

## **Al-Azhar International Medical Journal**

Volume 5 | Issue 8

Article 7

8-31-2024 Section: Ophthalmology

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## How to Cite This Article

Mahrouz, Mostafa Mostafa; Rabea, Mahmoud Abdel Haleem; and Tawfik, Ahmed Mohamed Raafat (2024) "A Comparative Study of Corneal Endothelial Changes and Central Corneal Thickness among Diabetic and non Diabetic Patients after Phacoemulsification," *Al-Azhar International Medical Journal*: Vol. 5: Iss. 8, Article 7.

DOI: https://doi.org/10.58675/2682-339X.2583

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## ORIGINAL ARTICLE

## A Comparative Study of Corneal Endothelial Changes and Central Corneal Thickness among Diabetic and non Diabetic Patients after Phacoemulsification

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#### Abstract

Background: Endothelium of the cornea is important for being transparent and this is achieved by its effectiveness in maintaining the dried stroma through two key mechanisms: the active fluid pump and barrier functions, any impairment in those mechanisms may have an impact on clarity.

Aim of the work: To ascertain how phacoemulsification and foldable intraocular lens (IOL) implantation affect the cornea's central thickness and endothelial layer in diabetics compared to controls.

Patients and Methods: A prospective case-control research including 120 eyes is carried out,

to ascertain how phacoemulsification and foldable intraocular lens (IOL) implantation affect the cornea's central thickness and endothelial layer in diabetics compared to controls.

Results: With regard to preoperative data, all patients had a mean age of  $(59.4 \pm 4)$  years. Regarding gender, 64.2% of patients were female, and 35.8% of patients were male. Regarding DM data, patients had an average disease duration of  $(13.2 \pm 1.7)$  years, and their average HbA1C was  $(6.3 \pm 0.2)$  mg/dL. With regard to cataract type, patients had (25.8%) AC, (50.8%) NC, (17.5% PC), and (5.8% PSC).

Conclusion: Phacoemulsification with IOL implantation had a greater effect on diabetics' corneas endothelium layer and central thickness, particularly in reducing postoperative CD and increasing postoperative CCT, which leads to significant endothelial damage in DM patients. Phacoemulsification affects central corneal thickness due to edema of the cornea after phaco, which resolves slowly, but recovery may occur in diabetic patients after a long period.

Keywords: Cornea; Cataract; Specular Microscopy; Diabetes

### 1. Introduction

T he endothelium of the cornea is important for being transparent, and this is achieved by its effectiveness in maintaining the dried stroma through two key mechanisms: the active fluid pump and barrier functions. Any impairment in those mechanisms may have an impact on clarity. <sup>1</sup>

These days, the most common surgical treatment is the extraction of a cataract. The corneal endothelium may sustain damage from excessive phacoemulsification.<sup>2</sup>

As people age, their endothelium's condition deteriorates. Phacoemulsification becomes a crucial issue to take into account when considering endothelial damage during surgery.<sup>3</sup>

DM results in aberrant endothelium, such as pleomorphism and polymegethism, by damaging the corneal lining. Patients with DM are at a higher risk of endothelial damage after phacoemulsification. <sup>4</sup>

Diabetics may get cataracts at an early age. Research has shown a strong correlation between diabetes mellitus and cataracts. Twenty percent of cataract surgery patients have diabetes. One of the most popular methods for IOL implantation and cataract removals is phacoemulsification. <sup>5</sup>

Vision could be improved with minimal complications through phacoemulsification. Cautious measures could be taken with diabetics before surgery. <sup>5</sup>

Accepted 21 August 2024.

Available online 31 August 2024

https://doi.org/10.58675/2682-339X.2583

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The ultrasonic energy utilized during phacoemulsification may cause corneal endothelial cell loss; an excessive loss of corneal endothelial cells may result in postoperative problems including bullous keratopathy or inadequate healing of corneal edema.<sup>6</sup>

Patients with and without diabetes may experience significant differences in their corneal endothelial cell density, morphologies, hexagonal cell ratio and central corneal thickness following surgery. <sup>7</sup>

Patients undergoing phacoemaulsification, whether or not they have diabetes, will have their endothelial function assessed as part of this exploratory interventional study. The central cornea's thickness and endothelial function will be assessed using corneal specular microscopy.

