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ORIGINAL ARTICLE

Corneal Endothelial Changes after Phacoemulsification in Diabetic and Non diabetic Patients

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Abstract

Background: ***The corneal endothelium is a layer of hexagonal cells situated on the back of the cornea. It acts as a barrier to maintain the cornea's transparency.***

Aim and objectives: ***Comparing post-phacoemulsification corneal endothelium alterations in non-diabetic patients to type 2 DM patients with grade 2 nuclear cataracts using specular microscopy.***

Patients and Methods: ***This comparative prospective cross-sectional study was carried out on forty patients who had cataracts following phacoemulsification. The patients were divided into two equal groups: twenty patients with T2DM and twenty patients who did not have diabetes. The Ophthalmology Department of the Faculty of Medicine at Al-Azhar University for Boys was the source of the collected patients.***

Results: ***Regarding IOP, Best corrected visual acuity (BCVA) preoperative or postoperative, Coefficient of Variance (CoV) preoperative and postoperative, Hex preoperative, central corneal thickness (CCT) preoperative and postoperative, and CCT change, there was no statistically significant variation among the two groups while regarding random blood sugar (RBS), Endothelial cell density (ECD) preoperative and postoperative, ECD change and Hex changes, there was a highly statistical significant variation. Regarding CoV change and Hex postoperative, there was a statistically significant difference.***

Conclusion: ***There were significant changes in DM patients after phacoemulsification compared with non-diabetic patients. There was significance between the studied groups regarding ECD, CoV change, and Hexagonalty of the cells. There was a negative correlation between RBS (mg/dl) and endothelial cell density change and between Endothelial cell density and age.***

Keywords: Corneal Endothelial Changes; Phacoemulsification; Cataract

1. Introduction

The corneal endothelium, composed of hexagonal cells situated on the posterior aspect of the cornea, maintains corneal transparency by performing barrier and pump activities.[1]

Endothelial cell loss following surgery was 27.5 percent in diabetic patients and 18.3 percent in non-diabetic individuals, according to Kudva's study. Recovery following surgery is assured if the corneal endothelium is in good health. However, there is a significant danger associated with the diabetic cornea. Corneal edema worsens after intraocular surgery, and the endothelium lining the cornea can become decompensated in rare instances.[2]

During phacoemulsification, the corneal endothelium might be damaged. It is also known that the endothelial cell count diminishes with aging.[3]

Endothelial damage during surgery is becoming more critical as life expectancy increases, and the majority of patients undergoing phacoemulsification are elderly.[4]

With a frequency of 15.2 percent to 42.4 percent, type 2 diabetes is a global health crisis that will likely rank as one of the top seven killers by the year 2030.[5]

Eye complications such as diabetic retinopathy, cataracts, glaucoma, and corneal disorders are all brought on by diabetes. Corneal endothelium damage varies in severity between studies. However, corneal epithelial lesions and thickened corneas are negative side effects. The corneal endothelium is shielded from the surgical field to catch the eye of the attending physician.[6]

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There is a higher risk of endothelial damage in older diabetes patients having phacoemulsification. More evidence from prior research is needed to support this theory. 7 Although the matter is still up for debate. Type 2 diabetes mellitus has no bearing on any of the ocular endothelial cell characteristics in patients having cataract surgery, according to research by Inoue et al.[8]

For individuals with good glycemic control, Storr-Paulsen et al. demonstrated that corneal cell density morphology is unaffected by T2DM.[9]

This study compared post-phacoemulsification corneal endothelium alterations in non-diabetic individuals with grade 2 nuclear cataracts to those in managed T2DM patients to draw conclusions about the procedure's effectiveness.

