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ORIGINAL ARTICLE

Changes in Corneal Endothelium after Phacoemulsification in Diabetic and Non-Diabetic Cataract Patients in Zagazig University Hospital.

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ABSTRACT

Background: Corneal endothelium is a sensitive structure that can be easily damaged by a wide range of insults including the phacoemulsification procedure. Diabetes mellitus negatively affect the physiology and structure of various ocular structures including cornea. The aim of this study is to evaluate the corneal endothelial alterations in diabetic and non-diabetic cataract patients after phacoemulsification and IOL implantation in Zagazig University Hospitals.

Methods: A prospective study operated on total 46 patients, twenty-three patients were well-controlled type II DM patients and the other were non-diabetics. All the patients undergone uneventful phacoemulsification with IOL implantation in the bag. Specular microscopy was performed to all cases before the operation, 2 weeks, 1 month and 3 months after the operation. Collected data (ECD, CV, percentage of hexagonal cells and CCT) was statistically analyzed and presented in suitable charts and tables.

Results: The mean endothelial cell density (ECD) in diabetic group was 2687.65 ± 155.99 cell/mm2 and 2751.43 ± 152.65 cell/mm2 in non-diabetic group. After 3 months of operation, mean ECD in diabetic patients is 2272 ± 98.18 and 2438.43 ± 156.58 in non-diabetics. The difference between both groups after operation is statistically significant. The percentage reduction of ECD was 13% and 9% in diabetic and control group consecutively.

Conclusions: Despite good control of glycemic condition, corneal endothelium in diabetic patients is more vulnerable to trauma by phacoemulsification. This is reflected as increased endothelial cell loss in those patients rather than non-diabetic ones.

Keywords: Cornea; Endothelium; Phacoemulsification; Cataract; Diabetes.

INTRODUCTION

Diabetes is known by its negative impact on all ocular structures. Cornea is the principal refractive surface of the eye. Being lined by a single layer of endothelial cells, cornea remains dehydrated and clear under physiological conditions. Endothelial cells on the undersurface of cornea are subjected to a wide variety of harmful factors. In diabetes, the exerted metabolic burden by hyperglycemia puts the endothelial cells in an ongoing process of loss and replacement. Regeneration of corneal endothelium occurs by a process of migration and sliding of adjacent cells to replace the lost cell rather than by division of remaining cells [1, 2].

Large number of studies were done evaluating the behavior of endothelial cells in diabetic cataract patients when exposed to the ultrasound power of phacoemulsification. Needless to say that phacoemulsification constituted all old methods of cataract removal and now has become the standard cataract operation [3].

Together with disruption of corneal endothelial integrity, cataract surgery nowadays still have more challenges in diabetic patients. Beside the risk of development of postoperative macular edema and degradation of the visual gain, the risk for worsening of the effect of diabetes on the retina is exaggerated after operation [4].

In this study, cataract patients diagnosed with a well-controlled type 2 DM and corresponding non-diabetic controls are enrolled. The aim is clarification of the susceptibility of endothelial cells of diabetic patients to injury during phacoemulsification rather than non-diabetic patients.

METHODS

This is a prospective study operated on 46 eyes of different 46 patients diagnosed as having senile nuclear cataract grade II and grade III according to LOCS III classification. 23 patients with type 2 DM were included, the other were non-diabetic cataract patients included as controls.

Involved diabetic patients had a disease duration ranging between 5 and 10 years. All diabetic patients were well controlled (HbA1c<7%). Patients with history of intraocular surgeries, diagnosed with glaucoma, uveitis, PXF (pseudoexfoliation syndrome) or endothelial dystrophies and patients with corneal opacities that hinders good imaging quality were excluded from the study. Also patients with anterior chamber depth <2.5 mm and preoperative endothelial cell count less than 1500 cell/mm2 were not included in the study.

Prior to the commencement of study, informed consent was obtained from all involved subjects. The study design and methodology was approved by the IRB (Institution Review Board) unit of Zagazig University. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

All patients underwent detailed ophthalmological examination fulfilling the items of best corrected visual acuity, pupillary response and amount of dilation, detailed anterior segment and fundus exam. All patients were imaged by specular microscope (CEM-530, Nidek co., Ltd) and ECD (Endothelial Cell Density), CV (Coefficient value), percentage of hexagonal cells and CCT (central corneal thickness) were recorded prior to the surgical intervention. All imaging results were automated. A minimum number of clearly-defined 60 cells/frame was essential for imaging to be reliable.