This work aimed to ascertain how phacoemulsification and foldable intraocular lens (IOL) implantation affect the cornea's central thickness and endothelial layer in diabetics compared to controls.

### 2. Patients and methods

A prospective case control study was done in department of Ophthalmology at military hospitals on 120 eyes of patients suffering from drop of vision seeking medical advice for assessment in outpatient clinics, patients are classified into 2 independent groups; control group (60 eyes) and DM group (60 eyes).

The study included patients with a mean age group of 40 to 70 years for both sexes, wellcontrolled type 2 DM, a standard evaluation of glycosylated haemoglobin is performed with values less than 7.0, sixty patients in the same age group who do not have diabetes are used as controls. Best corrected visual acuity > 20/40), the onset of DM > 10 years, endothelial cell count is at least 2000 cells/mm2and cataract grades 1,2. The study excluded patients with HbA1c >7.0 %, age < 40 and > 70 years, history of ocular trauma, history of intraocular surgery, preexisting corneal diseases, intraocular inflammation, dense cataract grades 3 and 4, DM onset < 10 years. Endothelial cell count is less than 1000 cells/mm2.

Patients included in the study were subjected to the following: full medical history and surgical history (exclude any previous refractive, ocular surgery or ocular injuries). Also, the examination done is a laboratory report to prove the patient's type (diabetic patient or control).Visual acuity measurement using Snellen visual acuity chart. Manifest refraction using autorefractometer. Evaluating the anterior segment to detect any abnormalities in (iris, lens) and grading cataracts with Lens Opacities Classification System III. Fundus examination using a +90D lens or ophthalmoscope. Intraocular pressure measurement using applanation tonometry. Spectral microscopy: Topcon SP-3000P to assess the central corneal thickness (CCT), hexagonal cell ratio, coefficient of variation (CV), corneal endothelial cell density and biometrics to measure intraocular lens power. Specular microscopy is carried out prior to surgery, one week, one month and three months after surgery.

Preoperative regimen consisted of: 0.5% hydrochloride eye drops, 0.5% keto-tromethamine one drop every 6 hours 1 day before surgery, 0.8% tropicamide, 5.0% phenylephrine 1 drop every 15 minutes one hour before surgery, 5–6 ml peribulbar anesthesia of lidocaine (2% + adrenaline) (1:200,000); mydriasis (must be achieved before surgery).

All patients receive the same standard treatment in comparable settings from a single, using skilled operator the same phacoemulsification apparatus. A self-sealing corneal incision is made using a 3.2mm calibrated keratome, followed by the injection of a viscoelastic substance (hydroxypropylmethylcellulose 2%) into the anterior chamber, a 1-mm puncture incision made at a 60° angle using a 20-gauge micro vitreoretinal blade, and capsulorhexis. Following nuclear fragment removal, hydro dissection, rotation of the nucleus, and segmentation are carried out in a single way (stop and chop technique). After inserting a foldable IOL within the capsular bag, the viscoelastic material is removed, and a 30-gauge cannula is used to hydrate the incision. The eye was bandaged for the next morning.

The recommended treatments are prednisolone acetate 1% in gradually tapering doses, moxifloxacin hydrochloride 0.5% one drop four times daily for one week, and bromfenac sodium 0.9 mg/ml 1 drop twice daily up to four weeks.

For every patient undergoing specular microscopy, an ophthalmic examination is conducted one week, one month, and three months following surgery. After taking three readings, an average of three readings was ultimately obtained.

Ethical consideration: Each participant received an explanation of every step involved in the current study. All of the participants gave their consent. At the end of the study, patients received recommendations and the appropriate treatment after being informed of the results of the tests they had undergone.

Statistical Analysis: Data entry, processing and statistical analysis were performed using MedCalc ver. 20 (MedCalc, Ostend, Belgium). ROC Curve analysis, factorial ANOVA, spearman's correlation, Mann-Whitney's, and Chi-square tests were some of the significant tests used. The data was presented, and the appropriate analysis was performed based on the type of data (parametric and non-parametric) obtained for each variable; Pvalues were considered statistically significant if they were less than 0.05 (5%); P-value: P > 0.05 is considered non-significant (NS), P < 0.05 is considered significant (S), and P < 0.01 is considered highly significant (HS).