2. Patients and methods

This cross-sectional comparative prospective research was performed on 40 individuals of cataractous patients after phacoemulsification. It compared grade 2 cataract patients treated by phacoemulsification in controlled type 2 DM (Duration of DM 5-10 years) and non-DM patients. Patients were categorized into two equal groups: 20 patients for T2DM cases and 20 patient's non-diabetic patients. The Ophthalmology Department of the Faculty of Medicine at Al-Azhar University for Boys was responsible for collecting them. Sample size: The sample size was determined using the subsequent formula:

$$n = \left[\frac{Z_{\alpha/2}}{E}\right]^2 * P(1 - P)$$

Given the following values: n = sample size, $Z\alpha/2$ = 1.96 (the critical value that separates the middle 95 percent of the Z distribution from the 5% in the tail), E = the margin of error (the breadth of the confidence interval) = 0.0470, and P = the prevalence of the outcome variable = 2.3 percent.

2.1.Inclusion criteria: Patients aged between 55-65 years old, both sexes included, grade 2 nuclear cataracts by slit lamp examination using WHO cataract grading scale and duration of type 2 DM 5-10 years.

2.2.Exclusion criteria: Patients outside the included age range, complicated phaco, patients with ocular disease that could affect vision, such as glaucoma, patients with systemic autoimmune diseases, patients with previous ocular surgery, and patients with known corneal diseases, such as keratoconus.

2.3.Methods:

All participants were subjected to Complete history taking (personal, present, past medical, past surgical history and complaint & its duration), physical examinations (full Ophthalmologic examination including examination of visual acuity, slit lamp biomicroscopy for anterior segment examination, examination of the angles, fundus examination using indirect ophthalmoscopy and IOP evaluation) and specular Microscopy (SM)

Examination of visual acuity: uncorrected best-corrected visual acuity assessment was documented.

Slit lamp biomicroscopy for anterior segment examination. Examination of the Cornea: The slit beam could be used to assess the corneal epithelium, stroma, endothelium, and any signs of inflammation, scars, or infections. Examination of the Iris and Lens: The iris was examined for abnormalities, such as structural defects, inflammation, or signs of certain diseases. The lens, located behind the iris, was evaluated for signs of cataracts or other lens abnormalities. Assessment of the Anterior Chamber: It was examined for signs of inflammation. Examination of the angles. Some common techniques used to examine the angles are Gonioscopy and Van Herick Technique. Fundus examination using indirect 2.4.Ophthalmoscopy:

To detect any abnormality such as diabetic retinopathy or maculopathy and IOP evaluation. The most common methods for IOP evaluation were Non-contact, Goldmann Applanation Tonometry, Tono-Pen Tonometry, and Air-Puff Tonometry.

Specular Microscopy (SM): Specular microscopes (topcon specular microscope sp-1p) were performed before and one month after surgery. It provides different outcomes that include

Central corneal pachymetry by (µm) with an endothelial cell analysis, which included The cell density (CD) by (cells/mm2), Coefficient of variation of cell area (CV) by (%), Percentage of hexagonal cells (HEX) by (%).

Experienced surgeons operated on each patient using the infinite machine. The various stages of the procedure utilized a power range of 50–70 percent, a vacuum pressure of 20–300 mm of mercury, and a flow rate of twenty-five to thirty milliliters per minute for aspiration. During fragment removal, the bottle's height was increased from a minimum of 90 centimeters to a maximum of 110 centimeters. The posterior plane was the focus of careful phacoemulsification.

2.5.Administrative Design: The Ophthalmology Department, Al-Azhar University Hospitals approved the protocol and all supporting paperwork for IRB approval before the study began in compliance with local regulations. Obtaining written informed consent from each patient before the beginning of the study was mandatory, with attention to the following: The aim, procedures, and duration of the study explained. No modification to the expected level of medical care would have resulted from the patient's decision to decline participation. At any moment and for any reason, the patient could withdraw from participation in the trial.

2.6.Statistical Analysis: Software developed by SPSS Inc. of Chicago, Illinois, USA, version 26.0 for Windows, was used for data collection, tabulation, and statistical analysis. Percentages and counts characterized both qualitative and quantitative data. Minimum and maximum values and the mean, SD, and median were used to describe the quantitative data. There was a two-tailed test for significance in all of the statistical comparisons. A level of P-value ≤ 0.05 shows significant differences, highly significant differences are indicated by a p-value <0.001, and non-significant differences are denoted by a P-value > 0.05. Independent T-test, Pearson correlation coefficient, and Chi-square (X2) test of significance were the tests that were utilized.

