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Central corneal epithelial thickness in diabetic patients: a cross-sectional study

Samyakta Shetti, Thanuja G. Pradeep✉, Lahari Velivelli, Arun Bhatti

Ramaiah Medical College, Ramaiah University of Applied Sciences, Bengaluru, 560054, India
thanugopalp@gmail.com

Purpose *of the study: a cross-sectional study was conducted to compare the central corneal epithelial thickness (CCET) between patients with diabetes mellitus (DM) and age and gender matched controls. We also explored correlation between CCET and duration of DM, DM control and severity of diabetic retinopathy (DR).* ***Material and methods.*** *The study included 111 diabetics aged 57.62 ± 11.02 years and 111 controls of comparable age — 53.74 ± 15.98 years who underwent a comprehensive ophthalmology evaluation. Optical coherence tomography of anterior segment was performed on all participants to measure the central corneal thickness (CCT) and CCET. Demographic data and data on duration of DM and blood sugar control were recorded.* ***Results.*** *The mean CCT was significantly higher in diabetics (Mean = 514.8 ± 31.15 μm) compared to controls (Mean = 500.87 ± 32.34 μm; p-value = 0.001 with 95% CI 5.527 to 22.33). The mean CCET was lower in cases (Mean = 50.15 ± 4.49 μm) compared to controls (Mean = 50.6 ± 5.67 μm; p-value = 0.513) however, it was not statistically significant. A significant difference in CCT was observed between controls and patients with severe nonproliferative DR and proliferative DR (p = 0.034), but no significant difference in CCET was found between any subgroups of degree of DR (p > 0.05). There was no correlation between CCET and* Hb_{A1c} *levels and duration of DM.* ***Conclusion.*** *CCET showed no significant difference between diabetics and controls. There is no correlation between CCET and blood sugar control and duration of DM. Hence, corneal epithelial thickness may not be a contributory factor for diabetic keratopathy.*

Keywords: diabetes mellitus; central corneal epithelial thickness; diabetic retinopathy; duration of diabetes; central corneal thickness
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Центральная толщина эпителия роговицы у пациентов с сахарным диабетом: поперечное исследование

Самьята Шетти, Тануджа Г. Прадип✉, Лахари Веливелли, Арун Бхатти

Медицинский колледж Рамайи, Университет прикладных наук Рамайи, Бангалор, 560054, Индия

Цель *работы — сравнение центральной толщины эпителия роговицы (ЦТЭР) у пациентов с сахарным диабетом (СД) и в контрольной группе, сопоставимой по возрасту и полу, а также оценка корреляции между ЦТЭР и длительностью СД, контролем СД и тяжестью диабетической ретинопатии (ДР).* ***Материал и методы.*** *В исследование включены 111 пациентов с СД в возрасте 57,62 ± 11,02 года и 111 человек контрольной группы сопоставимого возраста — 53,74 ± 15,98 года, которые прошли комплексное офтальмологическое обследование. Кроме того, всем участникам проведена оптическая когерентная томография переднего сегмента глаза для измерения центральной толщины роговицы (ЦТР) и ЦТЭР. Регистрировались демографические данные, а также данные о длительности СД и уровне сахара в крови.* ***Результаты.*** *Средняя ЦТР была значительно выше у диабетиков (514,8 ± 31,15 мкм), чем в контрольной группе (500,87 ± 32,34 мкм; p = 0,001 с 95%-ным доверительным интервалом*

от 5,527 до 22,33). Средний ССЕТ был ниже у больных с СД (50,15 ± 4,49 мкм), чем в контрольной группе (50,6 ± 5,67 мкм; p = 0,513), однако это различие не было статистически значимым. Выявлена значительная разница в ЦТР между контрольной группой и пациентами с тяжелой непролиферативной и пролиферативной ДР (p = 0,034), однако значимой разницы в ЦТЭР между подгруппами с разными видами ДР обнаружено не было (p > 0,05). Корреляции между ЦТЭР, уровнями HbA1c и длительностью СД не выявлено. ***Заключение.*** *ЦТЭР не различалась у диабетиков и в контрольной группе. Корреляции между ЦТЭР и уровнем сахара в крови, а также длительностью СД не обнаружено. Следовательно, толщина эпителия роговицы, возможно, не является фактором, способствующим развитию диабетической кератопатии.*

