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A comparative study of central corneal thickness in diabetics and non-diabetics using ultrasonic pachymetry

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ABSTRACT

Aim: To determine association between central corneal thickness and type 2 diabetes mellitus in patients attending outpatient department of Ophthalmology at a tertiary care centre in North Karnataka.
Materials and Methods: This is a cross-sectional study conducted over a period of April 2018 – September 2020 on patients attending outpatient department of Ophthalmology at a tertiary care centre in North Karnataka. Study includes 168 subjects divided into 3 groups: 40 diabetics whose duration >10 years, 46 diabetics whose duration ≤10 years and 82 controls. Detailed ophthalmic examination was conducted in all patients and central corneal thickness was measured using ultrasound pachymetry.
Results: A statistically significant difference was found between mean central corneal thickness of diabetics (534.0581μ - right eye; 534.3605μ - left eye) and non-diabetics (525.8659μ - right eye; 525.8659μ - left eye); p value <0.05. Association between central corneal thickness and age, gender, laterality and duration of diabetes were not statistically significant.
Conclusion: Patients with type 2 diabetes mellitus have thicker corneas as compared to non-diabetics. Henceforth, it is important to measure central corneal thickness in all diabetics, as it affects IOP measurement which is vital for early diagnosis and timely treatment of glaucoma.

1. Introduction

Diabetes is fast gaining the status of a potential epidemic in India with more than 62 million diabetic individuals currently diagnosed with the disease. According to Wild et al. the prevalence of Diabetes is predicted to double globally from 171 million in 2000 to 366 million in 2030 with a maximum increase in India i.e. 79.4 million.[1,2]

The disease is characterized by hyperglycemia and development of micro-macro vascular disorders, leading to functional and morphological disorders in several organs. Ocular manifestations include anterior ischemic neuropathy, glaucoma, cataract, retinal vein and arterial occlusions and retinopathy/maculopathy. Development of many of the diabetic complications is related to duration of disease and degree of metabolic dysregulation.[3–5]

Several studies have indicated changes in human corneal endothelial cell morphology in patients with T2DM.[6–8] Hypothetically, these phenomena could be caused by chronic metabolic changes at cellular level that primarily affect the single layer of coherent endothelial cells.[9] These largely hexagonal cells have practically no proliferative activity. They are responsible for maintaining hydration of the stroma by actively removing water, thus playing a pivotal role in maintaining the transparency of cornea.

It is hypothesized that few ion transport systems exist in the corneal endothelial cells to maintain the hydration and transparency of the corneal stroma. These ion transport systems mainly are Na+ - K + - ATPase, carbonic anhydrase and bicarbonate ions systems. The stroma imbibes water

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and swells up when the corneal epithelial and endothelial cell barrier is damaged, ultimately resulting in increased hydration of the corneal stroma and thickness.[10]

CCT is a sensitive indicator of health of cornea and serves as an index for corneal hydration and metabolism. Thicker and thinner corneas may lead to either overestimation or underestimation of intraocular pressure, which is the most important causal and treatable risk factor for glaucoma. It is also an important indicator of patency of corneal endothelial pump and can be objectively measured by ultrasound pachymetry, the current standard for corneal thickness measurement. Factors influencing corneal pachymetry include time of the day, age, use of contact lens, corneal degeneration.[11]

Effect of diabetes on CCT has not yet been clearly established. Few studies state that CCT is unaffected by diabetes, while few state that it would significantly increase in diabetics when compared to non-diabetics. Moreover, studies on this subject in Indian population are quite very few. This necessitated further evaluation of the association between CCT and diabetes mellitus.

2. Materials and Methods

This is a cross-sectional study carried out during the period of April 2018–September 2020 at tertiary care centre in North Karnataka. The study includes 168 adult subjects divided into 3 groups:

1. 46 patients with T2 DM for a duration ≤ 10 years
2. 40 patients with T2 DM for a duration > 10 years
3. 82 controls

Patients were explained about the study and patients' willful consent was taken. Details including history, clinical examination, investigations were recorded. Clinical examination includes visual acuity (by Snellen's chart), slit lamp examination, dry and cycloplegic (if required) retinoscopy with streak retinoscope and subjective correction. Pachymetry and IOP (by applanation tonometry) were recorded.