3. Results

Table 1. Demographic characteristics among the study population

	DIABETIC GROUP (N = 20)	NON-DIABETIC GROUP (N = 20)	TEST OF SIG.	P
GENDER			X2 = 0.1	0.752
- MALE	11 (55%)	10 (50%)		
- FEMALE	9 (45%)	10 (50%)		
AGE (YEARS)			t = 1.797	0.081
MEAN ± SD.	60.55 ± 1.9	59.35 ± 2.3		
MEDIAN (IQR)	61 (59 - 62)	60 (57 - 61.25)		
RANGE (MIN-MAX)	7 (57 - 64)	7 (56 - 63)		

STANDARD DEVIATION (SD) & CHI-SQUARE (x2) tests p-value for comparisons between the groups under study, t-test (independent T-test), & IQR (interquartile range) Significance: P-value < 0.05; P-value > For a p-value less than 0.001, very significant; for a 0.05, nonsignificant.

Table 1 showed that regarding Gender and age, there was no statistical significant variation among the 2 studied groups (p= 0.752), (p=0.081) respectively.

Table 2. IOP (mmHg) and RBS (mg/dl) among the study population

	DIABETIC GROUP (N = 20)	NON-DIABETIC GROUP (N = 20)	TEST OF SIG.	P
IOP (MMHG)			t = -0.125	0.901
MEAN ± SD.	13.15 ± 2.7	13.25 ± 2.34		
MEDIAN (IQR)	13 (11.75 - 15.25)	13 (12 - 14.25)		
RANGE (MIN-MAX)	9 (9 - 18)	10 (7 - 17)		
RBS (MG/DL)			t = 6.101	<0.001
MEAN ± SD.	149.05 ± 16.73	121.45 ± 11.37		
MEDIAN (IQR)	149.5 (137.5 - 165.25)	121.5 (113.75 - 128.25)		
RANGE (MIN-MAX)	55 (120 - 175)	44 (101 - 145)		

The abbreviations "t" for "independent T test," "SD" for "standard deviation," & "p" for "p value" when comparing the groups under study all stand for P-value less than 0.001: Extremely significant A p-value less than 0.05 is considered significant, whereas a p-value more than 0.05 is considered non-significant.

Table 2 showed that regarding IOP (mmHg) In terms of RBS (mg/dl), no statistically significant difference (p= 0.901) was seen between the 2 groups. The both groups were significantly different from each other (p= <.001).

Table 3. Preoperative and postoperative BCVA (LogMAR) results among the study population.

BCVA (LOGMAR)	DIABETIC GROUP (N = 20)	NON-DIABETIC GROUP (N = 20)	TEST OF SIG.	P. VALUE
PREOPERATIVE				
MEAN ± SD.	0.68 ±0.17	0.59 ±0.23	1.407	0.167
POSTOPERATIVE				
MEAN ± SD.	0.18 ±0.06	0.15 ±0.07	1.455	0.153
P. VALUE	0.0001*	0.0001*		

The abbreviations IQR, SD, t, & p show statistical significance when comparing the groups under study.

Table 3 showed that there was no statistical significant variation among the 2 groups in preoperative or postperative BCVA.

