significantly higher in healthy controls ($p=0.001$), no significant difference was observed between the groups in terms of age, gender, IOP, and axial length ($p>0.05$). While non-proliferative DR findings were observed in 31 of the DM patients, DRP was not observed in 30 patients. All DM patients were using oral antidiabetic agents.

Dynamic corneal response results between DM patients and the control group are summarized in Table 2. BCVA and HcPeak Distance were found to be significantly higher in the control group ($p<0.001$). SSI and corneal opacity densitometry were found to be significantly higher in the DM group ($p<0.001$).

The results of the subgroup analysis are summarized in Table 3. The mean duration of diabetes was 8.06 ± 5.01 years in the DM-DR group and 7.06 ± 2.43 years in the DM-non-DR group, with no statistically significant difference between the two ($p=0.630$). SSI was significantly lower in the control group than in the DM-DR and DM-nonDR groups ($p=0.029$, 0.018 , respectively). TBI was significantly lower in the DM-DR group ($p=0.036$). Corneal opacity density was significantly lower in the control group than in both DM groups ($p<0.001$), whereas no significant difference was observed between the DM-DR and DM-nonDR groups ($p>0.05$).

In the correlation analysis, HbA1c showed a moderate positive correlation with SPA1 and A2V ($r=0.501$, $p=0.015$ and 0.539 , $p=0.008$, respectively); while it showed a moderate negative correlation with A1V, HC peak distance, and HC def ampl (-0.408 , $p=0.043$, $r=-0.583$, $p=0.003$, and $r=-0.523$, $p=0.010$, respectively). Blood sugar level and TBI value showed a moderate positive correlation ($r=0.412$, $p=0.033$).

Table 1. Baseline characteristics of the normal control and diabetes mellitus groups

	DM (n=61)	Control (n=76)	<i>p</i>
Age (year)	55.70±11.54	54.22±11.32	0.761
Sex (M/F)	16/45	28/48	0.273
BMI (kg/m ²)	28.58±3.89	N/A	
BCVA (logmar)	0.17±0.18	0±0	<0.001
IOP (mmHg)	15.87±4.43	15.76±2.46	0.356
HbA1c (%)	7.91±3.94	N/A	
Blood glucose (mg/dL)	168.62±61.74	N/A	
ECC (cells/mm ²)	2225±523	2364±632	0.274
Axial length (mm)	23.32±0.82	23.43±0.76	0.765
CCT (µm)	544±40.82	546.82±40.47	0.609

HbA1c: Glycated hemoglobin, BCVA: Best-corrected visual acuity, BMI: Body-mass index, CCT: Central corneal thickness, DM: Diabetes mellitus, ECC: Endothelial cell count, IOP: Intraocular pressure.

Table 2. Corvis ST corneal deformation and corneal curvatures measurements of participant groups

	DM (n=61)	Control (n=76)	p
A1L (mm)	2.19±0.33	2.20±0.33	0.857
A1V (m/s)	0.15±0.03	0.14±0.04	0.328
A2L (mm)	1.89±0.49	1.88±0.36	0.760
A2V (m/s)	-0.27±0.04	-0.28±0.03	0.971
Peak distance (mm)	4.73±0.44	4.92±0.26	0.039
HC radius (mm)	7.08±2.26	6.99±0.78	0.251
Hc deformation amplitude (mm)	1.09±0.14	1.07±0.10	0.640
K1 (D)	43.42±1.73	42.14±1.52	0.052
K2 (D)	44.13±1.71	43.22±1.78	0.063
Kmax (D)	45.45±1.76	44.82±2.14	0.253
CBIF	6.34±0.42	6.35±0.51	0.702
e-staging	0.36±0.43	0.43±0.62	0.944
DA ratio	4.27±0.71	4.31±3.55	0.455
IR (mm ⁻¹)	8.80±1.34	8.62±2.06	0.187
ARTh	530.94±116.09	544.61±155.87	0.797
SPA1 (mmHg/mm)	111.53±44.90	110.90±18.72	0.773
SS-I	1.10±0.24	0.95±0.14	<0.001
TBI	0.35±0.29	0.28±0.29	0.118
CD ant	35.85±5.50	27.34±3.43	<0.001
CD center	25.51±4.88	18.57±3.28	<0.001
CD post	24.83±4.81	18.05±3.41	<0.001
CD total	28.72±4.80	21.32±3.21	<0.001
biOP (mmHg)	15.87±4.43	15.76±2.46	0.410