CCT was measured using a hand held ultrasonic pachymetry (PAC Scan plus, model: 300 AP+, Sonomed). Corneas of both the eyes were anesthetized with topical anaesthetic eye drops 0.5% Proparacaine and readings were taken after 90 seconds of instillation. Patient was seated and asked to fixate at a target in the front. Pachymetry probe is brought in light contact with the cornea centrally and perpendicularly and 5readings on each side are taken. CCT was taken as the average of those 5 readings. On the basis of a study, anticipated Mean±SD of CCT in Diabetics was 564±30 and CCT in non-diabetics was 538±35.[9] With the mean difference of thickness and common standard deviation, the minimum sample size is 40 per group with 95% level of significance and 90% power.

Formula used is

Calculated sample size per group = 40
Total sample size taken in the study is = 168
Diabetes for duration < or equal to 10 years N1 = 46
Diabetes for duration >10 years N2 = 40
Total study population= 86
Non-diabetics N3 = 82
Total sample size= 168

$N = 2[((Z_\alpha + Z_\beta) * S) / d]^2$

2.1. Statistical tools used for data analysis and results

Tables are evolved through Data Analysis Tool in Ms-Excel as an add on Tool

1. Covariance
2. Correlation
3. Analysis of variance (anova)

2.2. Inclusion criteria

1. Patients with T2DM >30 years of age
2. Glycosylated Hb ≤ 7.2%

2.3. Exclusion criteria

1. Patients who had already undergone intraocular or corneal surgery
2. Patients previously diagnosed with any corneal pathology
3. Patients who had worn rigid contact lens during the month prior to ophthalmic examination
4. Patients who had worn soft contact lenses 7days before ophthalmic examination
5. Raised IOP
6. Hypertension
7. Diabetics with neuropathy or nephropathy

3. Results

By looking at average CCT of two different groups, diabetic group has greater value of CCT average ANOVA.

Calculated F value (5.78)>tabulated F value (2.63), it is inferred that there is significant difference (increase in CCT value in diabetic group compared to non-diabetic group) since p=0.000726 <0.05.of CCT values within groups:

k = No. of columns

Comparison between LE CCT & RE CCT of diabetic group ≤ 10yrs AND comparison between LE CCT & RE CCT of diabetic group diabetic group> 10 years.

Calculated F value (0.0106) < tabulated F value (3.946), it is inferred that there is no significant difference in CCT values of RE and LE of diabetic age group of ≤ 10 years.

Calculated F value (0.0025) < tabulated F value (3.963), it is inferred that there is no significant difference in CCT values of RE and LE of diabetic age group of >10 years since p=0.960 >0.05.

Table 1: Comparison of CCT between diabetics and non-diabetics

Summary Groups	Sample size	Sum	Average	Variance
RE(NOND)	82	43121	525.8659	275.5743752
LE(NOND)	82	43184	526.6341	255.1484493
RE(D)	86	45929	534.0581	357.5377565
LE(D)	86	45955	534.3605	339.880301

Anova: Single Factor

Table 2: Comparison of mean CCT between diabetics and non-diabetics

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups, SSB	5346.556	k-1=3	1782.185	5.785575987	0.000726	2.631811
Within Groups, SSW	102269.1	N-k=332	308.0394			
Total	107615.6	335				

Table 3: Comparison of mean CCT between right eye and left eye in diabetic's ≤10 years

Summary Groups	Count	Sum	Average	Variance	Standard Deviation	Max.Value
RE	46	24449	531.5	294.7889	17.16941726	587
LE	46	24466	531.8696	294.6937	17.16664556	584
ANOVA						
Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	3.141304	1	3.141304	0.010658	0.918004731	3.946876
Within Groups	26526.72	90	294.7413			
Total	26529.86	91				

Anova: Single Factor

Table 4: Comparison of mean CCT between right eye and left eye in diabetics >10 years

Summary Groups	Count	Sum	Average	Variance	Standard Deviation	Max.Value
RE	40	21480	537	422.5128	20.55511665	598
LE	40	21489	537.225	384.9994	19.62140054	596
ANOVA						
Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	1.0125	1	1.0125	0.002508	0.960189073	3.963472
Within Groups	31492.98	78	403.7561			
Total	31493.99	79				