Ключевые слова: сахарный диабет; центральная толщина эпителия роговицы; диабетическая ретинопатия; длительность диабета; центральная толщина роговицы
Конфликт интересов: отсутствует.
Прозрачность финансовой деятельности: никто из авторов не имеет финансовой заинтересованности в представленных материалах или методах.
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Diabetes mellitus (DM) is a growing health concern and according to International diabetes Federation (IDF) 2021 there are currently 537 million diabetics worldwide and India has the second highest number of cases with 90 million which is projected to increase to nearly 152 million by 2045 [1]. DM affects all the ocular structures from lid margin, tear film, ocular surface, trabecular meshwork, lens and retina. While much of the focus has been on retinal complications, diabetic keratopathy — a condition affecting 46–64% of diabetic patients — has gained recognition as a significant complication [2].

Diabetes can affect all layers of the cornea, involving the epithelium, corneal nerves, stroma and endothelium. Clinical presentations can be delayed epithelialization after surgery or trauma, punctate keratitis, reduced corneal sensations, neurotrophic ulcers or corneal oedema [2]. There have been various studies on the epithelial basement membrane, corneal nerve density, lacrimal functional unit dysfunction, corneal endothelial count and corneal thickness [3], however fewer studies have focussed on corneal epithelial thickness in diabetes mellitus and its relation with duration of diabetes and blood glucose levels. Recent interest in corneal epithelial health in diabetic patients has led to hypotheses linking reduced epithelial thickness to dry eye, corneal neuropathy, and retinal photocoagulation [4].

This study aimed to assess the central corneal epithelial thickness (CCET) in diabetic patients and compare them with healthy controls and evaluate possible correlations between CCET and blood sugar control, duration of DM and severity of diabetic retinopathy.

METHODOLOGY

We conducted a cross- sectional observational study at a tertiary care hospital between August 2023 to April 2024. A total of 111 diabetic patient were compared with 111 age and gender matched nondiabetic controls. The study received institutional ethics committee approval (No: MSRMC/EC/AP-07/06-2023), and informed consent was obtained from all participants.

The **PURPOSE** and objectives of the study were: 1) to compare CCET and central corneal thickness (CCT) in patients with and without DM; 2) to determine the correlation between the CCET and the duration of DM, the grading of diabetic retinopathy (DR) and Hb_{A1c} level.

The cases included all diabetics with age > 18 years and age and gender matched non diabetic controls were included. Any patient with history of ocular trauma, any ocular surgeries in the past three months, prior refractive surgery, long term use of eye drops or systemic hormonal therapy, dry eye, any corneal pathologies like dystrophy, degeneration or opacity, contact lens users, retinopathy other than DR, glaucoma and retinal photocoagulation in the past three months were excluded from the study.

The study was conducted in the department of Ophthalmology of a tertiary hospital. After obtaining informed consent, information on demographic characteristics (age, gender), the duration of DM, and Hb_{A1c} level of diabetic patients were collected. All participants underwent a detailed ophthalmic examination including visual acuity assessment, anterior segment, dilated fundus examination, dry eye evaluation and intraocular pressure (IOP) measurement. DR was classified according to early treatment diabetes retinopathy study (ETDRS) group. Optical coherence tomography (OCT) of the anterior segment (ASOCT) was performed using the SD-OCT (TOPCON 3D OCT-1 MAESTRO). CCT and CCET were measured in the right eye; if right eye could not be assessed due to exclusion criteria, the left eye was evaluated. The average CCT was recorded by the machine and the CCET was recorded by single investigator to minimise errors and bias. The epithelial thickness was recorded in the central cornea using digital calipers on the OCT image (Figure).