ARTh: Ambrosio relational thickness, A1L: Cord length of the first applanation, A1V: Speed of the first applanation, A2L: Cord length of the second applanation, A2V: Speed of the second applanation, biOP: Biomechanically corrected intraocular pressure, CBIF: Corvis biomechanical factor, CCT: Central corneal thickness, CD ant: Anterior corneal optical density, CD center: Center corneal optical density, CD post: Posterior corneal optical density, CD total: Total corneal optical density, DA ratio: Ratio between the deformation amplitude at the apex. HC deformation amplitude; Corneal displacement at the highest concavity. HC Radius: Radius of curvature of the cornea at the highest concavity. IR: Integrated radius. Represents the amount of the corneal concave state. K1: Flat keratometry, K2: Steep keratometry. Kmax: Maximum keratometry. SP-A1: Stiffness parameter A1. The resulting pressure on the cornea is divided by the deflection amplitude at A1 over the time between A1 and A2. SSI: Stress strain index. Finite element modeling algorithm for the estimation of the non-linear *in vivo* biomechanical behaviour in corneal with normal topography TBI: Tomographic and biomechanical index.

Discussion

In this study, corneal biomechanical properties of DM patients and healthy subjects were evaluated using the CST device. In addition, the possible effects of the presence of reti-

nopathy on corneal biomechanical changes were analyzed by comparing diabetic patients with DR (DM-DR) and without DR (DM-nonDR). In our study, significant differences were found between healthy subjects and DM patients in corneal biomechanical parameters such as SSI and CD. In addition, TBI values were found to be significantly lower in the DM-DR group in subgroup analyses. Similarly, it has been reported in the literature that corneal biomechanical properties are different in diabetic patients compared to healthy subjects, and it has been suggested that corneal biomechanical parameters may be related to the severity of DR (15,16,23). In this context, our findings suggest that corneal biomechanical parameters can be used as a potential non-invasive biomarker to assess structural changes in diabetic eyes and provide valuable information about disease progression (4,8,16,18).

In our study, SSI and CD parameters were significantly higher in the DM group compared to the healthy group ($p < 0.001$). These results are consistent with the literature and support the biomechanical changes caused by diabetes in the cornea (16,23). Pérez-Rico *et al.* reported that corneal hardening increased in diabetic patients, and this hardening may be related to diabetes-induced hyperglycemia (8). Similarly, Ohn *et al.* emphasized that there are significant differences in diabetic patients compared to healthy controls and that especially high SSI values represent corneal stiffness (16). A meta-analysis by Wang *et al.* also showed that biomechanical parameters such as corneal hysteresis (CH) and corneal resistance factor (CRF) were significantly higher in diabetic patients compared to healthy controls (15). The findings of our study are consistent with the results of other studies in the literature and suggest that this increase in corneal stiffness reflects the chronic effect of diabetes on ocular tissues.

In our study, significant differences were found in corneal biomechanical parameters between diabetic patients with and without DRP. Especially, TBI values were found to be lower in the group with DRP. This suggests that DR may have an additional effect on corneal biomechanical properties. Similarly, Ramm *et al.* reported that patients with DR had significant differences in corneal deformation amplitude and maximum deflection amplitude and that the corneal deformation process was prolonged as the severity of DRP increased.^[23] Other studies in the literature also support that the presence of retinopathy is associated with corneal biomechanical parameters and that these biomechanical differences become more pronounced as the severity of retinopathy increases (15,16). In this regard, our results suggest that corneal biomechanical properties may be associated with DR and that corneal biomechanical parameters can be used as a potential indicator in the assessment of the severity of DR (15,16,23,24).