Anova: Single Factor

Table 5: Comparison of CCT between diabetic groups of ≤10 years duration and >10 years duration

Summary Groups	Count	Sum	Average	Variance
RE (=<10 yrs)	46	24449	531.5	294.7889
LE (=<10 yrs)	46	24466	531.8696	294.6937
RE (>10 yrs)	40	21480	537	422.5128
LE (>10 yrs)	40	21489	537.225	384.9994

Anova: Single Factor

Table 6: Comparison of mean CCT between diabetics >10 years duration and ≤ 10 years duration

Anova						
Source of Variation	**SS**	**df**	**MS**	**F**	**P-value**	**F crit**
Between Groups	1264.773	3	421.5909	1.220745	0.30384	2.658399
Within Groups	58019.69	168	345.3553			
Total	59284.47	171				

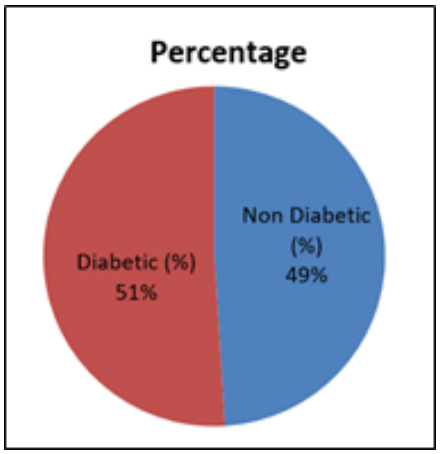

Fig. 1: Distribution of cases and contr

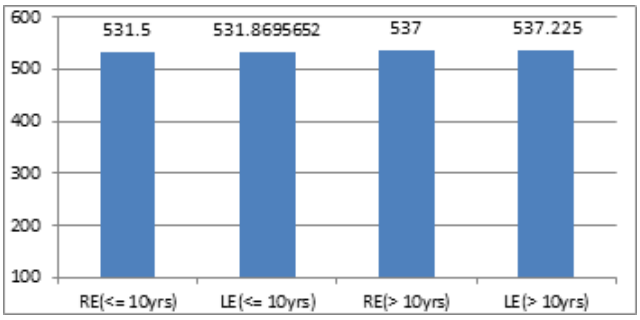

Fig. 2: CCT averages in diabetics ≤10 years duration and >10yrs duration

Calculated F value (1.220) <tabulated F value (2.658), it is inferred that there is no significant difference of CCT averages of these two groups, however by comparing averages, diabetic >10yrs group has relatively higher averages of CCT, since p=0.303 >0.05.

Calculated value of F (0.007433) <tabulated value of F (2.646), it is inferred that there is no significant difference in CCT values among mild, moderate & severe NPDR groups, since p=0.999 >0.05.

Calculated value of f (15.651)>>tabulated value of f (2.652), it is inferred that there is significant difference in CCT values of PDR group in comparison with the population since p=0.0000000039 <0.05.

Calculated value of F (1.95) < tabulated value of F (2.63), it is inferred that there no significant difference in CCT values of male group in comparison with the female group.

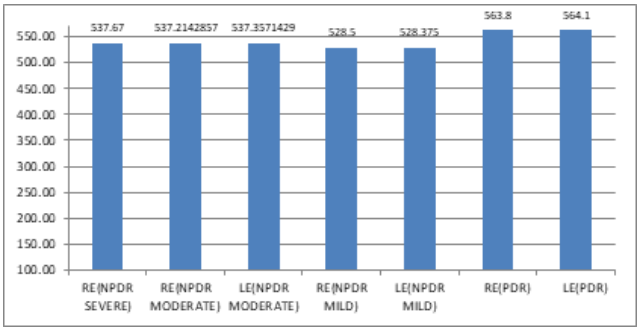

Fig. 3: Mean CCT of mild, moderate and severe NPDR and PDR Association between PDR and CCT

However based on the above graph, male group has slightly larger value of CCT average compared to that of female group, since p=0.12 >0.05.