Table 4. postoperative & Preoperative Endothelial cell density results among the study population

	DIABETIC GROUP (N = 20)	NON-DIABETIC GROUP (N = 20)	TEST OF SIG.	P
ECD PREOPERATIVE			t = -4.77	<0.001
MEAN ± SD.	2401.15 ± 162.9	2604.3 ± 98.71		
MEDIAN (IQR)	2421 (2312.75 - 2529.75)	2622 (2537 - 2658)		
RANGE (MIN-MAX)	519 (2100 - 2619)	376 (2421 - 2797)		
ECD POSTOPERATIVE			t = -7.643	<0.001
MEAN ± SD.	2114.2 ± 167.5	2455.05 ± 108.27		
MEDIAN (IQR)	2160.5 (2030.25 - 2227.5)	2470 (2393.25 - 2505.5)		
RANGE (MIN-MAX)	581 (1776 - 2357)	493 (2247 - 2740)		
ECD CHANGE			t = -11.68	<0.001
MEAN ± SD.	-286.95 ± 40.68	-145.8 ± 35.58		
MEDIAN (IQR)	-283.5 (-304 - -262.75)	-150.5 (-168.75 - -125.25)		
RANGE (MIN-MAX)	166 (-364 - -198)	143 (-200 - -57)		

Table 4 showed that there was a highly statistical significant variation among the 2 groups as regard ECD preoperative, ECD postoperative and ECD change.

Table 5. Preoperative and postoperative Coefficient of Variance results among the study population

	DIABETIC GROUP (N = 20)	NON-DIABETIC GROUP (N = 20)	TEST OF SIG.	P
COV PREOPERATIVE			t = 0.877	0.386
MEAN ± SD.	33.2 ± 3.09	32.4 ± 2.66		
MEDIAN (IQR)	34 (32.75 - 35)	33 (31.75 - 34)		
RANGE (MIN-MAX)	11 (26 - 37)	10 (27 - 37)		
COV POSTOPERATIVE			t = 1.665	0.104
MEAN ± SD.	35.6 ± 3.62	33.7 ± 3.6		
MEDIAN (IQR)	36 (33 - 38)	34 (30.75 - 36.25)		
RANGE (MIN-MAX)	14 (28 - 42)	12 (28 - 40)		
COV CHANGE			t = 2.354	0.024
MEAN ± SD.	2.4 ± 1.54	1.3 ± 1.42		
MEDIAN (IQR)	3 (1 - 3)	1.5 (0 - 2.25)		
RANGE (MIN-MAX)	5 (0 - 5)	4 (-1 - 3)		

SD refers to standard deviation, t for independent T test, & p for p-value when comparing the populations under study.

Table 5 showed that there was no statistically significant variation among both groups as regard CoV preoperative and CoV postoperative & a statistically significant distinction concerning CoV change.

Table 6. Preoperative and postoperative hexagonal cellularity results among the study population

	DIABETIC GROUP (N = 20)	NON-DIABETIC GROUP (N = 20)	TEST OF SIG.	P
HEX PREOPERATIVE			t = -0.757	0.454
MEAN ± SD.	72.15 ± 4.16	73.05 ± 3.32		
MEDIAN (IQR)	71.5 (70 - 74)	73 (71 - 75.25)		
RANGE (MIN-MAX)	17 (64 - 81)	14 (65 - 79)		
HEX POSTOPERATIVE			t = -2.809	0.008
MEAN ± SD.	67.5 ± 4.35	71.3 ± 4.21		
MEDIAN (IQR)	68.5 (64.75 - 70.25)	72.5 (68.75 - 74)		
RANGE (MIN-MAX)	16 (59 - 75)	16 (63 - 79)		
HEX CHANGE			t = -7.28	<0.001
MEAN ± SD.	-4.65 ± 1.04	-1.75 ± 1.45		
MEDIAN (IQR)	-5 (-5.25 - -4)	-1.5 (-2 - -1)		
RANGE (MIN-MAX)	3 (-6 - -3)	6 (-6 - 0)		

Table 6 showed that there was no statistically significant variation among the both studied group as regard Hex preoperative, statistical significant difference as regard Hex postoperative & a highly statistical significant difference as regard Hex change

Table 7. Preoperative and postoperative Central corneal thickness results among the study population