Table 3. Corvis ST measurements of subgroups of DM patients

	DM-DR (n=31)	DM-nonDR (n=30)	Control (n=76)	P1	P2	P3	P4
A1L (mm)	2.27±0.37	2.10±0.26	2.20±0.33	0.451			
A1V (m/s)	0.15±0.02	0.15±0.03	0.14±0.04	0.444			
A2L (mm)	1.92±0.42	1.86±0.57	1.88±0.36	0.566			
A2V (m/s)	-0.27±0.03	-0.26±0.05	-0.28±0.03	0.823			
Peak distance (mm)	4.76±0.28	4.71±0.57	4.92±0.26	0.116			
HC radius (mm)	6.79±1.22	7.38±3.03	6.99±0.78	0.403			
Hc deformation amplitude (mm)	1.11±0.12	1.06±0.16	1.07±0.10	0.588			
K1 (D)	43.63±1.53	43.19±1.95	42.14±1.52	0.082			
K2 (D)	44.40±1.59	43.84±1.85	43.22±1.78	0.112			
Kmax (D)	45.84±1.63	45.04±1.85	44.82±2.14	0.324			
CBIF	6.30±0.39	6.39±0.46	6.35±0.51	0.760			
e-staging	0.42±0.46	0.30±0.41	0.43±0.62	0.854			
DA ratio	4.20±0.86	4.34±0.51	4.31±3.55	0.742			
IR (mm ⁻¹)	8.80±1.35	8.80±1.38	8.62±2.06	0.390			
ARTh	542.35±94.23	518.78±138.05	544.61±155.87	0.956			
SPA1 (mmHg/mm)	107.11±23.00	116.26±33.60	110.90±18.72	0.756			
SS-I	1.10±0.27	1.11±0.20	0.95±0.14	0.001	0.03	0.007	1.00
TBI	0.22±0.18	0.48±0.32	0.28±0.29	0.036	0.97	0.042	0.14
CD ant	35.26±5.17	36.49±5.94	27.34±3.43	<0.001	<0.001	<0.001	0.818
CD center	24.22±3.88	26.88±5.57	18.57±3.28	<0.001	<0.001	<0.001	0.45
CD post	23.71±4.18	26.02±5.28	18.05±3.41	<0.001	<0.001	<0.001	0.42
CD total	27.73±4.21	29.78±5.31	21.32±3.21	<0.001	<0.001	<0.001	0.57
biOP (mmHg)	14.83±3.14	16.98±5.38	15.76±2.46	0.458			

ARTh: Ambrosio relational thickness, A1L: Cord length of the first applanation, A1V: Speed of the first applanation, A2L: Cord length of the second applanation, A2V: Speed of the second applanation, biOP: Biomechanically corrected intraocular pressure, CBIF: Corvis biomechanical factor, CCT: Central corneal thickness, CD ant: Anterior corneal optical density, CD center: Center corneal optical density, CD post: Posterior corneal optical density, CD total: Total corneal optical density, DA ratio: Ratio between the deformation amplitude at the apex, HC Deformation amplitude; Corneal displacement at highest concavity. HC Radius: Radius of curvature of the cornea at the highest concavity. IR: Integrated radius. Represents the amount of the corneal concave state. K1: Flat keratometry, K2: Steep keratometry. Kmax: Maximum keratometry, TBI: Tomographic and biomechanical index, SS-I: Stress-strain index, SP-A1: Stiffness parameter A1. The resulting pressure on the cornea is divided by the deflection amplitude at A1 over the time between A1 and A2. Finite element modeling algorithm for the estimation of the non-linear biomechanical behaviour in corneal with normal topography. P1: Overall P-value from one-way analysis of variance, P2: DM-DR versus control (Bonferroni-adjusted), P3: DM-nonDR versus Control (Bonferroni-adjusted); P4: DM-DR versus DM-nonDR (Bonferroni-adjusted)

In this study, corneal biomechanical parameters of diabetic patients with (DM-DR) and without (DM-nonDR) DRP were compared. In our results, we observed that TBI values were significantly lower in patients with DR. This finding is consistent with the results previously reported in the literature that the presence of retinopathy may affect corneal biomechanical parameters (15,16,23). Ramm *et al.* reported that the duration of corneal deformation was prolonged and the maximum deflection amplitude changed significantly with increasing severity of DR (23).