### 3. Results

The demographic and clinical variables in 120 eyes who were included in the study are shown in the following tables & figures:

Table 1. Specular microscopy and CCT data among 120 eyes:

Variables	Mean	SD
CD (mm <sup>2</sup> )	2421.1	455.64
CV	35.2	6.13
HEX (%)	53.3	13.79
CCT (µm)	513.17	40.05

Cell Density (CD), Central Corneal Thickness (CCT), Hexagonal Cell Shape Variability (HEX) and Endothelial Cell Coefficient of Variation (CV).

Table 2. Intraoperative and postoperative data among 120 eyes:

Variable		Mean	SD
Intra-operative data	IOL (mm)	19.3	3.74
Post-operative data (1 week)	CD (mm <sup>2</sup> )	2224.2	421.95
	CV	35.9	6.24
	HEX (%)	52.9	13.69
	CCT (µm)	511.3	78.77
Post-operative data (1 month)	CD (mm <sup>2</sup> )	2162.5	419.64
	CV	36.4	6.34

	HEX (%)	52.5	13.62
	ĊС́Т (µm)	514.9	41.56
Post-operative data (3 months)	CD (mm <sup>2</sup> )	2118.2	418.86
	CV	36.6	6.38
	HEX (%)	52.3	13.55
	CCT (µm)	514	41.28

IOL: Intra ocular lens implantation.

Table 3. The sociodemographic information of the groups is compared using Mann-Whitney'sUand Chi square tests:

Square				
VARIA	BLE	CONTROL GROUP	DM GROUP	U TEST
		(60)	(60)	FOR
				MANN-
				WHITNEY'S
		Median (IQR)	Median (IQR)	P value
AGE (YE	EARS)	60.5 (57 – 62.5)	59 (56.5 - 61.5)	= 0.08005
VARIA	BLE	Control group	DM group	Chi square
		(60)	(60)	test
				P value
GENDER	Female	40 (66.7%)	37 (61.7%)	= 0.5695
	Male	20 (33.3%)	23 (38.3%)	

\* The Inter Quartile Range (IQR) as a percentage of the total column.

*Table 4. Using Mann-Whitney's U test; compare the groups' preoperative specular microscopy and CCT data:* 

0010000			
VARIABLE	CONTROL GROUP	DM GROUP	MANN-
	(60)	(60)	WHITNEY'S
			U TEST
	Median (IQR)	Median (IQR)	P value
CD (MM <sup>2</sup> )	2429 (2129 – 2755)	2505 (2172 – 2672)	= 0.8051
CV	35.5 (31 – 39)	35 (30 – 40)	= 0.8129
HEX (%)	54 (47 – 62)	55 (48.5 - 60)	= 0.8582
CCT (µM)	506 (485 – 528)	514 (499 - 537)	= 0.1503

# Table 5. Using Mann-Whitney's U test, compare the groups' intraoperative and postoperative data: VARIABLE CONTROL GROUP DM GROUP MANN (60) (60) (60) WULTNEY'S

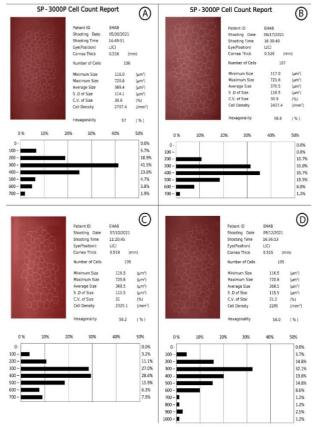
		(60)	(60)	WHITNEY'S U TEST
		Median (IQR)	Median (IQR)	P value
INTRA-OPERATIVE DATA	IOL (mm)	21 (17 – 22)	20.5 (17 – 22)	= 0.8116
POST-OPERATIVE DATA (1 WEEK)	CD (mm <sup>2</sup> )	2318 (2030 – 2637)	2210 (1909 – 2351)	= 0.036*
	CV	36 (31.5 – 39.5)	35.9 (30.9 - 41)	= 0.5269
	HEX (%)	53.7 (46.7 – 61.7)	54.3 (48 – 59.2)	= 0.9497
	CCT (µm)	509 (488 – 530)	520 (509 – 543)	= 0.028*
POST-OPERATIVE DATA (1 MONTH)	CD (mm <sup>2</sup> )	2292 (2002 – 2600)	2116 (1828 – 2244)	= 0.0033**
	CV	36.4 (31.8 - 39.9)	36.5 (31.8 - 41.7)	= 0.3554
	HEX (%)	53.5 (46.5 - 61.5)	53.8 (47.7 – 58.8)	= 0.9288
	CCT (µm)	506 (485 – 528)	515 (501 – 539)	= 0.0713
POST-OPERATIVE DATA (3 MONTHS)	CD (mm <sup>2</sup> )	2271 (1981 – 2573)	2046 (1768 – 2178)	= 0.00042**
	CV	36.5 (31.9 – 40)	36.8 (32.1 - 42.1)	= 0.3059
	HEX (%)	53.3 (46.3 - 61.2)	53.6 (47.4 – 58.4)	= 0.9018
	CCT (µm)	506 (485 – 528)	514 (499 – 538)	= 0.1208