	DIABETIC GROUP (N = 20)	NON-DIABETIC GROUP (N = 20)	TEST OF SIG.	P
CCT PREOPERATIVE			t = 0.25	0.804
MEAN ± SD.	512.3 ± 15.63	511.05 ± 16		
MEDIAN (IQR)	512.5 (507.5 - 519.75)	510 (502.25 - 522.75)		
RANGE (MIN-MAX)	60 (476 - 536)	57 (481 - 538)		
CCT POSTOPERATIVE			t = 0.44	0.663
MEAN ± SD.	517.05 ± 17.13	514.95 ± 12.73		
MEDIAN (IQR)	513.5 (506.75 - 528.5)	514.5 (507 - 526.75)		
RANGE (MIN-MAX)	71 (486 - 557)	42 (493 - 535)		
CCT CHANGE			t = 0.546	0.589
MEAN ± SD.	4.75 ± 5.69	3.9 ± 4.01		
MEDIAN (IQR)	3 (1 - 8)	4 (2 - 5.25)		
RANGE (MIN-MAX)	23 (-2 - 21)	16 (-3 - 13)		

Table 7 showed that there was no statistical significant variation among the both studied group as regard CCT preoperative, CCT postoperative & CCT change

4. Discussion

Our present investigation found no significant disparity between the two examined groups regarding gender (p=0.752) and age (p=0.081).

Hugod et al.[10] studied thirty diabetes patients and thirty healthy controls, all scheduled to undergo cataract surgery. Both groups had identical ages before the procedure (P = 0.90). A routine blood glucose test was conducted on nondiabetic nondiabetic people to detect latent diabetes. The study findings revealed that the refractory blood pressure (RBS) in the diabetes group ranged from 120 to 175, with a mean value of 149.05 ± 16.73, as indicated by the standard deviation (SD). Conversely, in the group without diabetes, the random blood sugar (RBS) levels range between 101 and 145 milligrams per deciliter (mg/dl), with an average ±SD of 121.45 ± 11.37. The distinction between both groups was extremely statistically significant (p= <.001). Furthermore, the diabetic group exhibited a range of intraocular pressure (mmHg) from 9 to 18, with a mean value of 13.15 ± 2.7. The intraocular pressure (IOP) in the nondiabetic nondiabetic group varied between 7 and 17 mmHg, with an average value of 13.25 ± 2.34 mmHg. Nevertheless, no statistically meaningful distinction (p= 0.901) was observed between both groups.

Our findings, which align with the study conducted by Chowdhury et al.[11] indicate that individuals diagnosed with type 2 diabetes exhibit elevated intraocular pressure. Although there were changes between the experimental and control groups, these differences did not reach statistical significance.

Contrary to our results, Briggs et al.[12] observed that diabetic individuals exhibited elevated (IOP) (P<0.0001) in comparison to the control group.

In continuation of our current research, specifically with BCVA (LogMAR): Prior to the surgery, the average ± standard deviation of the preoperative in the diabetic group was 0.68±0.17, whereas in the non-DM group, it was 0.59±0.23. Both groups did not exhibit a statistically significant difference (p= 0.167). The average ± standard deviation (BCVA) of the diabetic group was 0.18 ± 0.06 during the postoperative period. In contrast, the group without diabetes had a best-corrected visual acuity of 0.15 ± 0.07. No statistically significant difference (p= 0.153) was seen between both groups. Both groups noted Significant visual acuity enhancement following the surgical procedure. However, no statistically significant difference was observed between either group.

Our findings align with those of Hugod et al.[10] who demonstrated that postoperative visual acuity improved significantly equally in both groups.