All patients underwent cataract removal surgery using phacoemulsification with foldable IOL implantation in the capsular bag in the hands of a single experienced surgeon (A.MB). The procedure is preceded by topical application of mixture of phenylephrine 2.5% and cyclopentolate 0.5% in the conjunctival sac to achieve the suitable degree of pupillary dilation. After skin preparation, a total volume of 4 cm3 of lidocaine 2% was injected around the globe. Irrigation of the fornices and exposed part of conjunctival sac with diluted povidone iodine solution (betadine) 5% followed.

The procedure started by creation of corneal incisions in a self-sealing approach. Throughout the operation, the anterior chamber was constantly filled with hydroxypropyl methylcellulose 2% for space maintenance and corneal endothelial protection from ultrasound energy and colliding particles. Capsular opening in a circular fashion was done with capsulorhexis forceps. Phacoemulsification of the lens material in a “stop and chop” technique and “chip and flip” of the remaining epi-nucleus was made. Remnant cortical matter was aspirated. Foldable IOL was implanted inside the capsular bag. The corneal inlets were sealed by hydration of adjacent stroma with sterile ringer solution.

Fortunately, all surgeries were uneventful. Intraoperative variables including total operation time, total phacoemulsification time, amount of ultrasound power, vacuum pressure, aspiration flow rate and bottle height were noted and statistically-analyzed.

After operation, follow up took place in the outpatient clinic. Patients were imaged by specular microscope at 2 weeks, 1 month and 3 months. Comparison was made between both groups in term of postoperative ECD, CV, CCT and percentage of six-sided cells.

Statistical analysis

Data analysis was performed using the software SPSS (Statistical Package for the Social Sciences) version 20. Quantitative variables were described using their means and standard deviations.

Categorical variables were described using their absolute frequencies and were compared using Chi square test. Kolmogorov-Smirnov (distribution-type) and Levene (homogeneity of variances) tests were used to verify assumptions for use in parametric tests. To compare means of two groups, Mann Whitney test (for non-normally distributed data) and independent sample t test (for normally distributed data) were used.

Repeated measure ANOVA test was used to assess change over time in normally distributed data in each group over time. Friedman test was used to measure change in non-parametric variable over time in each group. Spearman correlation coefficient was used to measure correlation between two continuous variables. The level statistical significance was set at 5% ($P < 0.05$). Highly significant difference was present if $p \le 0.001$.

RESULTS

Analysis of preoperative demographic data revealed that most of diabetic group were female patients (16 females versus 7 males) while (12 females versus 11 males) in the non-diabetic group. The preoperative best corrected visual acuity expressed in decimal fraction was 0.064 ± 0.033 and 0.052 ± 0.033 in diabetic and non-diabetic patients.

The mean age was 58.56 ± 5 and 60.17 ± 3.13 years in diabetic and non-diabetic patients.

No significant difference was observed between both groups regarding age, preoperative endothelial cell parameters (ECD, CV, percentage of hexagonal cells and CCT), Preoperative BCVA and operative variables (table 1)

A significant improvement of best corrected visual acuity was noted in all patients in the first visit after the operation. While there was no difference between both groups regarding preoperative and postoperative BCVA. The regain of visual performance continued on subsequent visits at 1 month and 3 months.

It was clearly-observed that there is a significant difference between the diabetics and controls regarding endothelial cell parameters in the postoperative period. The endothelial cell density was less in diabetic patients than in the control group. The difference in endothelial cell loss was statistically-significant at 2 weeks, 1 month, 3 months' visits (table 2)

The percentage of endothelial cell loss 3 months after surgery was 15.5 % in the diabetic groups compared to 11.4% in the non-diabetic group.

The change in size of cells, represented by CV, was significantly higher in diabetic group at all postoperative visits. The percent change of CV was statistically significant in both groups. (Figure 1)

The degree of pleomorphism increased significantly in both groups. The percentage of regular hexagonal cells diminished significantly in both groups and was less in the diabetic group at 2 weeks and 1 month visits. At the 3 months' visit, the percentage of hexagonal cells was similar to preoperative values in both groups with no statistically-significant difference between diabetic and non-diabetic patients.

The central corneal thickness (optically-imaged) was significantly increased in both types of patients in the first month after operation. The difference between both groups was significantly-high at 2 weeks and 1 month visits. At three months' visit, the mean CCT in both groups is slightly higher than the preoperative CCT. There was no significant difference between both groups regarding the central corneal thickness values at 3 months. (Figure 2)

Table 1: Comparison between the studied groups regarding operative data.