*Table 6. Spearman's correlation analysis for postoperative (3 months) specular microscopy and CCT factors associated with HbA1C:* 

ASSOCIATED FACTOR		HBA1C		
		Rho	P value	
POST-OPERATIVE DATA (3 MONTHS)	CD (mm <sup>2</sup> )	-0.169	=0.0649	
	CV	0.0867	=0.3463	
	HEX (%)	0.0947	=0.3035	
	CCT (µm)	-0.00904	=0.9219	
rho: Spearman's rho (correlation coefficient).				

Table 7. Ro	Table 7. Roc-curve of specular microscopy and CCT data to predict its effect on DM patients:				
VARIABLE	AUC	MAXIMUM CUT POINT	SENSITIVITY	SPECIFICITY	P VALUE
		(CRITERION)	(%)	(%)	
CD (MM <sup>2</sup> )	0.687	≤2180.7	78.33	56.67	0.0001**
CV	0.554	>41.2	31.67	85	0.3071
HEX (%)	0.507	≤58.6	78.33	31.67	0.9027
CCT (µM)	0.582	>500	73.33	45	0.1183

(AUC) Area Under the Curve, and (ROC) Receiver Operating Characteristic.



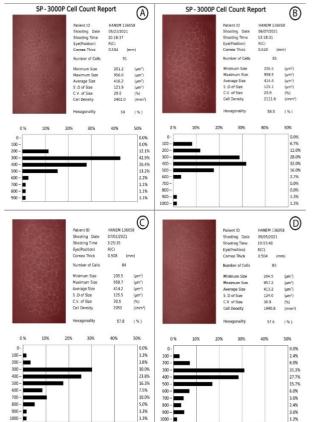


Figure 1. SP - 3000P cell count report showing pre-operative count (A), post-operative 1- week count(B), one month count (C), 3 months count(D), of a diabetic case no 1.

Figure 2: SP - 3000P cell count report showing pre-operative count (A), post-operative 1- week count(B), one month count (C), 3 months count(D), of a diabetic case no 2.

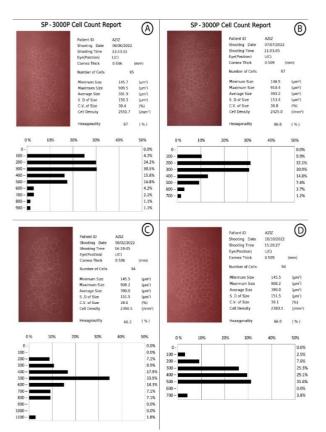


Figure 3. SP - 3000P cell count report showing pre-operative count (A), post-operative 1- week count(B), one month count (C), 3 months count(D), of a control case no 1.

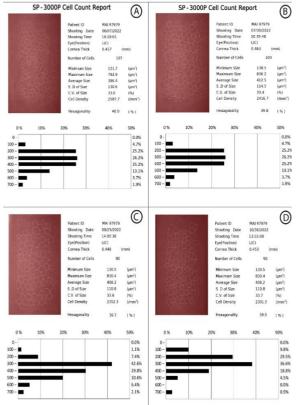


Figure 4. SP - 3000P cell count report showing pre-operative count (A), post-operative 1- week count(B), one month count (C), 3 months

count(D), of a control case no 2.

#### 4. Discussion

A case-control study involving 120 eyes was conducted to ascertain how phacoemulsification and foldable intraocular lens (IOL) implantation affect the cornea's central thickness and endothelial layer in diabetics compared to controls.