Sample size calculation and statistical methods. Sample size calculation was based on a study by E. Yusufoglu et al., which reported average CCT values of 544.33 ± 31.20 μm for diabetic patients and 533.77 ± 24.45 μm for controls. With a confidence level of 95% and a power of 80%, a minimum of 111 participants per group was required [4]. Data were analysed using Statistical Package for Social Sciences (SPSS) for Windows, version 16.0 (SPSS Inc., Chicago, IL, USA). Descriptive statistics were summarized as means and standard deviations (SD). Independent t-tests were used to compare CCT and CCET between groups, and Pearson correlation analysis was conducted to assess relationships between CCT, CCET, and DR severity.

RESULTS

We included 111 diabetes patients and 111 controls. The mean age of the diabetic group was 57.62 ±11.02 yrs comparable with the mean age in controls of 53.74 ± 15.98 yrs (p-value = 0.535). Among the diabetic patients, 66 (59.5%) were male, and 45 (40.5%) were female, compared to 49 (44.11%) males and 62 (55.9%) females in the control group. Other demographics data and anterior segment findings in both groups are shown in Table 1.

Significant differences were observed in IOP between the groups, with diabetic patients showing higher IOP (15.01 ± 2.6 mm Hg) compared to controls (14.14 ± 2.23 mm Hg,

p = 0.012). The CCT and CCET between the two groups is shown in Table 2. The mean CCT was significantly higher in diabetics compared to controls (p-value = 0.001 with 95% CI — 5.527 to 22.33). The mean CCET was lower in cases compared to controls with a p-value = 0.513; 95% CI — 1.806 to 0.905, but it was not statistically significant.

The diabetic group was further stratified based on severity of DR as: no DR, mild to moderate DR, severe and very severe non proliferative DR (NPDR) and proliferative diabetic retinopathy (PDR). The CCT and CCET in these groups have been shown in Table 3. A significant difference in CCT was observed between controls and patients with severe and very severe NPDR and PDR (p = 0.034), but no significant difference in CCET was found between any subgroups (p > 0.05).

We compared CCT and CCET among different subgroups which is depicted in Table 4. A significant difference in CCT was observed between controls and patients with severe NPDR and PDR (p = 0.034), but no significant difference in CCET was found between any subgroups (p > 0.05).

We did a subgroup analysis to look for any correlation between degree of blood sugar control or duration of DM and CCT or CCET as shown in Table 5. The duration of DM was divided as less than or more than 5years while Hb_{A1c} was compared to less than or greater than 8. We found no correlation between blood sugar control or duration of DM and CCT or CCET.