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e Operative data	**Study groups Study groups**		**X^2/X^2/t**	**p p**
	Diabetic group	**Non-diabetic group**		
	N=23 (%)	**N=23 (%)**		
Total operation time(minutes) Mean ± SD Range	9.87 ± 1.15 8 - 12	9.59 ± 1.23 7- 12	0.805	0.425
Total Phaco time(minutes) Mean ± SD Range	1.4 ± 0.3 0.8 - 2	1.33 ± 0.31 0.9 - 2	0.827	0.412
Amount of irrigation fluid(ml) Mean ± SD Range	64.17 ± 8.05 50 - 80	63.09 ± 6.62 52 - 80	0.5	0.62

Table 2: Comparison between the studied groups regarding endothelial cell density pre and postoperatively

Endothelial cell density (ECD) cell density (ECD)	**Di Diabetic group**	**Non-diabetic group**	**t/Z**	**P**
	Mean ± SD	**Mean ± SD**		
Preoperative	2687.65 ± 155.99	2751.43 ± 152.65	-1.402	0.168
2 weeks postoperative	2332.87± 99.61	2506.13 ± 159.31	-4.423	<0.001**
One month postoperative	2282.35 ± 97.93	2447 ± 157.16	-4.264	<0.001**
Three months postoperative	2272 ± 98.18	2438.43 ± 156.58	-4.319	<0.001**
P (repeated measure ANOVA)	<0.001**	<0.001**		

**p≤0.001 is statistically highly significant, Z: Mann Whitney test, t: Independent sample t test.

Figure (1): multiple line graph showing change in mean CV over time among the studied groups

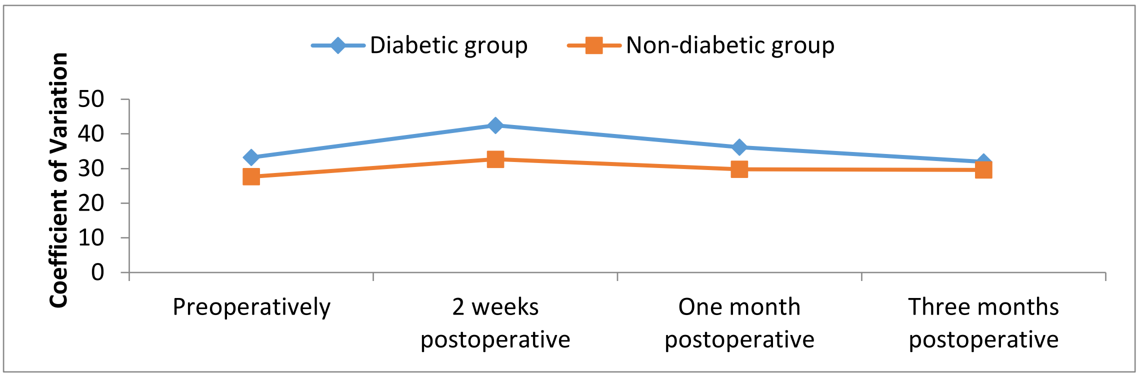
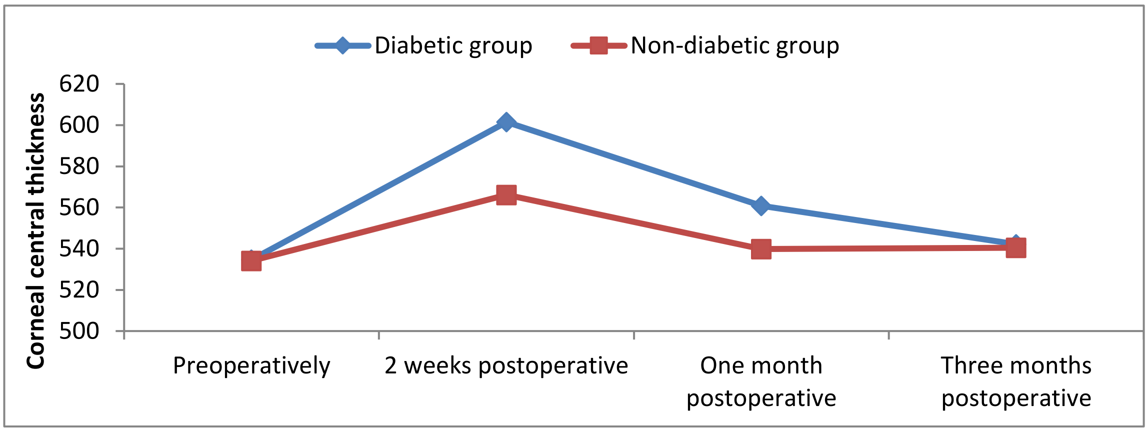


Figure (2): Multiple line graph showing change in mean CCT over time among the studied groups



DISCUSSION

This is a prospective study comparing the effect of phacoemulsification on corneal endothelial cells in patients with well-controlled type 2 DM patients and non-diabetic cataract patients. The overall aim of the study is to find if there is an added risk for phacoemulsification-induced endothelial injury in diabetic patients.