However, Kumar et al.[13] noted no substantial alteration in the average BCVA between both groups before the surgery. During the postoperative follow-up at one week, four weeks, and three months, the average values of (BCVA) in the nondiabetic nondiabetic group were significantly higher than those in the diabetes group. We are researching to observe the study population's preoperative and postoperative endothelial cell density results. When comparing both groups, the preoperative (ECD) in the diabetic group ranged from 2100 to 2619, with a mean value of 2401.15 ± 162.9. Conversely, in the group of individuals without diabetes, the preoperative (ECD) ranged from 2421 to 2797, with an average ± standard deviation of 2604.3 ± 98.71. The observed variation among both groups was extremely significant ($p < .001$). In the diabetic group, the ECD postoperative varied from 1776 to 2357, with a mean ± standard deviation of 2114.2 ± 167.5. In contrast, within the nondiabetic nondiabetic group, the postoperative (ECD) varied from 2247 to 2740, with an average ± standard deviation of 2455.05 ± 108.27. The observed variation among both groups was extremely statistically significant ($p < .001$). Upon comparing both groups, it was observed that the Endothelial cell density change in the diabetic group varied from -364 to -198, with an average value of -286.95 ± 40.68. Conversely, in the group without diabetes, endothelial cell density (ECD) decreased from -200 to -57, with an average ± standard deviation of -145.8 ± 35.58. The observed difference was extremely statistically significant ($p < .001$).

Our research revealed a significant decrease in corneal endothelial cell density in the diabetes group compared to the nondiabetic nondiabetic group (2629.3 ± 221 cells/mm2) ($P < 0.001$). This result is consistent with the findings of Kadri et al.[14] who stated that the average (CECD) in the diabetes group was 2521.3% ± 300.7 cells/mm2.

Al-Sharkawy[15] discovered that there was no notable disparity in the preoperative corneal endothelium loss between individuals with and without diabetes. This conclusion contradicts the facts we obtained. Although there was no noticeable disparity in ECL following phacoemulsification between both groups, several distinctions were identified.

Our study found no statistically significant variation among both groups in terms of preoperative and postoperative CoV. However, both groups had a statistically significant difference in the change in CoV.

The results of our investigation, which align with the findings of Kumar et al.[13] suggest that there was no statistically significant disparity in the coefficient of variation (CoV) between those with diabetes and those without diabetes before undergoing surgery ($P = 0.129$). Although the mean CoV values after surgery were greater in the diabetes group than in the nondiabetic group after three months, the difference was not statistically significant ($P = 0.066$). Despite the diabetic group having a higher mean CoV value, this was still the case.

Erika et al.[16] found significant variations between the groups' CoV values for pre-surgical and postoperative follow-up visits. This is in opposition to the data that we acquired. Our current study discovered no statistically significant disparity between both groups regarding hex preoperative conditions. However, we did observe a statistically significant difference in hex postoperative conditions and a highly statistically significant difference in hex change.

The results of the study conducted by Hugod et al.[10] Three months post-surgery, the diabetic group had a statistically significant decrease in the fraction of hexagonal cells ($P = 0.01$) compared to the control group.

Our current investigation found no statistically significant differences between groups regarding the CCT preoperative, CCT postoperative, and CCT change parameters.

Erika et al.[16] found no statistically significant changes regarding postoperative (CCT) measurements between the groups. The average values for the two groups were 557.8 ± 48.0 and 543.3 ± 41.0 µm, respectively ($p = 0.472$).

Strength points: This study was a comparative prospective cross-sectional study that took enough time to follow up with patients.

Recommendations and limitations: Future studies should be performed, including a larger number of patients, for a longer duration of follow-up, and include a representative sample of patients with similar age, gender, and disease severity. We recommend that future research include multicenter studies to validate our findings.

4. Conclusion

About the findings that we obtained, we discovered that diabetic patients underwent considerable modifications following phacoemulsification in comparison to patients who did not have diabetes. Regarding ECD, CoV change, and the hexagonal thickness of the cells, there was a significant variation among the groups that were evaluated. The correlation between ECD Change and RBS (mg/dl) and between ECD and age were detrimental. As a result, the corneal endothelium in diabetic individuals is prone to metabolic stress. It is more susceptible to surgical trauma, such as phacoemulsification than it is in non-diabetic subjects. This is the case even though the patients have good control of their blood glucose levels and no corneal abnormalities before surgery. The implications of these findings should be considered when planning cataract surgery for diabetic patients who might require additional protection during ophthalmic surgery.

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