In our study, we evaluated the relationship between diabetic parameters such as duration of diabetes, HbA1c, and blood

glucose with corneal biomechanical properties and analyzed the potential effects of these parameters on the development and progression of DRP. According to our findings, HbA1c level was moderately positive with SPA1 and A2V values; A1V, HC, peak distance, and HC deflection amplitude showed a moderate negative correlation. In addition, there was a moderate positive correlation between blood glucose levels and TBI, and a significant negative correlation between diabetes duration and A2 time. Similar results have been reported in the literature, and it is emphasized that high HbA1c levels and long duration of diabetes cause significant changes in corneal biomechanical parameters, and these changes may be associated with DR

(15,16,23,25). Sahin *et al.* reported that significant differences in CH and CRF occurred as the duration of diabetes and HbA1c levels increased, and these differences may be associated with the development of DR (25). In addition, a systematic review and meta-analysis by Wang *et al.* reported that HbA1c levels were associated with corneal biomechanical changes in diabetic patients and that these changes were associated with the severity of DR (15). In this perspective, monitoring the effects of metabolic control on corneal biomechanical properties may play an important role in the early identification and clinical follow-up of patients at risk for DR.

Most studies investigating CD in diabetic patients observe that diabetes is associated with higher backward light scattering (i.e., increased densitometry) than healthy individuals, particularly in the anterior corneal layers (26-29). In our study, CD was higher in DM patients compared to healthy volunteers, supporting the literature. Özyol and Özyol^[29] reported significantly higher densitometry values among diabetic patients, whereas Gao *et al.* (28) similarly reported increased corneal optical density associated with hyperglycemia-related changes in collagen and corneal nerve function. In a study conducted with children with type 1 DM, Tekin *et al.* (13) showed that the CD of healthy children and children with type 1 DM were similar. The difference in this study may be due to the inclusion of children with type 1 DM, well-controlled diabetes, and shorter duration of DM. In contrast, Ramm *et al.* (30) describe a cohort of diabetic patients with unexpectedly lower CD than controls.

Subgroup analysis according to the presence of DR and evaluation of the relationship between corneal biomechanical parameters and metabolic parameters are the aspects that contribute to the literature. However, our study has some limitations. These include cross-sectional design, relatively small sample size, and the fact that HbA1c and blood glucose levels were not measured in the healthy control group. In addition, possible time-dependent changes in corneal biomechanical parameters could not be evaluated because the measurements were performed at a single time point. Another limitation of this study is the absence of a PDR group. Including patients with PDR, ideally those who have not yet undergone treatment, could provide valuable insights into how advanced retinal pathology affects corneal biomechanics and densitometric parameters. Future investigations that incorporate this subgroup may help clarify disease progression and guide more targeted management strategies.

Conclusion

Corneal biomechanical parameters and densitometry are significantly altered in type 2 diabetes, especially among patients who have non-proliferative retinopathy. The correlations between glycemic control and corneal biomechanics

underscore the potential utility of these metrics as non-invasive indicators of disease-related ocular changes. These alterations may be significant in clinical practice for the accuracy of IOP measurements and the eligibility of individuals with diabetes for keratorefractive surgeries. In the future, the role of corneal biomechanical changes in the development of DR can be examined in more detail with larger sample sizes, prospective, and long-term follow-up studies.

Disclosures

Ethics Committee Approval: This study was approved by the Basaksehir Cam and Sakura City Hospital Ethics Committee (Date: 15.07.2025, Number:) and conducted in accordance with the tenets of the Declaration of Helsinki.

Informed Consent: Written informed consents were obtained from all patients.

Conflict of Interest: None declared.

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