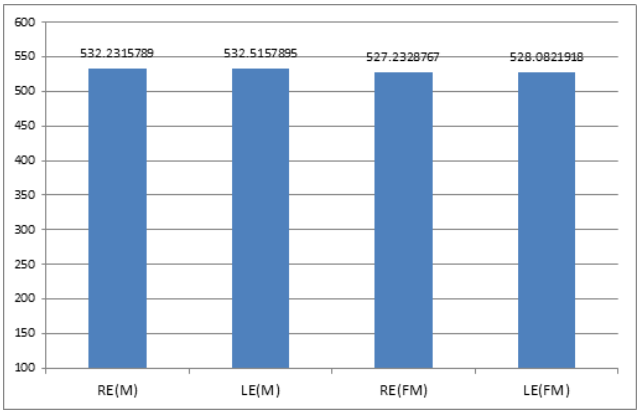

Fig. 4: Gender vs CCT

Calculated value of F (0.38) < tabulated value of F (2.66), it is inferred that there no significant difference in CCT values of diabetic male group in comparison with the diabetic female group. However based on the graph male group has larger variance of CCT compared to that of female group. There is no significant difference in averages CCT's of diabetic male and female group since p=0.76 >0.05.

Correlation coefficient here is -0.2654. It indicates that these two variables have poor inverse correlation.

Correlation coefficient here is -0.27094. It indicates that these two variables have poor inverse correlation.

Calculated value of F (2.057) < tabulated value of F (2.153), it is inferred that there is no significant difference

Table 7: Comparison of mean CCT among diabetics with mild, moderate & severe NPDR

Summary						
Groups	**Count**	**Sum**	**Average**	**Variance**		
RE	86	45929	534.0581	357.537756		
LE	86	45955	534.3605	339.880301		
RE(NPDR)	25	13362	534.48	149.01		
LE(NPDR)	25	13362	534.48	138.093333		
ANOVA						
Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	6.7689	3	2.2563	0.00743337	0.999117	2.646014
Within Groups	66171.01	218	303.5368			
Total	66177.78	221				

Anova: Single Factor

Table 8:

Proportion of NPDR patients over diabetic population	25/86	0.290698
Proportion of PDR patients over diabetic population	10/86	0.116279

Table 9: Comparison of mean CCT between diabetics with PDR and diabetics without PDR

Summary						
Groups	**Count**	**Sum**	**Average**	**Variance**		
RE	86	45929	534.0581	357.5378		
LE	86	45955	534.3605	339.8803		
RE(PDR)	10	5638	563.8	247.2889		
LE(PDR)	10	5641	564.1	217.8778		
ANOVA						
Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	15851.83	3	5283.945	15.65193	3.96E-09	2.652646
Within Groups	63467.03	188	337.5906			
Total	79318.87	191				

Anova: Single Factor

Table 10: Comparison of mean CCT between males and females

Summary						
Groups	**Count**	**Sum**	**Average**	**Variance**		
RE(M)	95	50562	532.2316	316.8607		
LE(M)	95	50589	532.5158	301.3588		
RE(FM)	73	38488	527.2329	343.2367		
LE(FM)	73	38550	528.0822	318.382		
ANOVA						
Source of Variation	SS	Df	MS	F	P-value	F crit
Between Groups	1866.46	3	622.1535	1.953253	0.120841	2.631811
Within Groups	105749.2	332	318.5216			
Total	107615.6	335				

Anova: Single Factor

in CCT values of different age groups and by looking at the average CCT's, elderly diabetic group has lesser CCT average compared to early diabetic groups, since p=0.060 >0.05.

Correlation co-efficient here is 0.046404 is an indication that these two variables are having poor proportion correlation.

Correlation coefficient here it is 0.163762 is an indication that these two variables are having considerable proportion correlation.

Here positive correlation of 0.163 indicates 1.63% increase in FBS will result in 10% increase in CCT (RE).

Correlation coefficient here is 0.037918 is an indication that these two variables are having poor proportion correlation.