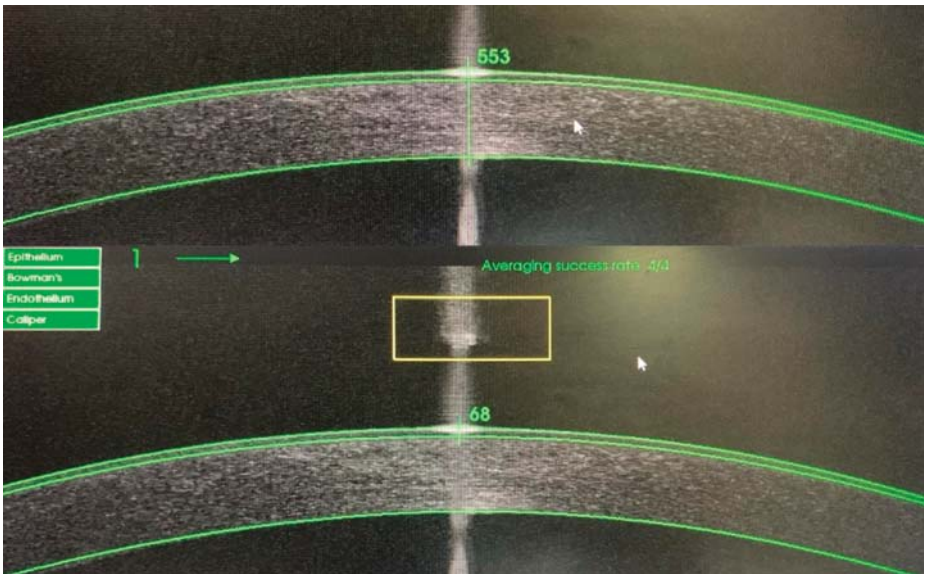

Figure. CCT and CCET measurement using digital calipers
Рисунок. Измерение ЦТР и ЦТЭР с помощью цифрового штангенциркуля

DISCUSSION

Ocular surface complications of DM have been attributed to diabetic

Table 1. Demographic data and anterior segment findings
Таблица 1. Демографические данные и результаты обследования переднего сегмента глаза

Variable Показатель	Cases Случаи	Control Контроль	p-value
Age, yrs Возраст, лет	Mean = 57.62 SD = 11.02	Mean = 53.74 SD = 15.98	0.535
Sex Пол	Male = 66 (59.5%) Female = 45 (40.5%)	Male = 49 (44.11%) Female = 62 (55.9%)	
BCVA МКОЗ	> 6/18: 85 (76.6%) 6/24–6/60: 20 (18%) < 6/60: 6 (5.4%)	> 6/18: 82 (73.9%) 6/24–6/60: 21 (18.9%) <6/60-8 (7.2%)	
OD/OS for recording of ASOCT and diabetic retinopathy ОКТ ПОГ	OD — 87 (78.4%) OS — 24 (21.6%)	RE — 84 (75.7%) LE — 27 (24.3%)	
IOP, mm Hg ВГД, мм рт. ст.	Mean = 15.01 SD = 2.6	Mean = 14.14 SD = 2.23	0.012

Note. BCVA — best corrected visual acuity, ASOCT — anterior segment optical coherence tomography.
Примечание. МКОЗ — максимальная корригированная острота зрения, ОКТ ПОГ — оптическая когерентная томография переднего отдела глаза.

Table 2. The central corneal thickness (CCT) and central corneal epithelial thickness (CCET) in cases and controls
Таблица 2. Центральная толщина роговицы (ЦТР) и центральная толщина эпителия роговицы (ЦТЭР) у пациентов с СД и в контрольной группе

Variable Показатель	Cases СД	Controls Контроль	p-value, t test for equality of means 95%, confidence interval of the difference (CI) t-критерий равенства средних значений 95%-ный доверительный интервал различия (CI)
CCT, μm ЦТР, мкм	Mean = 514.8 SD = 31.15	Mean = 500.87 SD = 32.34	p-value = 0.001, CI [5.527, 22.328]
CCET, μm ЦТЭР, мкм	Mean = 50.15, SD = 4.49	Mean = 50.6 SD = 5.67	p-value = 0.513, CI [-1.806, 0.905]

Note. Mean — average value, SD — standard deviation.
Примечание. Mean — среднее значение, SD — стандартное отклонение.

Table 3. Central corneal thickness (CCT) and central corneal epithelial thickness (CCET) comparison in varying degree of diabetic retinopathy (DR)
Таблица 3. Сравнение центральной толщины роговицы (ЦТР) и центральной толщины эпителия роговицы (ЦТЭР) при различных стадиях диабетической ретинопатии (ДР)