For each participant, an ophthalmic examination using specular microscopy is conducted prior to surgery, one week, one month, and three months after surgery.

Preoperative data: the group's average age was  $(59.4 \pm 4)$  years; 64.2% of patients were female, and 35.8% were male; these results align with those of Sahu et al. and Bamdad et al. <sup>1,8</sup>

Regarding the data from the direct message, the average duration of diabetes was  $13.2 \pm 1.7$  years, and the average HbA1C level was  $6.3 \pm 0.2$  mg/dL for the patients. These results align with the findings of Hugod et al., Sahu et al. 8, 10

Two distinct groups, the Control group (60 eyes) and the diabetic group (60 eyes), were created from the 120 eyes.

Age, sex, and all ophthalmic examination data showed non-significant differences between the groups in a comparative study (p-value > 0.05), which agrees with the conclusions of Hugod et al. and Mahmoud et al. <sup>10,11</sup>

All preoperative CCT data and specular microscopy data showed non-significant differences between the groups in a comparative study (p-value > 0.05), which is in line with the findings of Hugod et al., Nashwa et al. and Yang et al. <sup>10, 12, 13</sup>

Upon comparing the two groups, it was observed that the diabetic group had a significantly lower postoperative CD rate (p-value < 0.05) than the control group. This aligns with the conclusions of Hugod et al., Sahu et al., Bamdad et al., Erfan et al., Mahmoud et al., Chaurasia et al. and Abdeen et al.. <sup>1, 8, 10, 14, 15, 16, 17</sup>

Our findings differ from those of Chowdhury et al., who discovered that, although these differences were not statistically significant, diabetic patients had higher coefficients of variation, lower hexagonality, less endothelial cell density, thicker central corneal thickness, and higher endothelial cell density when compared to controls. <sup>15</sup>

A comparison of the groups' postoperative CCT at one week showed a highly significant increase in the diabetic group (p = 0.028) when compared to the control group; this is in line with studies by Bamdad et al. (2018), Abdelhalem et al. and Chaurasia et al. <sup>1, 16, 18</sup>

Bamdad et al. found that the CCT increased significantly from 530.47±2.60 to 540.91±36.07 using the paired samples t-test and the Wilcoxon

signed Rank test.<sup>8</sup>

Additionally, Abdelhalem et al. found that the mean CCT preoperative value in the control group was  $500.80 \pm 23.73\mu$ m,  $508.90 \pm 28.33\mu$ m one week postoperatively (P value = 0.021), and  $501.10 \pm 24.33\mu$ m one month later (P value = 0.011). The mean CCT values in the diabetic group without retinopathy were 508.50 ±6.75µm preoperatively,  $535.20 \pm 16.98\mu$ m one week after surgery (P value = 0.021), and 527.60 ±16.63µm one month later (P value = 0.011). <sup>18</sup>

Following the uneventful surgery, a significant difference was seen overall between the two groups. Before undergoing cataract surgery, a thorough evaluation is advised. It is important to apply viscoelastic materials correctly and take precautions with lens power intensity and ultrasound energy during the procedure to reduce the risk of endothelial damage.<sup>18</sup>

Compared to non-diabetics, diabetic patients' corneas are subject to metabolic stress and have reduced preservative capacity. After phacoemulsification, diabetics recovered more slowly than non-diabetics. <sup>12</sup>

According to a recent analytical study, diabetics experience more corneal endothelial damage from phacoemulsification than controls. Moreover, those patients experience a delayed recovery of corneal endothelial function and morphology. When performing cataract surgery on diabetics, clinicians should pay greater attention to the health of their corneas. <sup>13</sup>

#### 4. Conclusion

Because diabetes causes significant corneal endothelial damage, the central corneal thickness and corneal endothelium were more affected by phacoemulsification with foldable intraocular lens implantation in diabetics than in controls, particularly in reducing postoperative CD and increasing postoperative CCT. Since there is significant corneal edema following surgery, which eventually resolves, phacoemulsification may have an impact on the central corneal thickness. Diabetics may also experience a delay in the healing of corneal oedema.

#### Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

All authors have a substantial contribution to the article

Funding

No Funds : Yes

Conflicts of interest

There are no conflicts of interest.

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