Table 11: Comparison of CCT between male and female diabetics

Summary						
Groups	**Count**	**Sum**	**Average**	**Variance**		
RE(M)	52	27842	535.4231	422.2881		
LE(M)	52	27843	535.4423	422.4476		
RE(FM)	34	18087	531.9706	260.8779		
LE(FM)	34	18112	532.7059	217.9109		
ANOVA						
Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	402.9165	3	134.3055	0.383199	0.765241	2.658399
Within Groups	58881.55	168	350.4854			
Total	59284.47	171				

Anova: Single Factor

Table 12: Correlation between age and CCT

	Age	**RE**
Age	1	
RE	-0.26541	1

Table 13: Correlation between age and CCT

	LE	**Age**
LE	1	
Age	-0.27094	1

Table 14: Comparison of mean CCT among diabetics ≤45 years, 46-60 years and >60 years

Summary						
Groups	**Count**	**Sum**	**Average**	**Variance**		
RE(Early Dia)	12	6554	546.1667	205.0606		
LE(Early Dia)	12	6549	545.75	232.2045		
RE(Mid Dia)	37	19733	533.3243	350.2252		
LE(Mid Dia)	37	19757	533.973	335.6937		
RE(Elderly Dia)	37	19642	530.8649	371.3979		
LE(Elderly Dia)	37	19649	531.0541	341.2192		
ANOVA						
Source of Variation	SS	Df	MS	F	P-value	F crit
Between Groups	4127.251	6	687.8752	2.057744	0.060879	2.153911
Within Groups	55157.21	165	334.2861			
Total	59284.47	171				

Anova: Single Factor

Table 15: Association between diabetic CCT(RE) and RBS

	RE	**RBS**
RE	1	
RBS	0.046404194	1

Table 16: Association between diabetic CCT(RE) and FBS

	RE	**FBS**
RE	1	
FBS	0.163762	1

Table 17: Association between diabetic CCT(RE) and PPBS

	RE	**PPBS**
RE	1	
PPBS	0.037918	1

Table 18: Association between CCT(RE) diabetic and HbA1C

	RE	HbA1C
RE	1	
HbA1C	0.046277	1

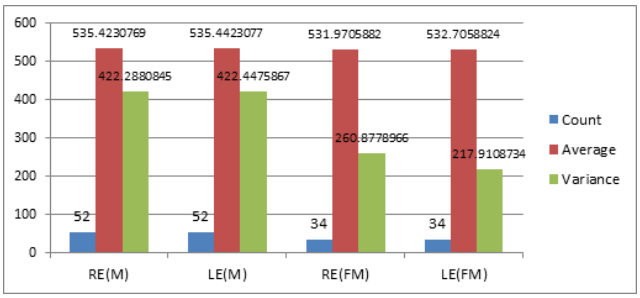

Fig. 5: Gender vs CCT

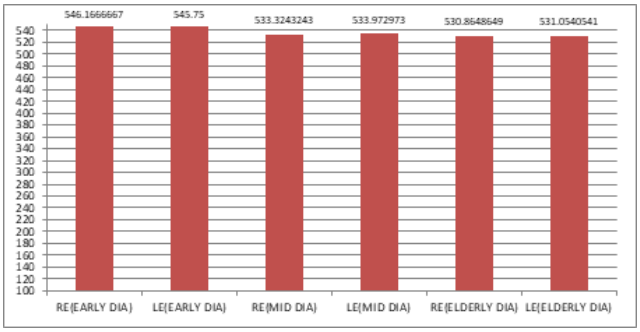

Fig. 6: Mean CCT of different age groups of diabetic patients

Correlation coefficient here it is 0.046277 is an indication that these two variables are having poor proportion correlation.

4. Discussion

In our present study, mean CCT in diabetics was 534.0581μ in right eye and 534.3605μ in left eye and in non-diabetics it was 525.8659μ in right eye and 526.6341μ in the left eye. Since calculated F value (5.78) > tabulated F value (2.63), it is inferred that there is significant difference (increase in CCT value in diabetic group compared to non-diabetic group; P = 0.000726 <0.05 by ANOVA test). This is in accordance with the studies reported by Busted N et al who found that diabetic corneas were significantly thicker than normal corneas in a sample size of 81 diabetic subjects.[12] Ozdamar Y et al. in 2010 also reported that the CCTs of diabetic patients were thicker than that of normal subjects.[13] Storr-Paulsen et al. studied 107 patients with T2DM and 128 nondiabetic controls and concluded that CCT was increased among T2DM patients compared to controls.[14]

In our study, there is no significant difference in mean CCT values between right eye and left eye among diabetics≤10 years duration (calculated F value 0.0106<tabulated F value 3.946; P value 0.918004 >0.05). Also, there is no significant difference in mean CCT between right eye and left eye among diabetics>10 years duration (calculated F value 0.0025 <tabulated F value 3.963; P value 0.960 >0.05).