Sub-groups in DR Подгруппы с ДР		CCT, μm ЦТР, мкм	CCET, μm ЦТЭР, мкм
No DR Без ДР	Mean	522.24	50.57
	n	37	37
	SD	36.565	4.413
Mild NPDR Слабая степень НПДР	Mean	508.70	49.80
	n	20	20
	SD	32.076	5.095
Moderate NPDR Средняя степень НПДР	Mean	509.00	51.71
	n	14	14
	SD	27.321	4.410
Severe and very severe NPDR Тяжелая или очень тяжелая степень НПДР	Mean	514.10	48.90
	n	20	20
	SD	26.222	4.745
PDR ПДР	Mean	511.90	49.90
	n	20	20
	SD	26.034	3.810
Total Всего	Mean	514.80	50.15
	n	111	111
	SD	31.155	4.499

Note. NPDR — non proliferative diabetic retinopathy, PDR — proliferative diabetic retinopathy, n — number of eyes, Mean — average value, SD — standard deviation.
Примечание. НПДР — непролиферативная диабетическая ретинопатия, ПДР — пролиферативная диабетическая ретинопатия, n — количество глаз, Mean — среднее значение, SD — стандартное отклонение.

keratopathy or lacrimal functional unit dysfunction. Diabetic keratopathy has been recognised as manifestations such as decreased corneal sensitivity, delayed epithelialization, basement membrane abnormality, corneal neuropathy and endothelial decompensation [3]. Many reasons have been hypothesised for diabetic keratopathy but it still remains enigmatic thus warranting further studies.

There have been many studies correlating an increased CCN in diabetics compared to healthy controls but some studies have failed establish a link between degree of DM and CCT [5, 6]. An increase in CCT in diabetics has been established in Indian patients by studies done by S. Daigavane, V. Mallareddy [7] and S. Pandey et al. [8]. Endothelial dysfunction leading to increased CCT has been established and poor blood sugar control and duration of DM have been correlated with progressive reduction in endothelial cell count and coefficient of variation. In our study too we found that the CCT was increased in diabetics compared to controls and when severe NPDR and PDR were compared to controls it showed statistical significance substantiating that endothelial dysfunction increases with DM and also correlates with severity of DR.

Table 4. Central corneal thickness (CCT) and central corneal epithelial thickness (CCET) comparison between different subgroups of diabetic retinopathy (DR)
Таблица 4. Сравнение центральной толщины роговицы (ЦТР) и центральной толщины эпителия роговицы (ЦТЭР) в подгруппах пациентов с диабетической ретинопатией (ДР)

Subgroups Подгруппы	CCT, μm ЦТР, мкм	CCET, μm ЦТЭР, мкм
Controls Контроль n = 111	Mean = 514.8, SD = 31.15	Mean = 50.15, SD = 4.49
Mild NPDR to PDR Слабая НПДР и ПДР n = 74	511.08 SD = 27.59 p = 0.023	49.95 SD = 4.56 p = 0.406
Mild and Moderate NPDR to PDR Средняя НПДР и ПДР n = 34	508.82 SD = 32.34 p = 0.504	50.59 SD = 4.85 p = 0.652
Severe NPDR and PDR Тяжелая или очень тяжелая НПДР и ПДР n = 40	513.00 SD = 32.34 p = 0.034	49.40 SD = 4.27 p = 0.366

Note. PD — proliferative diabetic retinopathy, NPDR — non proliferative diabetic retinopathy, n — number of eyes, Mean — average, SD — standard deviation.
Примечание. ПДР — пролиферативная диабетическая ретинопатия, НПДР — непролиферативная диабетическая ретинопатия, n — количество глаз; M — среднее значение, SD — стандартное отклонение.

It has been shown that ultrastructural abnormalities of corneal layers precede the onset of clinical kerato-eptheliopathy and hence identification of these change play an important role in diagnosing and preventing this condition. Changes have been identified in all sublayers of the cornea. Q. Zhou et al. proposed that diabetic keratopathy results from accumulation of advanced glycation products and imbalance of growth factors and signalling pathway [9]. K. Naik et al. attributed keratopathy to dry eye and found that there was a statistically significant difference between severity of dry eye and corneal staining in DM > 10 years duration [10]. K. Shih et al. in their systematic review propose that corneal epithelium is the first layer of the eye subjected to wear and tear and diabetics and result in impaired wound healing of the epithelium [11].