Preoperatively, the corneal endothelium characteristics were quite similar in both groups. Revising the demographic data of involved patients did not yield a significant difference between both groups.

Greater loss of endothelial cells was observed after phacoemulsification in patients with type 2 DM even if they were well-controlled. ECD was significantly lower in diabetic patients than non-diabetics all through the early postoperative period (3 months). The more loss in endothelial cells in diabetic corneas is explained by the less tolerability of these cells to injurious events. Even if the patient is under good diabetic control (HbA1c<7%), diabetes exerts a cumulative negative effects on endothelial cells.

Increased variability of the size and shape of cells after surgical intervention is documented in all patients included in the study. However, patients of diabetic group show more increased variation in the arrangement and morphology of cells. This is translated to a more rise of CV and a more reduction of percentage of regular six-sided cells in the early follow-up period. The difference in CV is significantly-higher in diabetic patients rather than controls in the first month after operation.

Postoperative VA and CCT were nearly the same in diabetic and control groups. Despite the proven effect of phacoemulsification on diabetic corneas, the functional state of endothelium is little affected after surgery as well as the visual performance of patients.

Various previous studies were conducted to clarify the increased risk in diabetic patients for endothelial failure after cataract removal surgery. Morikubo et al operated a study including 93 diabetic patients and a similar number of non-diabetic cataract patients. All patients underwent phacoemulsification procedure for cataract removal with a foldable IOL settled in the capsular bag at the end of surgery. A reduction of ECD was noted in both types of patients in the first month after operation. There was a significantly-higher loss in diabetic patients during the entire postoperative period. Although postoperative CV was higher and percentage of hexagonal cells was lower in diabetic patients, the difference between the 2 groups was not significant. The recording of results stopped at 1 month postoperatively neglecting further follow-up duration [5].

Hugod et al further published a study to compare the endothelial parameters after cataract removal in both controlled diabetic patients and non-diabetic ones. The study involved 30 diabetic and 30 non-diabetic patients diagnosed with cataract taken as controls. The mean glycosylated hemoglobin values for the diabetic group was 7.08%. The patients were imaged by specular microscope 3 months after the operation. The revised data of specular microscopy reports showed a more reduction in postoperative ECD and number of regular hexagonal cells per frame in diabetic group of patients. The study did not monitor the amount of intraoperative ultrasound power used. The study did not comment on grade of nuclear hardness of involved cataract patients [6].

In another related study covering the incidence of corneal edema after phacoemulsification and its relation to diabetes, Tsaousis et al had showed that the pre-existing humbled state of corneal endothelial cells as in diabetic patients is a strong determinant for the development of corneal edema in the period after phacoemulsification. Diabetic corneas are at much risk for development of corneal edema after surgery and the risk rises with the degree of nuclear stiffness. The process of restoring the original corneal thickness and clarity takes longer time in diabetic individuals. The study did not rely on counting of endothelial cells before and after the operation [7].

The result of this study is consistent with the finding of He et al. Retrospective comparative evaluation of amount of endothelial cell loss after phacoemulsification procedure in both diabetic and non-diabetic patients took place. The study reported the exaggerated ECL among diabetic patients. No defined difference was found when comparing the amount of phaco-energy used during operation nor the level of preoperative HbA1c. Despite the good study architecture, the relation between degree of glycemic control and rate of endothelial cell loss after operation was unclear [8].

Bamdad et al compared the endothelial cell changes before and after phacoemulsification. The study included a total number of 85 patients, only 11 patients were diagnosed as diabetics. The patients were subjected to cataract removal surgery using phacoemulsification. A significant difference was found between mean preoperative ECD and postoperative one 2791.15±99.86 and 2472.87±472.14 cell/mm2 consecutively. The degree of loss was higher in diabetic patients. However, the patients included had a wide variation of anterior chamber depths (2.00±3.33 mm), degree of nuclear hardness (2.0±1.0) and axial lengths (22.46±5.34 mm). Data about degree of glycemic control of diabetic patients is imprecise [9].

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