Effect of duration of diabetes on CCT was studied by Lee et al. who reported that CCT was significantly higher for diabetes of over 10 years' duration than for diabetes of under 10 years' duration.[15] In our study also mean CCT in subjects with diabetes of more than10 years duration was higher(537μ) than those having it for ≤10 years(531μ), but the difference was not statistically significant. (calculated F value 1.220 < tabulated F value 2.658; P=0.303> 0.05).

In the current study, no significant difference was found in CCT between 3 diabetic subgroups i.e., those with mild NPDR, moderate NPDR and severe NPDR (calculated F value 0.007433 < tabulated F value 2.646; P=0.999 >0.05). Busted et al.[12] and Wiemer et al.[16] also found that CCT increased in DM regardless of the severity of retinal disease.

In our study, we found a statistically significant difference in CCT between diabetics with PDR and diabetics without PDR (CCT was much thicker among diabetics with PDR; calculated F value 15.651 >> tabulated F value 2.652; P=0.0000000039 <0.05). Ozdamar et al. reported that patients with PDR had thicker CCT than those with NPDR and no retinopathy; however, the difference was not statistically significant.[13] In this study (both diabetics and non-diabetics), mean CCT of males (532.2μ) is greater than mean CCT in females (527.2μ), but difference is not statistically significant (calculated F value 1.95 < tabulated F value 2.63; P=0.12 >0.05).

Mean CCT for male subjects in diabetic group in present study (535.4μ) was higher when compared to female subjects in diabetic group (531.9μ). However, difference was not statistically significant between the two groups (calculated F value 0.38 < tabulated F value 2.66; P =0.76>0.05). Another study done for Indian eyes have reported significantly higher CCT in males (515.6± 33.8μ) than females (508.0 ± 32.8μ) with p value 0.001.[17]

We observed a decrease in CCT with age in both diabetic and non-diabetic groups. However, the correlation was a poor inverse correlation.

4.1. For right eye and -0 27094 for left eye

In this study, we did not observe any significant difference in mean CCT values among diabetics of different age groups (diabetics≤45 years of age, diabetics > 46 years and ≤60

years, diabetics>60 years), as calculated F value 2.057 < tabulated F value 2.153; P =0.060> 0.05.

We observed a poor positive correlation between RBS, PPBS, HbA_1C and CCT in T2DM. This is probably due to inclusion of study subjects in our study whose glycemic status is relatively under control. Storr Paulsen et al,[2] in their study, reported that HbA1c did not have any impact on the CCT. McNamara et al.[18] observed positive correlation between HbA1c level and CCT in T1DM but reported thicker corneas in diabetics but found no direct correlation with HbA1c level in T2DM similar to our study. This observation was reinforced by Yasgan S et al.[19]

Another study, Mehmet et al[20] reported that diabetic patients with HbA1c levels > 7% had thicker corneas than patients with HbA1c levels < 7% (P = 0.021).

Increase in FBS showed an increase in CCT. We found a positive correlation between FBS and CCT in T2DM patients in our study. A position correlation of 0.163 was obtained, which means that 1.63% increase in FBS will result in 10% increase in CCT.

5. Conclusion

1. Diabetics showed a higher CCT as compared to non-diabetics.
2. Diabetics with PDR showed a higher CCT as compared to diabetics without PDR.
3. Age of diabetics irrespective of age did not have significant effect on CCT. Elderly diabetics showed a relatively lesser CCT.
4. There is no statistically significant difference in CCT between diabetics of ≤10 years duration and diabetics >10 years duration, but diabetics >10 years have a relatively higher CCT.
5. CCT is not affected by the severity of NPDR.
6. There is no statistically significant difference in CCT between males and females in diabetics and non-diabetics.
7. Increase in CCT was observed with increased FBS values.
8. Henceforth, it is important to measure the central corneal thickness in all diabetics, as it affects the IOP measurement which is vital for early diagnosis and timely treatment of glaucoma.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare no conflict of interest.

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