Recent studies have shown conflicting results on DM and corneal epithelial thickness with L. D'Andrea et al showing a thicker epithelium (55.48 ± 3.67 μm) in diabetics as compared

to controls (51.80 ± 4.67 μm) [12] while E. Yusufoglu et al. showed that the epithelium is thinner in diabetics compared to healthy controls (52.5 ± 3.61 μm vs 53.95 ± 3.05 μm) [4]. H. Elmekawey et al. [13] and M. Gunay et al. [14] found no difference in CCET between diabetics and non-diabetics. M. Rosenberg et al. used Tandem confocal scanning and found a reduced epithelial thickness in patient with diabetic neuropathy (p = 0.017) but found no reduction in any other systemic diabetic complication [15].

In our study we found the CCET was reduced in patients with DM (50.15 um ±) as compared to controls (50.90 um ±) but this was not statistically significant (p = 0.513, 95% CI [-1.806, 0.905]). We did not find any corelation between duration of DM, Hb A1C or the degree of DR.

Limitations of the study: The study had a relatively small sample size in each subgroup, limiting the ability to draw definitive conclusions. Further research with larger sample sizes is needed to explore potential correlations between corneal epithelial thickness and DM and the degree of DR.

Table 5. Central corneal thickness (CCT) and central corneal epithelial thickness (CCET) correlation between Hb_{A1c} levels and duration of DM
Таблица 5. Корреляция центральной толщины роговицы (ЦТР) и центральной толщины эпителия роговицы (ЦТЭР) с уровнем гликозилированного гемоглобина (Hb_{A1c}) и длительностью СД

Diabetic control and duration Контроль СД и продолжительность заболевания	CCT, μm ЦТР, мкм	CCET, μm ЦТЭР, мкм
Hb_{A1c} < 8, n = 48	511.75 ± 32.82	49.79 ± 5.00
Hb_{A1c} > 8, n = 63	517.13 ± 29.877 p = 0.37	50.43 ± 4.09 p = 0.462
Duration < 5 years Продолжительность < 5 лет	510.87 ± 26.87	50.04 ± 4.64
Duration > 5 years Продолжительность > 5 лет	517.48 ± 33.701 p = 0.274	50.23 ± 4.43 p = 0.835

CONCLUSION

In this study, CCET did not differ significantly between diabetic and non-diabetic patients. Additionally, there was no correlation between CCET and glycemic control, DM duration, or severity of DR. These findings suggest that diabetic keratopathy may involve factors beyond epithelial thickness, warranting further investigation into corneal layer changes and denervation in diabetic patients.

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INFORMATION ABOUT THE AUTHORS/ИНФОРМАЦИЯ ОБ АВТОРАХ

Ramaiah Medical College, Ramaiah University of Applied Sciences, Bengaluru, 560054, India
Samyakta Shetti — assistant professor, department of ophthalmology
Thanuja Gopal Pradeep — associate professor, department of ophthalmology, ORCID 0000-0002-8492-1733
Lahari Velivelli — junior resident, department of ophthalmology
Arun Bhatti — associate professor department of ophthalmology
For contacts: Thanuja Gopal Pradeep, thanugopalp@gmail.com

Медицинский колледж Рамайи, Университет прикладных наук Рамайи, Бангалор, 560054, Индия
Самьята Шетти — доцент, отделение офтальмологии
Тануджа Г. Прадип — ассистент, отделение офтальмологии, ORCID 0000-0002-8492-1733
Лахари Веливелли — младший научный сотрудник, отделение офтальмологии
Арун Бхатти — доцент, отделение офтальмологии
Для контактов: Тануджа Г. Прадип, thanugopalp@gmail.com